TRAINING MANUAL

- FOOD SAFETY -

RISK ANALYSIS AND SELF-ASSESSMENT IN PRODUCTION

COLEACP

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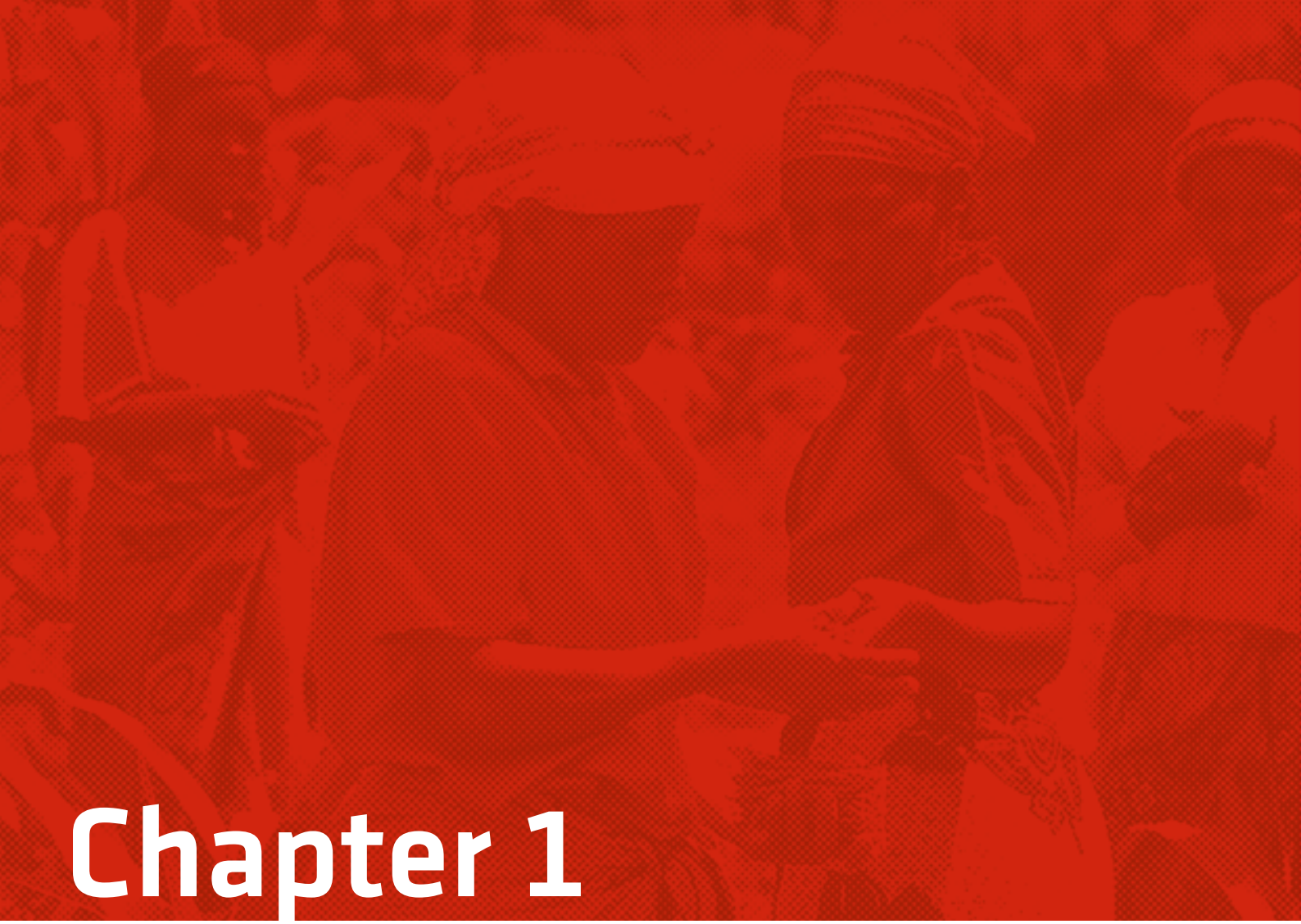

Chapter 1

Basic principles of risk analysis

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1.1. Hazards and risks

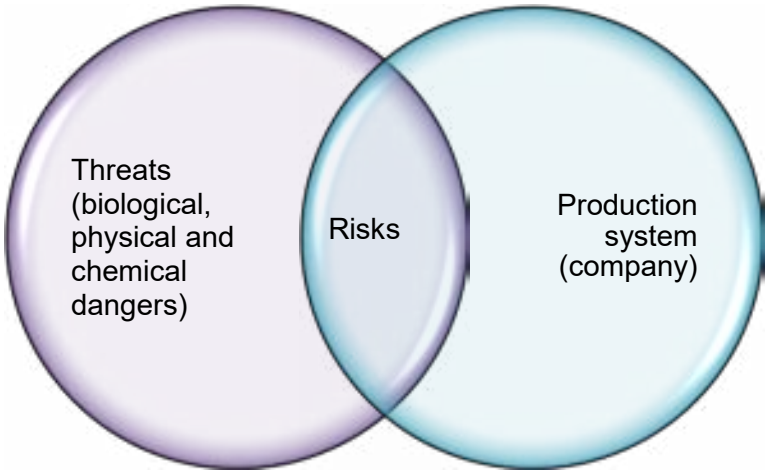
1.1.1. The birth of a ‘risk’

Producing, processing and distributing food products are ‘risk’ activities. In daily practice, agri-food businesses, food distribution companies, community food service companies and others must take into account the fact that most of their products are ‘perishable’ and "sensitive" and that they are not ‘consumer goods’ like others... because we eat them!

The production systems of these companies must deal with a number of ‘**threats**’[1] that can create a set of risks for themselves and their clients (the risk of non-conforming products which may need to be destroyed, risk of consumer food poisoning or allergies, the risk of loss of brand image, the risk of losing market etc.).

The diagram below shows that **risk management** requires reducing the overlapping areas between the ‘**target**’ (the production system) and the ‘**threat**’ (the possibility of biological, physical or chemical contamination).

The birth of a ‘risk’



Risk management is a ‘challenge’ for companies but also for the authorities who have to ‘handle risks’ and set the limits between what constitutes an ‘acceptable’ risk and what doesn’t!

[1] The word ‘threat’ is preferred to ‘hazard’ because a threat can be turned into an opportunity (e.g.: a company can differentiate itself thanks to its Health Quality Management System)... but a hazard can’t be!

❑ For companies

In order to meet regulatory and commercial requirements, agri-food companies must identify all facets of their activities that determine the **safety** and **healthiness** of their products.[2]

It is essential for operators to **manage all hazards, at every step** of the life cycle of their products (design, production, storage, transport, distribution) to comply with specifications (regulatory and commercial) and guarantee consumer safety.

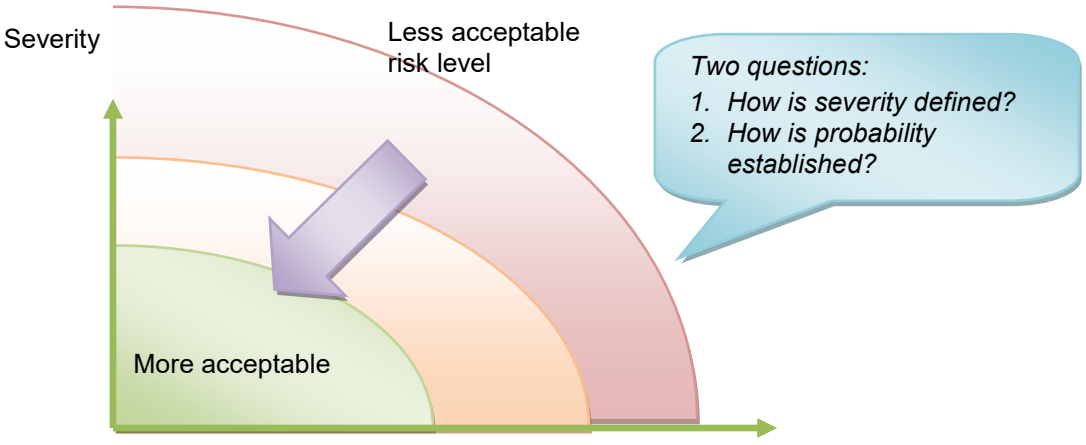
Operators in the food chain must be able to:

1. **Identify all hazards** (physical, biological or chemical) that could potentially contaminate their products at the different production steps.
2. **Assess the level of risk for each** (the probability of appearance) based on working conditions, procedures and practices in effect.

It is based on this that appropriate management measures, suited to the type and level of risk will be adopted by the **company**. It will have to ensure that the measures are implemented, complied with and reviewed on a regular basis. **Managing a company means managing risks!** A company will be able to succeed when it is able to deploy an effective risk management policy for all types of risks (Metayer, Y. and Hirsch, L., 2007).

❑ For authorities

It will be up to the 'authorities' to **define acceptable risk levels**. This implies characterizing risks, classifying them and differentiating them in terms of priorities. It is based on a correct understanding of risks that the supervising authority will take management measures suitable for all operators in the food chain and reduce risk to a more acceptable level: setting of standards (**acceptable limits**), of regulations (**obligations**) and organization of monitoring (**verification**).



[2] The two components of product hygiene.

1.1.2. The concepts of 'hazard' and 'risk'

It is important to distinguish between the terms 'hazard' and 'risk':

Hazard: a physical or biological agent or a substance that has the potential to have a proven harmful effect on health.

Risk: the probability of harm. The degree of risk depends both on the probability and severity of the results (type of harm, number of persons affected, etc.). 'Risk' is tied to exposure to hazard, that is, to the consumption of the contaminated food (quantity and frequency of consumption).

'**Hazard**' refers to two concepts: first, only '**relevant**' hazards should be considered, that is, those for which there is a probability that they will occur in a given product because of its composition and/or its production methods (processes and environment), and secondly, the hazard has to have a **proven harmful effect** on consumer health. The severity of the effects on health is a matter for specialists (e.g. toxicologists) who provide opinions on toxicity and set admissible tolerance '**thresholds**'.

Speaking of a '**risk**' implies answering the following **questions at least**:

- What type of risk are we speaking of? In what field?
- What are the known or emerging risks in this field?
- What must be done to correctly assess the level of risk?
- How can identified risks be managed while maintaining normal operations?
- How do we know that we are dealing with an "incident" (a "problem" manageable at the company level)? What steps must be taken to return to a normal operations process?
- How do we know that we are dealing with an "accident" (or "food crisis")? What steps must be taken to manage the situation and ensure the best outcome?

What happens when scientific uncertainty remains about the harmful health effects of a suspected hazard? The precautionary principle should prevail!

In particular cases where an evaluation of available information reveals the **potential** for harmful effects on health but a **degree of uncertainty**, European Regulation 178/2002 calls for the use of the '**Precautionary principle**'.

Temporary risk management **measures** required to ensure a high level of health protection can be implemented while waiting for further scientific information enabling a more complete assessment of the risk (e.g.: for genetically modified plants – GMP).

In fact the following distinctions can be made:

- **Caution**: is intended for proven risks, that is, those that have been proven to exist and whose frequency can be estimated ('prevalence').

- **Prevention**: is intended for proven risks when their frequency cannot be estimated (e.g.: nuclear risk. The risk isn't uncertain but its occurrence is).

- **Precaution**[3]: is intended for probable risks that have not yet been scientifically proven but whose probability can be identified based on empirical and scientific knowledge.

The boundaries between these concepts, and especially the 'classification' of certain risks, are the subject of intense debate between specialists, the public and politicians! The application or non-application of the "precautionary principle" is at the heart of these discussions.

In order to avoid all arbitrary decisions on the matter, use of the precautionary principle should only be justified when **three prior conditions** are met: potentially negative effects have been identified, available scientific data have been examined in depth and despite this scientific uncertainty remains high.

1.1.3. Analysis of 'dangers' and analysis of 'risks'

❑ **Different objectives**

There is often some confusion between the terms '*hazard analysis'* (usually carried out as part of an HACCP plan[4]) and '*risk analysis*' because they are often used in the same discussions.

However, although the two approaches have points in common, it is important to differentiate between them. Given that they developed from different sources, they also reached **completely different conclusions** (AFSCA, 2005).

The table on the next page makes comparing the two approaches easier.

With:

FSMS Food Safety Management System
ACS Auto-Control System (self-assessment)
CCP Critical control point for risk management (HACCP)
POA: Point of Attention in the risk management process (HACCP)

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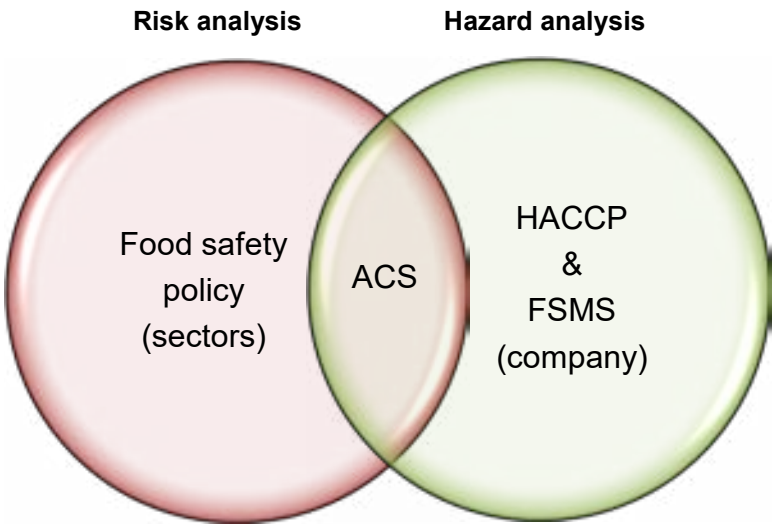
[3] This is the case, for example, where there is no scientifically established evidence of adverse effects, of demonstrated links between a contaminant and observed effects, as is often the case with chemicals (such as endocrine disrupters), which act at extremely low levels of concentration, and that the possible causes of an overall observed effect on a population are multifactorial. For this type of contaminant (residues of certain pesticides, Bisphenol A etc.), it is compulsory to work at the scale of entire populations, which makes studies much more complex.

[4] Hazard Analysis Critical Control Points: analysis of hazards and critical points for their management.

Hazard analysis	Risk analysis
Implemented at the company level and specific to the given company (a link in the) supply chain Tied to the company's production process Calls on internal expertise (the company's quality control manager) **Outcomes**: - Prevent and manage risks - Implement an FSMS - Identify the internal skills required **Important activities**: - Identify and assess hazards: - Set POAs and CCPs - Implement control measures - Check the FSMS - Train employees	Implemented at the sector or food chain level and involves all operators (the entire *food chain*) Related to the health policy of a country or sector and to the management methods implemented Calls on internal and external expertise (scientific and independent) **Outcomes**: - Adjust the health policy - Communicate with operators - Identify emerging risks **Important activities**: - Identify and assess hazards - Set standards and regulations - Validate the auto-control guides - Schedule controls - Communicate

The difference between the two approaches can also be summarized as follows. This enables visualization of the 'auto-control system's' position at the intersection of the two types of analysis:



ACS: self-assessment system

❑ Hazard analysis

Hazard analysis is a term used in the HACCP system. **Hazard analysis is carried out at the company level** and, as a result, is **specific to that company**.[5]

It is tied to the processes implemented in a particular company.[6] These processes must be described in detail.

First of the seven basic HACCP principles (*Codex Alimentarius* Commission, 1999):

"Identify the potential hazard(s) associated with all stages, undertake a hazard analysis and identify all measures to control the identified dangers".

According to the Codex, hazard analysis must consist of **two parts**:

1. **Hazard identification**: identification of biological, chemical and physical agents that:
   - Are relevant because they may be present in a specific food or group of foods
   - Depending on the nature of their effects, can have significant harmful consequences for consumer health.

   This is a **strictly qualitative approach** tied to scientific knowledge (Saegerman, C. and Berkvens, D., 2005).[7]

2. An **assessment** of the hazards listed which will include the following items:
   - The probability that these hazards will occur and the severity of their harmful effects on health
   - A qualitative and/or quantitative evaluation of the presence of hazards
   - For micro-organisms, their ability to survive and/or multiply, production or persistence in toxin foods
   - The persistence in foods of chemical or physical agents despite the operations carried out during the process

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5 In fact, a hazard analysis can also be carried out at the sector level - as part of the development of a self assessment guide, for example - but it must then be refined at the company level. It is to avoid this confusion that risk analysis at the sector level is also discussed in the guide although it is far less extensive than when working at the overall food chain level.

6 Note: a process is a set of activities which are, in general, transversal to the company's organisation. There are several types of processes in a company:
   - Management processes: tied to strategic planning, policy creation, goal setting, communication set-up, the supply of required resources and management reviews.
   - Resource management processes (or "support processes"): supply of the resources required for the production processes.
   - Production processes (or "operations processes"): processes that enable the company to achieve expected results (= products).
   - Measurement processes (or piloting processes): inspections, audits and improvements required to gather and measure data for performance analysis and improvements in effectiveness and efficiency.

7 Note also that the OIE (World Organization for Animal Health) makes identifying hazards a prerequisite for risk analysis. It differs from the *Codex* Alimentarius on this point.

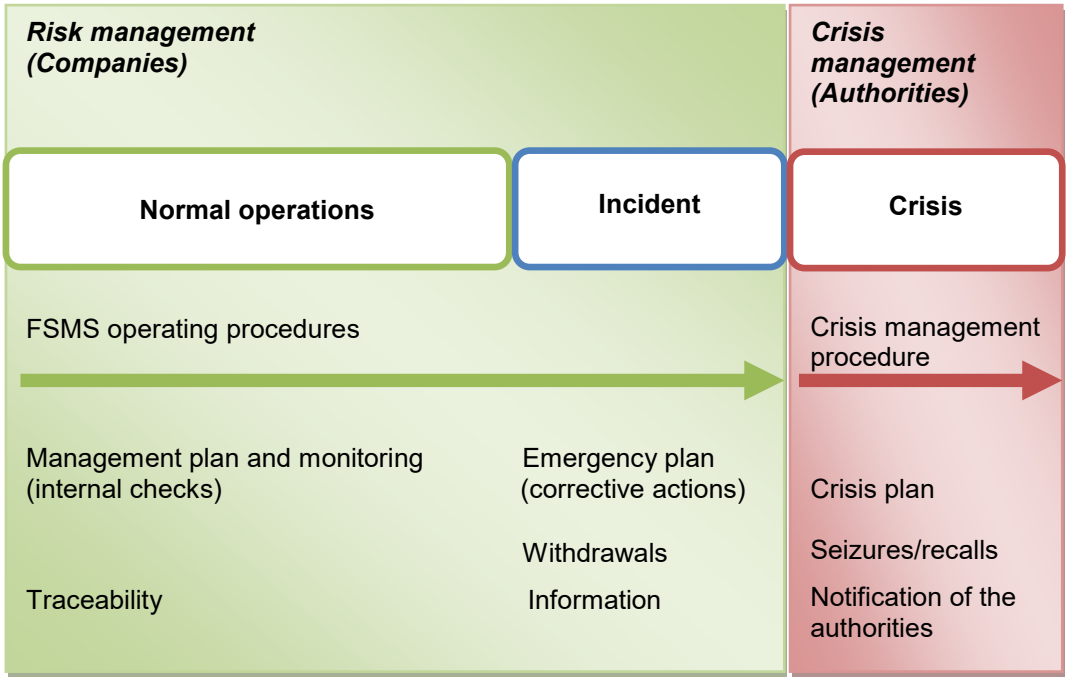
- The conditions leading to the above-mentioned items.

For each hazard identified, we therefore determine **at what point** it becomes necessary (or critical) to manage it in order to guarantee the food's safety and healthiness.

Effective management measures must then be decided on to prevent or eliminate the hazard or to bring it back to an acceptable level. These measures are 'operating modes' (or procedures) within a 'management and monitoring plan' or in a self-assessment guide.

1.1.4. Operating areas and risk management

Managing a company means both managing risks…and planning for the worst! The various 'areas of operation' can be presented as follows for easier visualization of the limits of risk management (and therefore of FSMS):



We can see that 'operating modes' (or procedures) cover both the 'normal operations' and 'incidents'. They must therefore implement the procedures to be followed in the event of an FSMS failure. The authorities should be notified when a critical limit – a parameter that affects product health safety - is exceeded (e.g.: a MRL is exceeded): This is 'notification'.

The different operating areas can be described as follows:

❑ **'Normal' operations**

The production process is 'effective' if it satisfies client (external or external) requirements: This is '*normal*'. However, normal operations are only easy to characterize

if the **processes have been correctly described and performance indicators have been clearly identified.**

The **frequency** of indicator monitoring is **key**. It must be done daily, hourly, by shift, seasonally, yearly etc.

Risk prevention consists in ensuring that the production process remains in 'normal' mode. All observations and all recorded values should conform to instructions. This is the goal of implementing an FSMS (Health Quality Management System) and self-assessment.

❑ **'Incidents'**

'Incidents' occur when the process no longer operates effectively:

- at least one of the production process indicators (key process) does not comply with instructions. One of the identified risks is present and the tolerance limit has been exceeded;
- a significant number of process indicators (including support processes indicators) are non-compliant and this could have an impact on products when they leave the production process.

In the event of an incident, the information/indicators to be taken into **consideration tend to be** '**upstream**' (of the sale of products).

An incident situation does not necessarily imply serious consequences. This is not yet a crisis situation. However, '**corrective action**' must be taken, such as:

- reviewing the process management system (FSMS);
- reviewing the traceability system;
- reviewing indicators and better evaluating their qualities (relevance etc.);
- redefining controls, their frequency, observation methods etc.;
- reviewing indicators and objectives;
- improving employee training.

However, if 'incidents' recur, it may be necessary to:

- redefine the process or processes;
- change the manager of the process or processes or re-define their responsibilities;
- increase controls, either temporarily or permanently;
- revise indicators and objectives (change the type of controls);
- etc.

All of these actions and reactions will normally be managed and implemented with the company's usual resources. There is no need at this point to find new methods or call on special outside help.

❑ **'Accidents'**

A '*crisis*' occurs when the process or processes no longer function normally or as intended (this is an accident). The crisis can affect part of the process or part of the company. **It requires immediate action** by management.

Contrary to an incident, it is unlikely that 'upstream' information will enable definition of the state of crisis. It is more **likely to be downstream signals** such as (Metayer, Y. and Hirsch, L., 2007):

- the closing of certain markets, financial losses;
- the loss of significant numbers of customers, an increase in complaints;
- a media campaign against the company, against its products, against the source of the products;
- etc.

Crisis resolution will require **cooperation between the company and the authorities**, and, usually, the use of specialized external resources which will also act at the company level if required (in-depth reorganization of the company and of its FSMS).

1.2. Definitions, value and components of risk analysis

1.2.1. The origin of the concept of risk analysis

Originally, risk analysis was designed as a tool to help make suitable decisions about the risks of certain **carcinogenic hazards**. In 1983, the National Research Council (NRC) published the document *Risk Assessment in the Federal Government: Managing the Process*.[8] It became the basis for the general concept of risk assessment and laid a clear foundation for the assessment of chemical risks and risk management.

The definitions found in this document were sufficiently broad to be applied in a general way and specific enough to avoid confusion when communicated. For a few years now, this risk analysis system has also been used for other hazards in situations including microbiological, physical and chemical hazards which are important in the food industry.

Despite the fact that the same basic system is used, there are visible differences in the approach and terminology used for the assessment of these types of risk. As a result, within the *Codex Alimentarius*, **specific directives** were created for the **assessment and management of biological risks** (AFSCA, 2005).

Information and techniques from **very diverse disciplines** are used to carry out a 'risk analysis'. These include microbiology, chemistry, toxicology, medicine, epidemiology, statistics, management, sociology etc.

1.2.2. The usefulness of risk analysis

The end goal of risk analysis is to be able to take **a strategic decision based on a qualitative or quantitative result.**

> Based on the results of a risk assessment (quantitative and qualitative) a supervising authority can take risk management measures and provide information to the groups/persons concerned (quantitative risk analysis data can be included in the information).

This is the process within the framework of commercial exchanges between countries. The World Trade Organization's (WTO) Marrakesh Agreement of April 1994[9] on the application of sanitary and phytosanitary measures (SPS Agreement) states that countries have the right to define the level of consumer protection that they feel is **appropriate and to restrict international trade, if necessary**, in order to protect the lives of people, animals and plants.

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8 NRC, *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington D.C., 1983.

9 WTO, Agreement on the Application of Sanitary and Phytosanitary Measures European Parliament and Council, *OJEC*, L31/1 of 1 February 2002.

SPS measures **cannot, however, include any unfounded, arbitrary or disguised restrictions** that hinder trade. **The existence of a risk must be scientifically proven**,[10] except in the event of emergency measures or within the framework of the precautionary principle.

Two options can be used for this purpose:

1. Reference to standards and recommendations (e.g., those of the *Codex Alimentarius*) or international directives (harmonization of requirements).[11]
2. Otherwise, use of a scientific risk assessment[12] in which the cost/benefit ratio of the various management options and methods is taken into consideration in the conclusion of the analysis.

The risk assessment must not be confined to a blind application of standards.

The development of in-depth collective assessment expertise within each country is essential to the proper execution of a risk assessment. The deployment of this expertise should not be limited to public services agents. Remember! Private operators have primary responsibility for the food chain.

Risk analysis is the basis for health policies managed within '**SPS systems**' (sanitary and phytosanitary food management systems) because there are **different ways to guarantee the same level of protection** (equivalency principle) and the measures taken must be announced as quickly as possible (transparency principle) (Saegerman, C. and Berkvens, D., 2005).

1.2.3. The components of risk analysis

According to the *Codex Alimentarius*, risk analysis **consists of three** logically related **parts**:

1. **Risk assessment**
2. **Risk management**
3. **Risk communication**

The structure of the risk analysis system can be illustrated in different ways. The figure below is used most often:

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[10] That is, completely transparent and free of any pressure, and using a scientifically recognised methodology.

[11] The SPS Agreement recognises the international nature of the standards established by the World Organization for Animal Health (OIE), the Codex Alimentarius Commission (CCA) for the safety of foodstuffs and the International Plant Protection Convention (IPPC) for measures relating to plant health. These organisations, along with the European Food Safety Authority (EFSA) also enact directives for the methods and procedures for carrying out risk assessments.

[12] The SPS Agreement defines a scientific risk assessment as:
(i) The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences or, (ii) the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

Each of the three components will be further described below.

The first component is '*risk assessment*', a scientific **process** which must take place independently from risk management. It is further detailed below. Risk assessment is itself split into four components:

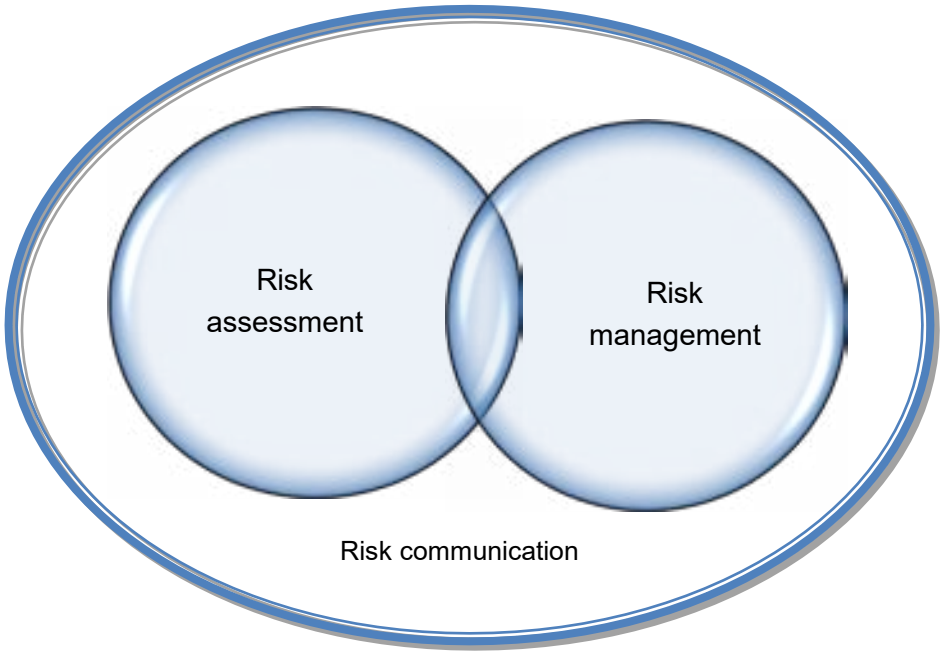
1. Hazard identification
2. Hazard characterization[13]
3. Exposure assessment
4. Risk characterization

'Risk management' measures are based on the results of the assessment. The second component refers to 'policy' decisions taken by the authorities to maintain risks at acceptable levels.

The third component is key. '*Risk communication'* enables all stakeholders to be informed about the nature, source and criticality of the risks. It enables the authorities to build a monitoring programme and to plan controls for the food chain. It also enables information to be sent to operators about the management measures that have been proven to be truly effective. It includes a watch on emerging or re-emerging risk.

Some authors have suggested another approach to better underscore the importance of communication in the risk analysis process:

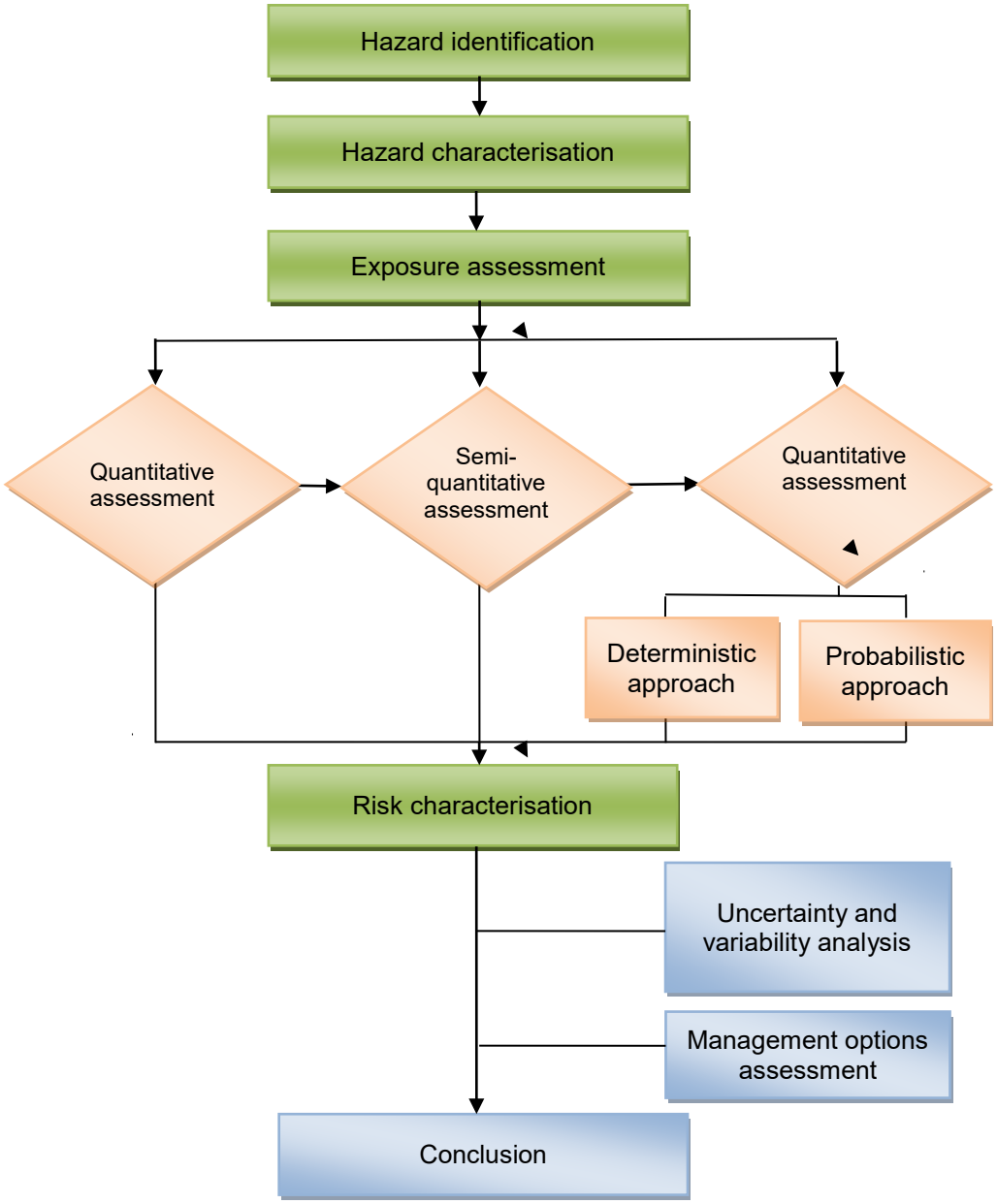
[13] Or dose-response assessment.



Risk assessment and management are ‘steeped’ in communication.

1.3. Risk assessment

Risk assessment is a structured, independent, objective and transparent process for **organizing and analyzing available data**. The process consists of **four steps** as follows: *(i)* hazard identification; *(ii)* hazard characterization *(iii)* exposure assessment and *(iv)* risk characterization. It can be shown as follows:



*Note that to be complete, **the analysis must not end with a 'figure'** characterizing the risk. Taking the quality of data into consideration, it is also important to **put the result obtained into perspective** by studying the related uncertainty and variability (e.g., use of extrapolation, analogies and more or less realistic scenarios, input of averages data, etc.).*

*In addition, since analysis is generally based on '**scenarios**' that can be varied, it is helpful to **produce commentary** on the potential changes to results when the various control measure possibilities are included in the scenario(s).*

It becomes apparent that the quality of the conclusions that can be drawn from a risk assessment **depends largely on the quantity and quality of data available** and on **the relevance** of the data used for the analysis.

The risk assessment approach includes a significant amount of collecting, consolidation and critical analysis of data. It also requires the development of more or less complex "models" (e.g.: deterministic and probabilistic approaches - these will be explained later).

Let's take a look at each step! Two examples are developed in the appendix.

❑ Step No. 1: Hazard identification

The goal of this step is **to describe** the (micro) biological, chemical and physical **hazards**[14] that are the cause of consumer health risks in the food safety field (in a broad sense, including diseases and infections in animals, and those that affect plant health[15]).

A number of questions must be asked in order to identify the dangers. The answers must be sought in scientific literature, study reports, analysis reports, databases, advice published by food agencies around the world etc.

Several questions must always be asked about **(micro) biological hazards**:

- Is the hazard known (taxonomy, virulence factors, epidemiology, pathology, ecology, interaction with the host, etc.)?
- What is its source and how is it transmitted?
- What are the symptoms?
- How serious is the disease?
- How many cases or outbreaks have been reported?
- What foods are affected?

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[14] The goal is to describe them as thoroughly as possible by consulting a maximum number of reliable scientific sources.

[15] The latter refer to diseases and destructive pests harmful to crops that can be transported to areas that until then were free of them: these are generally known as 'quarantine organisms' (see the appendices of Directive 2000/29/CE).

- What factors impact the growth and survival of the micro-organism?
- Is factual information on the danger available in data banks?

The identification of **chemical risks** consists of describing the harmful effects of the substance, its profile (age group, gender, etc.) and the size of the population group at risk. Given that epidemiological data in humans are often not available in sufficient quantities, the risk assessment must often be based on experimental toxicological studies carried out on laboratory animals and on in vitro studies. Several questions must always be asked when identifying chemical hazards:

- It the hazard known?
- What are the harmful chemical components?
- What is its source and how is it transmitted?
- What does the syndrome consist of?
- How serious is the disease?
- How many cases have been reported?
- What foods are affected?
- Can the hazard lead to poisoning?
- Does the hazard lead to hypersensitivity reactions (allergens)?
- Etc.

Where to find information on hazards

The main scientific sources are:

➢ ***The sites of major international organizations***

OMS: www.who.int
FAO: www.fao.org
OIE: www.oie.int

➢ ***Specialized databases***

PubMed: www.ncbi.nlm.nih.gov/pubmed
Toxnet: toxnet.nlm.nih.gov
IPCS: www.who.int/pcs
IARC: www.iarc.fr
ChemIDplus: chem.sis.nlm.nih.gov/chemid
Sciencedirect: www.sciencedirect.com
Google scholar: scholar.google.com
VDIC: www.vesalius.be

➢ ***The sites European food agencies***

EFSA: www.efsa.eu.int (European agency)
FASFC: www.afsca.fgov.be/home-en (Belgian agency)
ANSES: www.anses.fr/en (French agency)
VWA: www.vwa.nl (Dutch agency)
FSA: www.food.gov.uk (British agency)

❑ Step No. 2: Hazard characterization

Hazard characterization is the **qualitative assessment** (description of symptoms, effects) **and/or quantitative assessment** (description of the severity of the hazard based on the dose) **of the nature of harmful effects on health** associated with the biological, chemical and physical agents that may be present in foodstuffs:

- A determination of the dose-response should be carried out for biological and physical agents **if data can be obtained.**
- The **dose-response curve** of chemical agents should be **determined** (if data are available).

For (micro)biological hazards, the fact that their concentration and properties (degree of virulence, infectious character, toxin production etc.) **can vary depending on the matrix** and/or interaction with the host should be taken into account. Micro-organisms can cause acute or chronic infections or survive in a latent form and lead to ongoing or recurring excretion and contamination of the environment.

With respect to the **host**, **vulnerable groups** must be taken into account (based on age, vaccination status, pregnancy, nutritional state, etc.). If possible a **"number-response" curve** is used on which the different limit values are indicated including toxic concentration and the number of bacteria for infection, or causing the disease.

The following questions can be asked with respect to the characterization of (micro) biological hazards:

- What dose leads to infection, illness, hospitalization or death?
- How serious is the disease?
- What information on the dose/response relationship is available for documented cases, studies with volunteers and animal models?
- Is an infectious agent or bacteria producing the toxins involved?

For chemical hazards, hazard characterization consists in **describing the 'dose-response**' relationship for the most sensitive and harmful health effects. For this purpose, the active mechanism of the chemical substance, usually observed in experimental studies at high doses, is assessed to determine if it is also relevant in the exposure of humans at lower concentrations.

In the event that the toxic effect appears starting at a **limit value (toxicological reference value)**, hazard characterization of the contaminants will take **ingestion levels** into account:

- **Safe ingestion amount** (*Acceptable Daily Intake* – ADI[16]). The ADI value for a chemical hazard is obtained by a calculation based on toxicological tests on animals. The starting point is the dose for which no adverse effect is observed

[16] In French: Dose Journalière Acceptable or DJA (in mg/kg of body weight/day). The amount corresponding to the ADI is considered to be safe. Consequently, the further one moves away from the ADI (*i.e.* MRL's which are set well below ADI values) the greater the degree of consumer safety. The reference value to be taken into account for phytosanitary product residues can be the ARfD (Acute Reference Dose) rather than the ADI (see COLEACP Training Manual, *Principles of hygiene and food safety management*).

(NOAEL) in laboratory animals. A safety factor of 100 is then applied (a first safety factor of 10 takes into account potential differences in sensitivity to the toxic effects between humans and laboratory animals and a second safety factor of 10 takes into account the variability in sensitivity to the toxic effects between individuals or sub-groups in the population).

- **Tolerable Daily Intake** – (TDI). The TDI is a value similar to the ADI but is used for chemical contaminants that **are not voluntarily added** to the food chain (heavy metals, PCBs, dioxins, HAP, etc.). The toxicological reference values for genotoxic carcinogenic substances can vary depending on whether their calculation is based on a combination of epidemiological studies or on animal experiments. There are also other reference values such as the PTMI (Provisional Tolerable Monthly Intake) and the PTWI (Provisional Tolerable Weekly Intake).

❑ Step No. 3: Exposure assessment

Exposure assessment consists in **combining** information about the **prevalence** and the **concentration** of the hazard in food with **consumption** data. This will provide the **probability** that consumers could be exposed to variable quantities or concentrations of a biological, chemical or physical agent **via their food** or, potentially, via other means of exposure.

Data on the following are required to carry out this assessment:

1. ***The contamination of the food:***

   The **average quantity** of food pathogens or the **probable concentration** of contaminants to which consumers may be exposed at the time of consumption must be known. Information on the prevalence of the pathogen, on the concentration of pathogen numbers in a food, on the quantity of a given additive consumed daily by a representative consumer, on the concentrations usually found in residues is required (otherwise acceptable limits such as the MRL should be used).

2. ***On food consumption:***

   The calculation will require data on **dietary habits (consumption survey).** The estimate is based either on the average (in g/day) consumption/day of the overall population or, in order to take into account "heavy consumers" on the percentiles ($P_{97.5}$, P_{90}) of consumption/day. Certain specific population groups must also be taken into account when it's feasible and justified (e.g.: adults and children for which the risk level can be different due to differences in consumption and body weight).[17]

   Consumption data must take into account socio-economic and cultural factors (e.g.: vegetarians) and factors related to the seasons, age differences, consumer behavior (e.g.: ethnic groups, religious prohibitions), etc.

[17] And, in particular, groups at risk (YOPI's: *young, old, pregnant and immuno-suppressed*).

Exposure assessment must be done successively in a **qualitative, semi-quantitative and quantitative** way:

- It is recommended that a **qualitative assessment of the exposure be carried out first** before moving to the quantitative approach. The qualitative exposure assessment is based primarily on the **opinion of experts** and consists of the collection, consolidation and presentation of knowledge and certainties to support a conclusion about the risk. A descriptive scale can be used to express the level of risk (none, negligible, low, medium, high).

- Next, a s**emi-quantitative assessment** of the exposure should be carried out based on the results of the qualitative assessment. Partial digital processing of the data based on an "**analysis scenario**" should be done.

- Lastly, **a quantitative exposure assessment** should be done if enough information is available. A "**deterministic**" exposure assessment can also be done depending on the level of uncertainty in the data. For example: the average concentration (in bacteria, in residues) in the food is multiplied by consumption $P_{97.5}$ (that is, 97.5% of people consume at least this amount of the food/day) to obtain a quantified result.

The '**probabilistic approach**' uses concentration and consumption **data distributions** to obtain probability distributions. Computer programmes are normally used to process this data (e.g., software like @*Risk* for 'Monte Carlo' type simulations[18]).

Biological and chemical hazards can be differentiated:

1. For (micro)biological hazards

In the case of micro-biological hazards, **exposure assessment is based on the contamination of the food by the pathogen** (or by the toxins in it) and on consumption data. Quantitative exposure assessment of a biological hazard can be done using the deterministic or probabilistic method.

The frequency of contamination of the food by the biological agent and changes in its concentration over time must be taken into consideration. These parameters are affected by, among other things, the properties of the pathogen, the micro-flora present, the initial concentration of the contaminant in the food, the processing conditions during production, process factors, packaging and the conditions of distribution, storage, preparation and preservation of the food.

The level of bacterial contamination in a food can vary significantly **depending on environmental conditions**.[19] **Thus, the importance of using a structured modular approach for exposure assessment,** during which the hazard risk is assessed or calculated for the different intermediate steps of the channel, from primary production (in the field) through consumption and including the packaging and distribution processes.

The level of consumer exposure depends on various factors such as the initial degree of contamination of the **unprocessed product**, the characteristics of the **food** and

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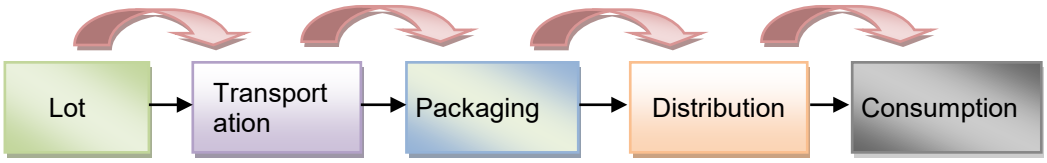
[18] This technique uses random sampling of each probability distribution in a model to produce a large number of scenarios or iterations. Sampling is carried out taking into account the shape of distribution.

[19] See the '5 M' method.

processing conditions, the proliferation or disappearance of bacteria and storage and preparation conditions before consumption. The possibility of cross-contamination must also be considered under certain circumstances.

Sample modular approach in a food channel:

Change in the bacterial population at each step?



Predictive micro-biological models can be used to **predict the change** (growth, inactivation, survival) **of the pathogen during the successive steps** of the production process, during distribution and during the storage of the food prior to consumption. The required data are for storage conditions (temperature, duration) and the method used to prepare the food (e.g., consumed cooked or raw).

2. For chemical hazards

The total amount of a chemical hazard ingested via food is evaluated to assess exposure to a chemical hazard. For some chemical substances, a single food must be taken into account whereas a number of different foods must be considered for others. Sometimes, the chemical substance ingested via food is only part of the total amount ingested.

A deterministic (point estimation) or probabilistic approach (taking distribution into account) can be used to calculate exposure assessment.

❑ ***Step No. 4: Risk characterization***

Risk characterization is an estimate obtained by **integrating all of the data obtained** in the previous steps. Its goal is **to determine the probability of a hazard occurring and the extent of unwanted related consequences**. Risk characterization provides a qualitative and/or quantitative estimate of the probability and severity of the harmful effects on health that might occur in a given group: **hazard x occurrence x consequences**.

Risk characterization **can be expressed qualitatively** (high, medium or low risk) **or quantitatively** (e.g., in % of the ARfD or the ADI for a given group of consumers).

Risk assessment **must explicitly account for variability**, **uncertainties** (incomplete data, partial knowledge) as well as for **assumptions made** with the aim of **providing a feel for the reliability of the risk assessment.**

The method used for risk characterization **depends on the information available** (or unavailable) about the probability of its occurrence and the consequences of the hazard in question. There are different ways to express the level of knowledge (or, inversely, of uncertainty) but it is the **responsibility of the risk evaluators(s)** to ensure that the

existing uncertainty **is correctly communicated to the risk managers.** They must know the level of reliability of the risk assessment to take decisions.

The assessment is completed with a description of potential risk management options: list of methods available, means available to control the risk. Changing the parameters of the risk assessment model enables experts to select and propose more effective options to managers.

A few rules to keep in mind for risk assessment

'Problem' definition is a key element for success!

Good risk assessment starts with a good question. Correct definition of the problem to be solved and of the objectives of the risk assessment to be implemented is essential (**terms of reference**, questions asked).

The risk evaluator must determine if the question is sufficiently clear and relevant. This **requires communication between managers and evaluators** to ensure that the final result is useful for taking decisions intended to ensure the safety of the food chain and consumer health.

Risk assessment requires a multi-discipline approach! An objective, transparent and unbiased assessment

Depending on the risk to be assessed, experts from several disciplines must work together to ensure successful risk assessment (e.g.: hygiene, chemistry, physics, biology, agronomy, epidemiology, risk assessment methodology, medicine, virology, bacteriology, parasitology, microbiology, food technology, sociology, etc.).

The expertise is not simply added together; the goal must be to create **synergy between them**.

A good risk assessment is based on an **objective and neutral scientific approach**. Value judgements about the economic, political, legal and environmental aspects of the risk should not influence the results of the assessment. **The experts must act with transparency and completely independently.** They do not, under any circumstances, represent their parent institutions. This is collective scientific assessment which must be structured and make the results obtained more relevant

Scientific knowledge and logical theories, the best data available… and an objective measurement of uncertainty!

Good risk assessment is based on scientific knowledge and **clearly formulated theories** which are important to counter missing knowledge and data. A good risk assessment must clearly **describe the theories, the models used and the calculations made** such that the risk managers and the parties concerned can better understand the risk assessment despite its complexity.

Good risk assessment uses **precise and reliable quantitative, qualitative and semi-quantitative data**. Validated computer models should be used whenever possible. Reference should be made to the data sources and to bibliographical information.

A good risk assessment explicitly describes the extent, significance, **nature and source of uncertainty**. Insofar as possible, uncertainty is reduced using the most appropriate techniques (expert opinions, basic examination, qualitative and quantitative techniques such as sensitivity analysis, probabilistic techniques and Monte Carlo analysis). If necessary, variability is described separately and explicitly.

Risk assessment versus the precautionary principle… It depends on uncertainty!

The boundary between a correct risk assessment and the presence of too great an uncertainty is not always clear and depends on the hazard in question. A risk can only be defined when certain minimum level of knowledge about the probability of its occurrence and its consequences is available. When this minimum knowledge is not available, risk manager(s) must be clearly informed **to enable them to apply the precautionary principle**. Of course, the precautionary principle should only come into effect after all other possibilities have been exhausted.

Continuous questioning!

Risk assessment is a **continuous process** and the risk assessed must be **re-evaluated on a regular basis**. Risk assessment is the basis for a management decision at a given time. However, when additional information that may reduce the degree of uncertainty becomes available, the risk assessment must be carried out again.

After management options have been selected and implemented by the risk managers, the assessed risk must be re-evaluated to ensure that it has been brought back to a level deemed acceptable. The impact of changes on the risk assessment must be reviewed when **international standards change**, when the risk deemed to be acceptable changes, **when uncertainties have been removed** by new scientific knowledge, **when external changes appear (changes to production processes**, climate change) and when **new data** become available.

1.4. Risk management

1.4.1. Defining the 'criticality' of a risk

The **criticality of a risk** ***(Cr)*** is defined as the **product of probability** ***(Pr)*** **by the severity of the effects** ***(Se)*** **of the risk** in question:

$$Cr = Pr \times Se$$

Criticality can be visually represented in a diagram (Farmer) using a rating system from 1 to 4 for "probability" and of 1 to 4 for the severity of the effects observed.

Severity of the effects ⬇					**Types of effects on health**
Significant	4	8	12	16	Irreversible damages (fatal)
Moderate	3	6	9	12	Effect is more or less serious but reversible
Low	2	4	6	8	Limited effect (short term)
Minimal	1	2	3	4	No known effect
Probability ➡	Minimal	Low	Moderate	Significant	
	Theoretical and not likely	Has already occurred in the past - this risk can recur	The risk occurs regularly	The risk occurs regularly to always	

This method enables the risk manager to easily prioritize each risk:

- Red squares: immediate priority action is required. The potential risks identified must be eliminated, prevented or reduced to an acceptable level (e.g., change in practices, withdrawal of certain products, discontinuation of certain operations etc.).
- Yellow squares: action is recommended to limit progress, increased monitoring.
- Green squares: no action required but application of good practices.

However, the formula used will naturally be more complex when the **risk** must be defined **for a company** or production sector:

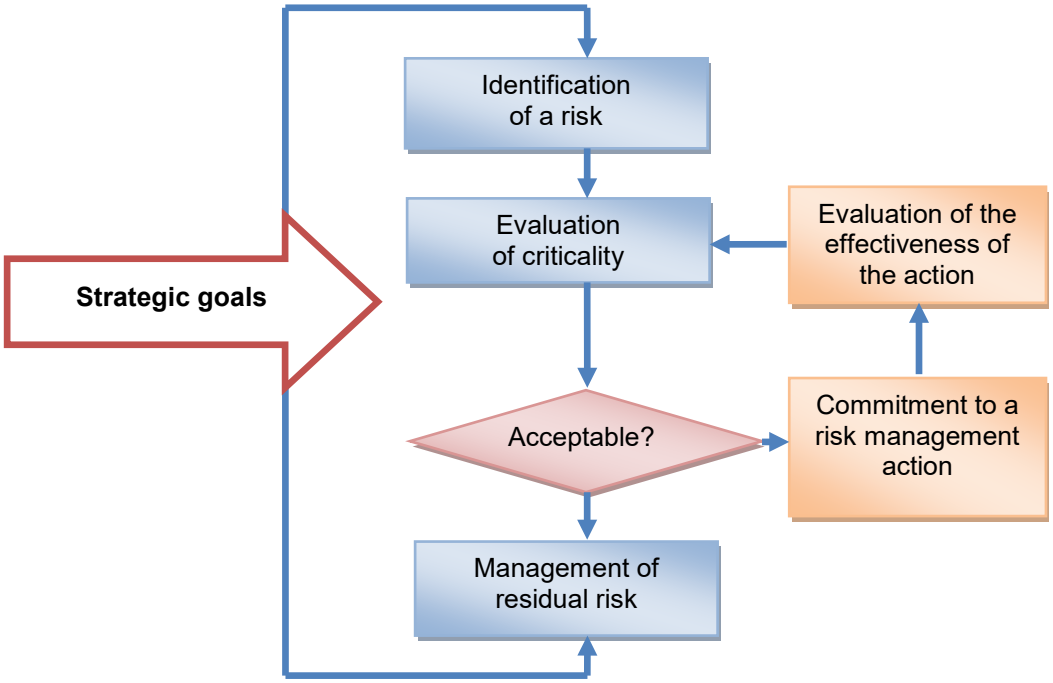
$$Cr = f(Pr, Se, Pnd, Pnc, Pnce)$$

where:

Pr: *Probability that the risk will occur*
Se: *Assessment of the severity of the effect*
Pnd: *Probability of non-detection of the risk*
Pnc: *Probability of non-correction*
Pnce: *Probability of non-compensation for the effect produced*

1.4.2. Role of the company manager, risk manager

'Risk management' (control) requires that **the company set strategic goals**. **This is the role of the company manager.** It is depending on these goals - and, therefore, globally on the strategy - that the decision to accept or to manage a risk is relevant or not:



A risk management policy defines, first and foremost, the levels of risk (criticality) that are deemed acceptable. The company must also include its stakeholders' requirements in its strategic goals... and first of all, those of its customers.

The goal of company management should be the creation of a Risk Management and Monitoring Plan (**RMMP**) that will be implemented and subject to appropriate 'controls'. Chapters two and three will describe the principles of the plan.

The development of a risk management and monitoring plan **is done at the company and sector level.** It must comply with certain basic rules:

- It must be done in **participative mode**: this is an essential condition to ensure quality, and in particular, the relevance of the risk identification and characterization.
- Development of the **management actions** must also be done in participative **mode** to optimize deployment and acceptance.
- The review process should be piloted via audits and/or periodic management reviews which should then be communicated to staff in a suitable format.
- All operators involved in and affected by the processes should be **trained**. This is key to ensuring both the quality of the deployment and their **motivation**. An internal recognition system should also be set up.
- A **self-assessment system** should be implemented (application of the RMMP).

The role of the head of the company will be:

- To set and ensure compliance with **the Food Safety Objective (FSO)**: this is a statement about the tolerable level of danger of a food and is linked to an appropriate level of protection. A FSO expresses the frequency and/or maximum concentration of a macro-biological hazard in a food at the time of consumption in order to meet the acceptable levels of risk (ALOP) set by the authorities (see below).

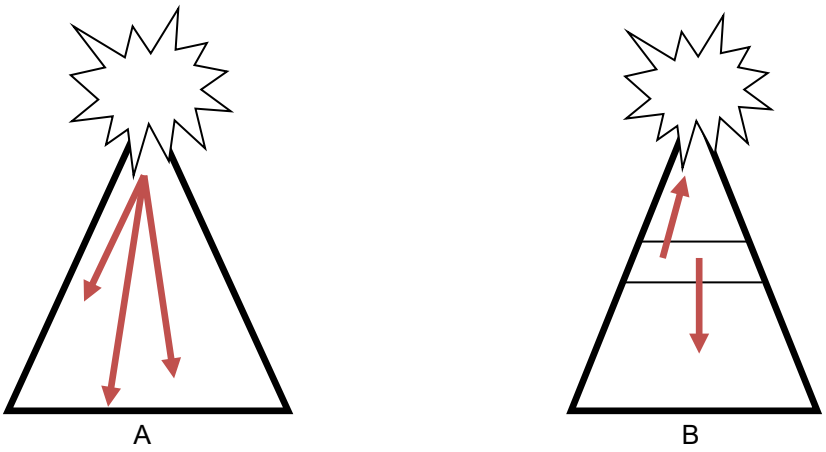
  This is normally a concentration of micro-organisms or toxins at the time of consumption. However, a FSO can also be used for chemical hazards (such carcinogens, pesticides, nitrates, etc.).

  A FSO translates the 'risk' into a well-defined 'goal' which must be attained via an FSMS based on good practices, HACCP and self-assessment. A FSO is preferably a quantitative and verifiable value.

- To set '**performance criteria**' for biological agents to be achieved thanks to the FSMS of the company. A performance criterion is **the result required from one or more control measures** during a production step or a combination of production steps. These measures are implemented to guarantee the conformity of food products.

  The initial level of food contamination by a micro-biological hazard and the **changes in microbial contamination** that occur during production, processing, distribution, storage and preparation through to the time of consumption must be taken into account when setting performance criteria.

➢ To deploy their company's RMMP. Deployment usually follows the two examples below:



'Top-down' deployment the energy starts with management which should attempt to disseminate the control measures throughout the company, both simultaneously and vertically **The boss should take the initiative.**	**'Business line' deployment**: energy is mainly expended at the intermediate level, **generally by the QTM (quality & traceability manager**). Management must provide 'validation' but that is its only role and it therefore expends less energy.

The deployment method used will depend on the environment and on the level of professionalism found in the sector.

Top-down deployment (Figure A) should have a greater chance of success in small organizations. However, company management often does not get involved in technical issues. This can complicate the deployment method due to a lack of a good understanding of the needs and stakes involved.

Business line development (Figure B) is usually used in companies that produce and export fruits and vegetables. Mid-level managers (particularly the QTM) play an essential role. However, they cannot achieve their goals without validation and commitment from management. The main obstacle is, therefore, communication between managers who are deemed too "picky" and management which can seem "uninterested" in the efforts needed and focused solely on results.

Management has other obligations which are not always met.

- **Setting an example**: both for risk management and everyday behavior. There is nothing worse than a boss who enters a packhouse without washing their hands, without protective clothing and does not comply with posted rules.
- **Transparency**: the effectiveness of a risk management approach rests on the confidence that employees have in the approach. There is nothing worse than discovering a major hidden risk such as, for example, the pollution of products with wastewater.

- **Visible personal commitment**: both in what is said… and through actions that include providing resources and setting aside time for training!

1.4.3. The role of the authorities, risk managers

❑ **Setting acceptable levels of risk**

It is up to the competent authority to define what is and isn't acceptable and to monitor compliance by operators with the limits set (this includes "standards" set in regulations).

➢ ***For (micro)biological hazards***

An **Appropriate Level of Protection (ALOP)** must be set for micro-biological hazards (tolerable level of risk/acceptable level of risk).

ALOP examples

"The number of cases of disease caused by a micro-organism in a food, per year and per 100,000 members of a population group deemed tolerable".

"There should be no more than 20 cases of a food-borne disease per 100,000 inhabitants per year in a given country".

The ALOP is the **level reached**, or that can be reached, by the micro-biological hazard for **which the following is taken into account:**

1) **Impact on public health;**
2) **technological feasibility;**
3) **economic consequences**, and where the authority makes a comparison with other risks of daily life in order to take the control measures deemed appropriate.

Once set, an **ALOP is an objective that must be met by the entire production sector** of a given food (from raw materials to finished product).[20]

➢ ***For chemical hazards***

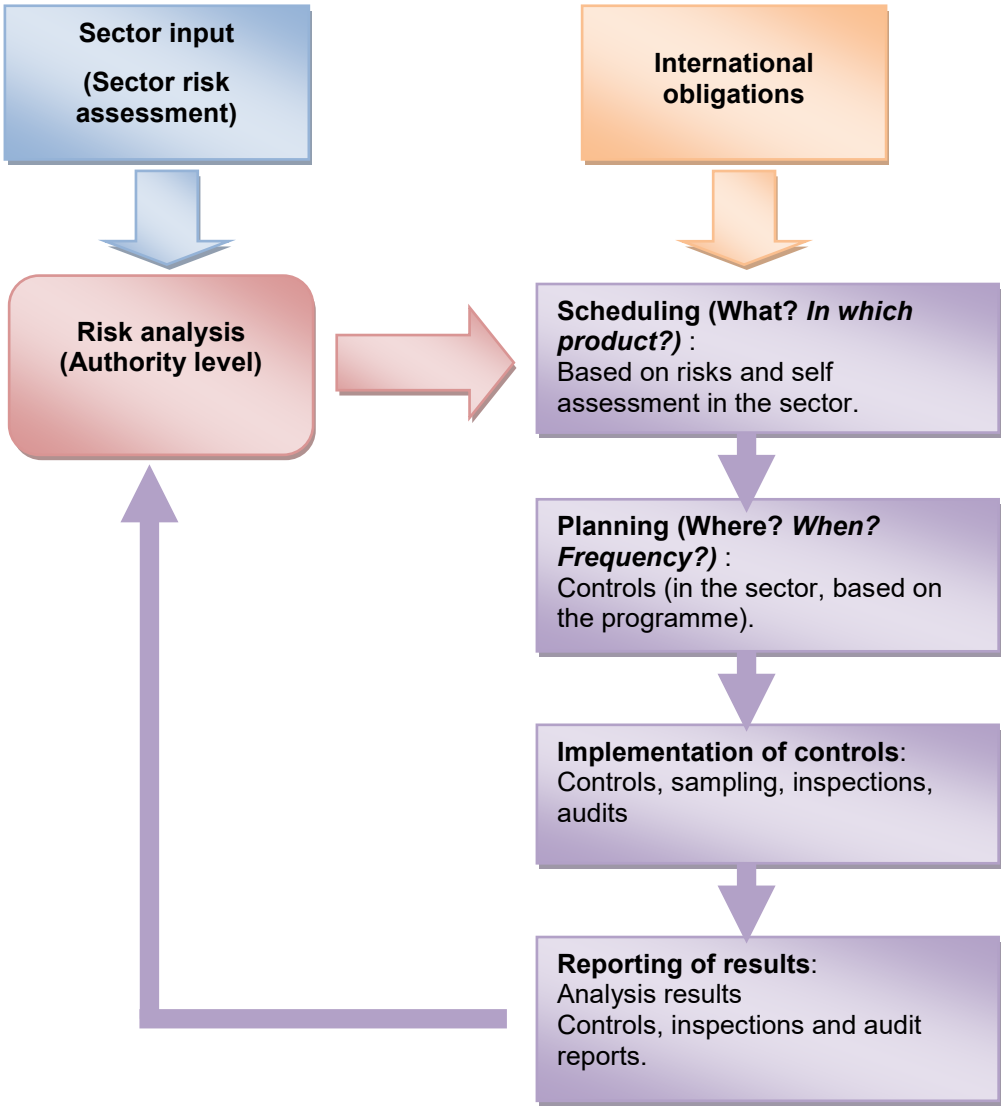
Limit values have been set in regulations based on a risk assessment for consumers. For example:

- MRL or maximum residue level applicable to pesticide residues: the maximum concentration of pesticide residue authorized in or on food and animal feed set based on good agricultural practices and the lowest exposure possible enabling protection of vulnerable consumers (Regulation [EC] 396/2005).
- MRL or maximum residue limit for veterinary medication: the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or in mg/kg on a fresh weight basis) which may be accepted to be legally permitted or recognized as acceptable in or on a food of animal origin (Regulation [EEC] 2377/90).

[20] To meet the ALOP at consumption time, operators must set and comply with Food Safety Objectives (FSO).

- ML *(Maximum Level)*: the maximum allowable level applicable for other contaminants (e.g.: heavy metals) (Regulation [EC] 1881/2006 setting maximum levels for certain contaminants in foods).

❑ **Planning and scheduling controls based on identified risks**



Official controls carried out by the authorities will be based on a series of choices. **Risk assessment** carried out both by experts working under the supervision of the authorities and by sector professionals (within the framework of the development of a self-assessment guide, for example) is an key element in **the selection of scheduled controls** because it takes into account the severity of the harmful effects caused by the hazards (heavy metals, pesticide residues, salmonella, etc.) and the importance of observations from previous years.

The legal obligations and recommendations of international bodies (e.g.: OIE, IPPC, WHO etc.) and the recommendations of the different committees (including the *Codex*

Alimentarius Committee) are also among the criteria considered for the scheduling of official controls.

The presence in a sector of a **validated self-assessment system** at a majority of operators and the results of inspections and previous sanctions for operators are **among the decisive elements in scheduling** controls.

Official controls are planned and organized by the authorities in a 'Control Programme'.[21] They consist of inspections (operator identification, examination of logs, hygiene inspections, for example), analyses (bacteriological, residues) and audits of self-assessment systems (including traceability systems).[22] The various possibilities that will condition the way in which the **number of analyses** is determined should be differentiated when the control programme with sampling is set up:

- the number of analyses is set by regulations (especially in the animal sector);
- the number of analyses is set by risk analysis (e.g., as part of self-assessment);
- the number of analyses is part of monitoring (national or international);
- the number of analyses is estimated ahead of time (if data is missing).

If need be, **the number of analyses can be adjusted** by the authorities to take into account media, political and consumer sensibilities and economic considerations (e.g., to renew confidence in a source).

Other controls cannot be carried out in addition to the planned controls. This means controls carried out following a positive or suspect analysis result, as part of an inquiry or action at border inspection posts (Houins, G., 2007).

[21] Control programme: a control plan as intended in Article 42 of Regulation (EC) 882/2004 on controls performed to ensure the verification of compliance of food products. The control programme concept covers scheduled controls with and without sampling. For example, control is also to verify regulatory provisions on the use of phytosanitary products and fertilisers since they can have a direct or indirect impact on the safety of the food chain.

[22] The concept of an 'audit' is reserved for controls to validate quality and self assessment systems.

1.5. Risk communication

1.5.1. What are the goals of risk communication?

Risk communication consists of **an exchange of information and opinions** about risks between those responsible for risk assessment and for risk management and other interested parties such as professional sectors and even the general public (for example, consumer groups, scientists). It ensures the transparency of the risk assessment carried out and its **consistency**.

Among other things, risk communication includes:

- the conclusions of the risk analyses carried out;
- the results (at least the summaries) of analyses carried out as part of self-assessment (for companies) or of the overall monitoring plan (for the authorities);
- control measures that have either been proven effective or not;
- measures campaigns that must be carried out and the reasons for them;
- complaints and product refusals and the crises faced;
- withdrawals and recalls;
- etc.

Risk communication **is primarily the responsibility of the authorities.** The risk manager must decide whether or not to inform professional sectors and/or the public about existing risks and about the preventive measures to be implemented or already implemented to reduce risks and bring them back to an acceptable level. It also means communicating on the effectiveness of the measures and on evolving risks.

It isn't, however, reserved solely for public risk managers. It involves all stakeholders and is, notably, **one of the tasks assigned to the heads of companies** who must also communicate about risks in their company and with the producers who supply them with the products they pack.

Special procedures (communication level, type of communication, key messages) must be defined depending on whether it is a communication from the authorities or the head of a company:

- to communicate effectively with **the various audiences.** The type of communication is therefore very important;
- to ensure that the information will circulate in a suitable way **between the parties concerned or between employees.** Messages must be clear and relevant for recipients and understandable by all.

1.5.2. General principles of communication

A few general principles were defined during a joint FAO/WHO meeting to ensure effective risk communication (FAO, 1998). They can be summarized as follows:

1. Know public opinion. Understand the motivation, opinions, concerns and impressions of individuals and groups who shape public opinion and designing

messages to communicate information on risks that deal with these issues enables better communication. **Listening to all parties** concerned is also an important aspect of risk communication.

2. **Involve scientific experts**. These experts must be involved because they can supply information about the risk assessment approach and its results and about subjective theories and opinions. This will provide the decision-makers responsible for risk management with complete information and a full understanding of the risks.
3. Make use of the competences of communication experts. Expertise in communication matters is essential to communicating the appropriate message in a clear, understandable and instructive way. It is therefore necessary to involve these experts in the process right from the outset.
4. **Be a credible information source**. Information from a credible source is likely to be better accepted by the public. Consistent messages from multiple sources will increase the credibility of the risk information message. In order to be credible, the public must be provided with the opportunity to see competence, reliability, honesty and impartiality. In addition, communication **specialists must work with facts**, demonstrate their expertise and be attentive to the well-being of the public, responsible, honest and have a good reputation**. Effective communication acknowledges the existence of problems and difficulties**. Its content and approach must be open and timely.
5. Share responsibilities. Communication must involve multiple actors, among which, the officials responsible for regulations, industrialists, consumers and the media. **Each has a specific role to play but by sharing responsibilities** each can assume theirs in a way that enables effective communication.
6. When developing a message to communicate information about risks, it is essential to separate fact from opinion.
7. Ensure transparency. To be sure that the public will accept the risk information messages, the process must be open and controllable by the parties concerned.
8. Put the risk in perspective. It's possible **to put the risk in perspective** by examining it under the angle of its potential advantages or **by comparing it with other, more familiar, risks**. However, this must not be done in such a way that it gives the public the impression that the comparison is being made to lessen the severity of the risk! It is important to avoid using certain inappropriate "images" or analogies.

1.6. Crisis management

1.6.1. The concept of a 'crisis'

There are various definitions of the word 'crisis' (of the state of crisis) because there are many types of crises:

1. industrial accidents (nuclear explosions, pollution, transportation accidents etc.);
2. natural catastrophes (earthquakes, tsunamis, fires etc.);
3. production site failures (general failures, major product defects, destruction of the sites etc.);
4. social crises(strikes, violence in the workplace, takeovers of premises, etc.) and humanitarian crises;
5. and of course, food crises such as: the dioxin crisis (chicken meat and eggs contaminated with dioxin); melamine in Chinese milk powder crisis; mad cow disease etc.

Most authors agree on a definition close to the following:

*"Crisis: a situation in which multiple organizations facing critical problems, **strong external pressure** and bitter internal tensions, are suddenly, and for a long period of time, **thrust to the front of the stage** and thrust into conflict with one another... in a mass communication society, that is, live and with **the guarantee of making headlines** for a significant period of time".*

The general idea resulting from this definition is that companies, and more generally, organizations (including countries) can become the focus of **heavy media exposure** when customers and the public are informed that a serious **dysfunction that can affect public health** has occurred and when, objectively or not, **they can no longer guarantee** that they can deal with the situation or solve the problem alone.

There are, therefore, **actual events** to be considered in a crisis (e.g., the exceeding of a standard found by analysis; the company's capabilities; the existence of internal procedures, etc.) and **subjective elements** (e.g., the lack of credibility of the operator whose competence is under fire: they are not thought to be capable of solving the 'problem').

The subjective elements make **the start and end of a crisis** difficult to pinpoint in time. **There is a crisis when the stability of the company is compromised.** Even after the problem is resolved (e.g., the defective products have been withdrawn or recalled, the causes of the crisis have been identified and production is perfectly under control) the moment customers and the public perceive as the return to 'normal' operations is sometimes difficult to pinpoint. **It can be difficult to know when a crisis is really over** (when 'doubt' disappears and customer confidence returns? What if it never comes back?)

The definition of a crisis emphasizes its media aspect. When media attention is drawn to another, more urgent event, the public's perception will change, the crisis will drift to the background or it will entirely disappear from the news. There is no longer a crisis... even though the crisis may still exist! Some groups (politicians, industrial groups, opinion

shapers) have become masters at the art of media manipulation... and at leaving the scene after creating a diversion.

1.6.2. Crisis management by the company

In the event of a food crisis, companies **must be able to react quickly and effectively** in order to, on one hand, be able return to normal operations as quickly as possible and, on the other, to be able to draw lessons from the crisis to improve their operations.[23]

It is therefore preferable that the company plan for the possibility of a crisis and prepare for it with **procedures to be followed** in the event that it occurs. The company will be ready to deal with it. The company should also define "**action thresholds**" with this type of procedures[24] to know if there is a crisis or not.

Regardless of the reason for a crisis, the company's reaction should always be the same:

1. **Accept that there is a crisis situation and acknowledge it** (to customers and the authorities). In terms of communication, the following should be done:
   - check the potential effects of the failure on customers. Thanks notably to **product traceability**, the number of lots involved and their destinations can be pinpointed**;**
   - **provide direct customers with all information needed** to help them in their own crisis management operations;
   - if a supplier is the cause of the problem, the company should also communicate with them (because other companies in the sector could be impacted);
   - inform the authorities if need be. Notification of the authorities is **not required** when a hazard arises and is discovered within the company, or during processing, **if the self-assessment system includes internal corrective actions** that will enable the elimination or reduction of the hazard to an acceptable level and as long as traceability of the corrective actions is ensured.

2. **Organize 'crisis management'**: a crisis team should be created for the duration of the crisis and should be provided with the authority to take the immediate decisions required. The measures that will be used most frequently are:
   - the **withdrawal of products** for which the company is still responsible: all measures aimed at preventing the distribution and sale of a products;
   - the **recall of products** after distribution: all measures aimed at preventing the consumption or use by consumers and at informing them of the danger they are facing if they have already ingested the product.

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[23] Unlike some authors, we won't go so far as to say that "all crises have a silver lining. Although it's may be possible to draw some benefit, most food crises lead to unacceptable health consequences (food poisoning) and considerable economic damage, not only for the company in question, but often for an entire sector: the consumption of a given product may collapse for several months regardless of the producer or the product's origin.

[24] An "action threshold" can be something other than a given value that indicates a crisis when it has been exceeded. It can also be the combination of a measure and a defective operation (e.g.: exceeding a MRL and the absence of traceability for certain lots).

Contrary to what certain people may think, the responsibility for withdrawal and recall of commercial products lies primarily with the companies involved. **The authorities informed of the crisis will not assume the operator's responsibility although dialogue is required in the event of a serious incident!**

3. **Quickly take all measures required to safeguard the company.** Protecting the company requires putting a quick end to the crisis which can include, amongst other things:
   - an in-depth review of responsibilities and, if necessary, new process managers;
   - an overhaul of the management team;
   - a complete review of the company's processes and, potentially, complete or partial re-engineering;
   - if need be, the use of external consultants or managerial expertise;
   - a review of the company’s overall strategy;
   - communication about the measures taken then about the end of the crisis.

Appendices

A.1. Recommended risk analysis terminology

Definition of the terms used, based on AFSCA (Belgium) and the Codex Alimentarius.

Deterministic risk assessment
The deterministic method uses a random estimate for each model variable (for example, an average) to determine the results of the model.

Dose-response
Determination of the relationship between the extent of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of the associated effects on health (response).

Exposure assessment
The qualitative and/or quantitative evaluation of the probable absorption [ingestion] of a biological, chemical or physical agent via food, and exposure to other sources if relevant.

Hazard analysis
The process of collecting and evaluating information about hazards and the circumstances leading to their appearance in order to decide which dangers are relevant to food safety and must be included in the HACCP plan.

Hazard characterization
The qualitative and/or quantitative assessment of the nature of harmful effects on health associated with biological, chemical and physical agents that may be present in foods. A determination of the dose-response curve is required for chemical agents. A determination of the dose-response should be carried out for biological and physical agents **if data can be obtained**.

Hazard evaluation
Evaluation of the risk resulting from the hazards mentioned. To do so, the probability that the hazard cited will occur must be verified and, if it does occur, what its effect will be on public health.

Hazard identification
Identification of biological, chemical and physical agents that can lead to harmful consequences for health and which may be present in a specific food or in a group of foods.

Incidence
Incidence is defined as the number of new cases of a disease per unit of time in a given population. Incidence should not be confused with prevalence which indicates how many people/animals in a given population are suffering from a disease at a given time.

Monte Carlo simulation
This technique uses random sampling of each probability distribution in a model to create a large number of scenarios or iterations. Sampling is carried out taking the shape of distribution into account.

Percentile
A percentile of a data set is one of the 99 points that separate the ordered data set into 100 equal parts. For example, the 95th percentile is a number which 95% of the data is less than or equal to and 5% is greater than or equal to.

Prevalence
Prevalence indicates how many people/animals in a given population are suffering from a disease at a given time.

Precautionary principle
European Regulation 178/2002 describes the precautionary principle as follows: In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure a high level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment.

Probabilistic risk assessment
Model variables are handled as distributions in the probabilistic method.

PTMI (Provisional Tolerable Monthly Intake)
The amount of a given compound, expressed in kg of body weight, that can be ingested monthly during an entire lifetime and not cause any health problems. This is typically used for contaminants with cumulative properties with a very long half-life in the human body. The ingestion should be considered a temporary value that can be modified if additional scientific information becomes available.

PTWI (Provisional Tolerable Weekly Intake)
The amount of a given compound, expressed in kg of body weight, that can be ingested weekly during an entire lifetime and not cause any health problems. This is typically used for contaminants with cumulative properties. This quantity should be considered a temporary value that can be modified if additional scientific information becomes available.

Risk analysis
A process including three interconnected facets: risk assessment, risk management and risk communication.

Risk assessment
A scientific process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

Risk characterization
A qualitative and/or quantitative assessment including uncertainties and related issues, of the probability of appearance and severity of the potential harmful effects on health in a given population group based on the identification and characterization of hazards and the exposure assessment.

Risk communication
The interactive exchange, during the entire risk analysis process, of information and opinions on the hazards and risks, the factors related to the risks and perceptions of the risks, between those responsible for risk assessment and risk management, consumers, the companies of the food and animal feed industries, universities and other concerned parties, and notably, an explanation of risk assessment results and the reasons for the risk management decisions taken..

Risk estimate
The results of risk characterization.

Risk management
A separate process from risk assessment that consists in weighing the various potential policies in consultation with the concerned parties, in taking into account the risk assessment and other legitimate factors and, if need be, in selecting the appropriate prevention and control measures..

Scenario analysis
In a scenario analysis, different risk management measures (also called scenarios) are compared to determine which is best suited to limiting the risk. The scenario analysis can also be used if current knowledge does not enable a single risk assessment, that is, if the information is missing or insufficient to be able to assign a probability to the various scenarios.

TDI (Tolerable Daily Intake)
The amount of a given compound, expressed in kg of body weight, that can be ingested daily during an entire lifetime and not cause any health problems. This is typically used for contaminants (as opposed to the acceptable daily intake).

TWI (Tolerable Weekly Intake)
The amount of a given compound, expressed in kg of body weight, that can be ingested weekly during an entire lifetime and not cause any health problems. This is typically used for contaminants.

Uncertainty
Uncertainty (also called epistemic uncertainty) is a lack of complete knowledge. The result of uncertainty, combined with variability, is that it is impossible to predict what will happen in the future.

A.2. Risk assessment examples (deterministic approach)

❑ **Case study No. 1:**

What is the risk of ethephon in concentrations above the MRL in pineapples? Is there a difference between groups of consumers?

This case study is an example of deterministic risk assessment for pesticide residues.

A batch of pineapples was analyzed on arrival on European soil. The ethephon residue value provided by the analysis laboratory was 3.3 mg/kg, above the MRL for pineapples[25] of 2 mg/kg. A risk assessment was therefore carried out.

➢ ***Step No.1: hazard identification***

The active substance ethephon ([2-chloroethyl] phosphonic acid) is a growth regulator with systemic properties (it penetrates inside the plant tissue and decomposes into ethylene, acting on the growth process). Ethephon is used on pineapples and other crops (e.g., tomatoes) notably to induce flowering. The MRL can be exceeded for several reasons:

- Non-compliance with the dose/ha?
- Non-compliance with the pre-harvest interval (PHI)?
- Non-compliance with the number of applications?
- Incorrect application?
- An anomaly in the product concentration?
- Unpredictable circumstances (climate)?

Review of the field log should enable determination of the source of the problem.

➢ ***Step No. 2: hazard characterization***

EFSA has set toxicological reference values. With respect to ethephon, the ARfD (acute toxicological risk for consumers) is 0.05 mg/kg bw/day (PRAPeR Meeting 54, EFSA, 2008, with a safety factor of 100).

An ADI of 0.03 mg/kg bw/day was also set by EFSA with a safety factor of 1000 (EFSA, 2009).

➢ ***Step No. 3: exposure assessment***

The risk of ingesting a food containing pesticide residues in excess of the MRL (Maximum Residue Limit) is assessed using the worst case scenario by calculating the PSTI (Predictable Short Term Intake). For this purpose, toxicological data on the pesticide, data on dietary habits (97.5th percentile) and the amount of residue in the food are needed.

Various food consumption data such as the GEMS/Food Regional Diets or PSD-UK data can be used for dietary habits. The following can be consulted for other data required for the PSTI calculation and interpretation of the PSTI results:

- Directive 2006/85/CE modifying Directive 91/414/EEC of the Council to add the active substances fenamiphos and ethephon.
- EFSA, *MRLs of concern for the active substance ethephon*, EFSA Scientific Report, Prepared by the Pesticides Unit (PRAPeR), 2008, No. 159, pp. 1-31.
- EFSA, “Review of the existing maximum residue levels (MRLs) for ethephon”, *EFSA Journal*, vol. 7, No. 10, 2009, p. 1347.

[25] MRL available at: ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.

- PSD (Pesticides Safety Directorate), "UK Technical policy on the estimation of acute dietary intake of pesticide residues", 13 January 1998
- SANCO, "Draft Proposal on how to notify pesticide residues in foodstuffs in the Rapid Alert System for Foodstuffs", REF. SANCO/3346, 2001, rev 3.

Data required for the PSTI calculation

Data	Value
Consumption data at the $_{97.5}$ percentile for an adult (UK-PSD, LP adult)	0.3456 kg
Consumption data at $P_{97.5}$ for a child (UK-PSDLP child)	0.4149 kg
Adult body weight (UK-PSD, bw adult)	76 kg
Child body weight (UK-PSD, bw child)	20.5 kg
Concentration of residue observed (OR)	3.3 mg/kg
Food unit weight (U)	1.6 kg
Variability factor (v)	5
Transformation factor (t) proposed by EFSA, removal of the pineapple skin)	0.25

The estimate of short-term exposure of two groups of consumers of contaminated pineapple to ethephon is done using the PSTI calculation formula (according to DG SANCO 3346 & PSD):

$$PSTI = \frac{((U * OR * v) + (LP\text{-}U) * OR) * p}{bw}$$

where:

U = unit (food unit weight) in kg
OR = observed residue, in mg/kg (here: 3.3 mg/kg > MRL)
v = variability factor = 5
p = processing factor, here: 0.25
bw = body weight of the group in question

		Adults	Children
Value of the ethephon residue observed in the pineapples: 3.3 mg/kg	**PSTI**	0.0750	0.3339
	PSTI using a processing factor of 0.25 :	0.0187	0.0835
	% ARfD :	37.4%	167.0%

➢ **Step No. 4: risk characterization**

The result of the exposure assessment (PSTI) compared to the ARfD (acute reference dose):

Adult group: (0.0187 / 0.050) x 100 = 37.4 %

Children's group: (0.0835 / 0.050) x 100 = 167.0 %

The toxicological risk is considered to be unacceptable for consumers if the PSTI > ARfD.

Conclusion

There is no risk of intoxication for the adult group (37.4% of the ARfD)… but there is a risk for children (167% of the ARfD!).

The contaminated lots should not be sold.

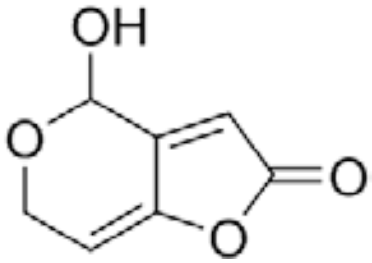
❑ **Case study no. 2:** (based on an article by K. Baert *et al*., AFSCA, 2007)

What is the risk of patulin in apple juice?
Is there a difference between organic and other juices?

➢ ***Step No. 1: hazard identification***

Patulin is a mycotoxin consisting primarily of *Penicillium expansum*, a mould often found on apples and pears.

Apples are infected during harvesting and storage. The mould continues to develop during storage and produces patulin.



Patulin ends up in the juice during the production of apple juice. This leads to consumer exposure.

Patulin is acutely toxic. It is also genotoxic, cytotoxic, teratogen, immuno-suppressive and potentially neurotoxic. However, it apparently has only local toxicity in humans.

➢ ***Step No. 2: hazard characterization***

Based on a dose-response study, the NOAEL for patulin was set at 43 µg/kg of body weight/day (µg/kg bw/day. Based on this value and a safety factor of 100, the JECFA (Joint FAO/WHO Expert Committee on Food Additives) has recommended the value (VTR) of 0.4 µg/kg of body weight/day as the TDI for patulin.

➢ ***Step No. 3: exposure assessment***

1. Contamination level

A study has shown that the **prevalence** of patulin in organic (12%), conventional (13%) and artisanal (10%) apple juice is not significantly different.

The **average** patulin **concentration** in contaminated samples is significantly higher in organic apple juice (41.3 µg/liter) than in conventional (10.2 µg/liter) and artisanal (10.5 µg/liter) apple juices.

We analyzed 177 apple juices for their patulin content for the contamination data of this case study.

2. Consumption data

Apple juice and apple nectar are the main sources of patulin. Young children are more exposed to patulin via apple juice. A study has shown higher ingestion of patulin in young children who consume significant amounts of juice compared to other population groups.

The consumption of apple juice was determined based on the study of nutritional habits of young children (2.5 to 6.5 years of age). It was assumed that consumers only drink one of the three types of apple juice (a drinker of organic apple juice will only drink organic apple juice). It was also assumed that the consumption habits of the three consumer groups (organic, artisanal and conventional) were the same.

3. Calculations

In this case study, the exposure of young children to patulin via the consumption of apple juice was determined using probabilistic techniques based on a Monte Carlo simulation.

The calculation was as follows:

Patulin ingestion (µg/kg bw/day) = patulin concentration in apple juice (µg/kg) x apple juice consumption (g/kg bw/day) x 0.001 (g/kg)

Exposure to patulin (µg/kg bw/day) for different apple juices (AJ)
(median [90% confidence interval]):

	Organic AJ	Conventional AJ	Artisanal AJ
P83*	0 [0-0]	0 [0-0]	0 [0-0]
P90	0.039 [0.014-0.069]	0.030 [0.011-0.049]	0.037 [0.013-0.066]
P95	0.072 [0.027-0.117]	0.059 [0.031-0.085]	0.065 [0.027-0.102]
P97.5	0.135 [0.053-0.229]	0.095 [0.057-0.133]	0.102 [0.047-0.151]
P99	**0.350** [0.143-0.822]	0.156 [0.106-0.206]	0.150 [0.084-0.229]
P99.9	**1.471** [0526-3066]	**0.328** [0210-0548]	0.298 [0156-0460]

*83rd percentile

Simulations show that 83% of children do not ingest patulin via apple juice. Only **very big consumers of organic apple juice** exceeded the TDI (= 0.4 µg/kg bw/day). The other groups came near.

➢ ***Step No. 4: risk characterization***

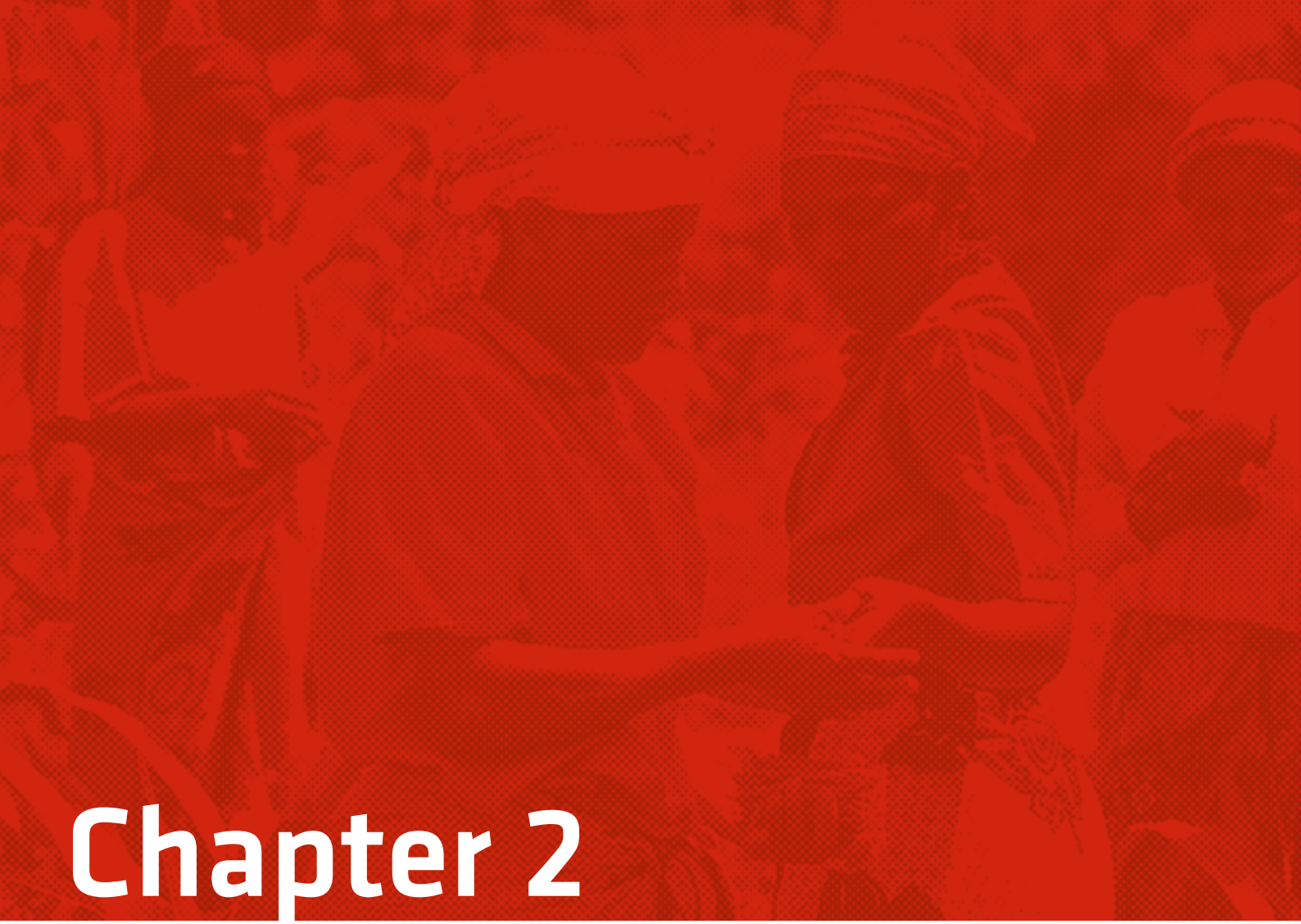
Simulation of exposure showed that the TDI for patulin is sometimes exceeded (organic juice). Children who drink conventional or artisanal juice do not exceed the TDI.

Bringing together the data from the hazard characterization and the exposure estimate showed that the probability of exceeding the TDI via the consumption of apple juice was 0.009 [IC 90%: 0.003-0.018], whereas for conventional and artisanal apple juices, it was 0.001 [IC 90%: 0-0.003] and 0 [IC 90%: 0-0.002] respectively.

Conclusion

The consumption of apple juice and, more precisely, of **organic apple juice by young children** can lead to exceeding the TDI. It is therefore recommended that:

- apple juice consumption be limited;
- storage time be limited for organic apples. The absence of fungicides promotes the development of the fungus, and therefore, the appearance of the mycotoxin. Sorting the apples and reduced storage times will ensure a reduction in the patulin concentration in juice products.



Chapter 2

Risk management

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2.1. Introduction

Risk analysis must occur in a context and, to be done effectively, requires a formal process. In a typical instance, a food safety problem or issue is identified and risk managers[1] initiate a risk management process, which they then see through to completion. 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. 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.

Ensuring food safety (Source: Eprofeel)

The generic risk management framework (RMF) presented in this handbook provides a practical, structured process for food safety regulators to apply all the components of risk analysis. It is comprised of four major phases and numerous specific activities. The four main phrases are:

- preliminary risk management activities;
- identification and selection of risk management options;
- implementation of risk management decision;
- monitoring and review.

The complete process is cyclical and there may be many iterative loops between phases and steps. Parts of the RMF can be repeated as new information becomes available, or as work done at a later phase indicates a need to modify or re-examine work done at an earlier stage.

2.1.1. Perspectives on risk

Food safety risks can be viewed in several ways and each of these perspectives may be applied by some participants in any given application of the food safety RMF. The 'technical' view is the primary one for decision-making, but risk managers also apply psychological and sociological risk perspectives, as appropriate, in establishing food safety standards.

[1] Risk managers are generally assumed to be officials of a national food safety authority (also called the 'Competent Authority' in language of the SPS Agreement). In practice, managers in industry and many other officials can also serve as risk managers.

Perspectives on risks

Technical paradigm: Focuses on and is limited to scientific evaluation of the likelihood and severity of harm. May include an economic subset in which harm can be described in terms of either health indices, such as Disability Adjusted Life Years (DALYs) or monetary value.

Psychological paradigm: Evaluates risk as a function of individual perception, giving weight to such attributes as voluntariness of exposure, controllability of risk, catastrophic nature of risk, and so on. Risk perceived in these ways may differ in 'magnitude' from technical risk estimates.

Sociological paradigm: Views risk as a social and cultural construct, with the goal of distributing costs and benefits in socially acceptable and equitable ways.

But risk managers also use the psychological and sociological perspectives of the risks, if any, in setting food safety standards.

As further described, food safety risk assessment is anchored to the greatest extent possible in the technical perspective, and risk assessors are expected to base their work on scientific data and methods.

The overriding consideration in the technical paradigm is that risk assessment is specific to the described scenario.

2.2. A generic risk management framework

A generic process for carrying out risk management is presented below. Such frameworks developed at the international level (e.g. the Codex Committee on Food Hygiene – CCFH - has developed principles and guidelines for the conduct of microbiological risk management[2]) provide useful templates for countries developing their own risk management system.

A **generic RMF** for food safety risk management must be functional in both strategic, long-term situations (e.g. development of international and national standards when sufficient time is available) and in the shorter term work of national food safety authorities (e.g. responding rapidly to a disease outbreak).

[2] FAO/WHO. 2005. Proposed draft principles and guidelines for the conduct of microbiological risk management. Appendix III in Report of the 37th Session of the Codex Committee on Food Hygiene. Buenos Aires, Argentina, 14-19 March 2005. ALINORM 05/28/13. Codex Committee on Food Hygiene (available at: http://www.codexalimentarius.net/web/archives.jsp?year=05).

In all cases, it is necessary to strive to obtain the best scientific information available. In the former situation, risk managers will usually have access to extensive scientific information in the form of risk assessment reports. In the latter situation, risk managers are not likely to have access to a complete risk assessment and therefore will need to rely on whatever scientific information on risks is readily available (such as human health surveillance and food-borne disease outbreak data) as a basis for preliminary decisions on control measures.

2.3. Understanding risk management

The first phase of the RMF consists of 'preliminary risk management activities'. After a food safety issue has been identified, available scientific information is aggregated into a risk profile that will guide further action. Risk managers may seek additional and more detailed scientific information on an assessment of risks from methodologies such as risk assessment, risk ranking or epidemiology-based approaches such as source attribution.

(Source: 123rf)

Ranking using tools that rely on knowledge of risk factors to rank risks and prioritize regulatory controls may be carried out either within or without risk assessments. Epidemiology includes observational studies of human illness such as case-control, analysis of surveillance data and focused research, and is used to apportion risks and contribute to setting risk-based standards. These approaches are often used in combination.

If a risk assessment is needed, it can be commissioned from those responsible for that function, with iterative discussions between risk managers and risk assessors to determine the scope of the risk assessment and to decide on questions it is to answer. Near the end of this preliminary stage, the results of the risk assessment are delivered back to the risk managers and further discussions are generally held on the results and their interpretation.

During this 'preliminary' phase, good risk communication is important. Communication with external interested parties often is 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. Internal communication between risk managers and risk assessors is vital for many reasons, such as to ensure that the scope of the risk assessment is reasonable and achievable, and that the results are presented in a readily understandable form.

The second phase of the RMF consists of identifying and evaluating a variety of possible options for managing (e.g. controlling, preventing, reducing, eliminating or in some other manner mitigating) the risk. As before, effective communication is a prerequisite for success, as information from and opinions of affected stakeholders, particularly industry and consumers, are valuable inputs to the decision-making process.

Weighing the results of the risk assessment as well as any economic, legal, ethical, environmental, social and political factors associated with the risk-mitigating measures that might be implemented can be a complex task. Economic evaluation of possible risk management interventions enables risk managers to examine the health impacts and feasibility of a proposed intervention relative to its cost. An open and participatory process helps ensure that the final decision is understood and widely supported by those affected by it.

When preferred risk management options have been selected, they must be **implemented** by the relevant stakeholders **(third phase of the RMF).** In many countries today, industry has the primary responsibility for implementing regulatory standards. However, some non-regulatory risk management options may be selected, such as quality assurance schemes at the farm level, or consumer education packages for food handling in the home. Generally, national food safety authorities must validate and verify implementation of regulatory standards.

Once control measures have been implemented, **monitoring and review activities should be carried out.** The goal is to determine whether the measures that were selected and implemented are in fact achieving the risk management goals they were meant to achieve, and whether they are having any other unintended effects. Both industry and government bodies are likely to be involved in monitoring and review activities. Both sectors usually monitor levels of hazard control, while government generally carries out health surveillance of the population to determine the level of food-borne illness. If monitoring information indicates a need to review the decision as to risk management options, the risk management process can begin a new cycle, with all interested parties participating as appropriate.

Control measures (Source: Belgianmeat)

When dealing with a given specific food safety issue, a RMF can be entered at any phase and the cyclical process can be repeated as many times as is necessary. What is most important is that appropriate attention is paid to all the phases in the process. More than anything else, application of the RMF represents a systematic way of thinking about all food safety issues that require risk management. The level of intensity of each phase will be matched to the needs presented by each food safety issue and may range from simple, qualitative processes to complex scientific and social evaluations.

The succeeding sections examine step-by-step application of the risk management framework, as described above.

2.4. Preliminary risk management activities[3]

2.4.1. Step 1: Identify and describe the food safety issue

Identifying and articulating the nature and characteristics of the food safety issue is an essential first task for risk managers. Sometimes the issue is already recognized and accepted as a food safety problem that needs formal risk assessment. At other times, the problem may be apparent but additional information is needed before further actions can be decided on and implemented.

A RMF can also be used to resolve food safety issues that do not necessarily require risk reduction. For example, as new processing technologies such as gas depleting of fresh meat carcasses become available, it is necessary to see whether these innovations produce any changes in bacterial contamination profiles that might affect the current level of consumer protection. In other situations, new technologies may require interventions to avoid increased risks. For instance, in the early stages of the BSE epidemic in the United Kingdom, the use of mechanical separation of muscle from bone in meat packing houses needed to be re-evaluated because this method commingles nervous tissue (a specific risk material) with meat fragments.

[3] Preliminary risk management activities were referred to as 'risk evaluation' in the past. In the 13th Edition of the *Codex* Procedural Manual, 'risk evaluation' was defined as a 'preliminary risk management activity' to differentiate it from 'risk assessment'.

Some food safety issues that benefit from application of a RMF

- A new or emerging potential hazard that constitutes an unknown level of risk; for example, 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; for example *Listeria monocytogenes* in delicatessen meats.
- A need to rank and prioritize risks posed by a group of similar hazards; for example, enteric pathogens, for risk management.
- An indication of a high level of risk to consumers associated with a category of foods; for example, imported spices.
- Evaluation of new animal production methods, such as the use of a new veterinary drug 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, such as an alternative pasteurization regime for a heat-treated food product.
- Development of a basis for reaching a judgement on the equivalence of different production and processing systems or individual food safety measures in different countries.

Food safety authorities learn about food safety issues that require resolution in a variety of ways. Safety problems may be identified by domestic and international (point of entry) inspection, food monitoring programmes, environmental monitoring, laboratory, epidemiological, clinical and toxicological studies, human disease surveillance, food-borne disease outbreak investigations, technological evaluation of novel foods and difficulties in achieving compliance with regulatory standards, among other ways.

Sometimes academic or scientific experts, the food industry, consumers, special interest groups or the media expose food safety problems. At other times, food safety issues that are not necessarily driven by concerns about food-borne risks to consumers become apparent through legal action and disruptions to international trade

Rating scheme (Source: Process)

A brief initial description of the food safety issue provides the basis for developing a risk profile, which in turn generates a context and guide for further action. This first step also usually requires risk managers to determine their initial public health objectives. If the problem is urgent and solutions must be implemented rapidly, any risk analysis may be limited and the range of options considered may be fairly restricted. For less urgent problems, the scope of a risk analysis could potentially be very wide. But resource limitations, legal and political considerations, and other factors generally help risk

managers make practical decisions about the depth and length of the risk analysis that is to be conducted in any given case.

Examples of step 1: Identifying a food safety issue

Methylmercury in fish was first identified as a food-borne hazard in the 1950s when an outbreak of severe neurological disease occurred in babies whose mothers ate fish from Minamata Bay in Japan, which had been polluted by mercury from local industry.

More recently, an epidemiological study in the Faeroe Islands, where the diet is rich in seafood, provided evidence that the amount of mercury in fish and whale meat in the absence of heavy pollution is still high enough in some circumstances to pose risks to the fetus.

Listeria monocytogenes has long been recognized as an important food-borne pathogen. Several recent outbreaks of listeriosis in the United States, traced back to ready-to-eat meat products, have elevated public and regulatory concerns and made assessing and managing *L. monocytogenes* risks a high priority for both government and industry in the United States.

The agent of BSE in meat from cattle was recognized as a food-borne risk to human health (as opposed to a disease of cattle only) in the United Kingdom in the 1990s. Since then, the World Organization for Animal Health (OIE) has been developing relevant risk-based standards taking into account the BSE disease status of cattle in the exporting country.

2.4.2. Step 2: Develop a risk profile

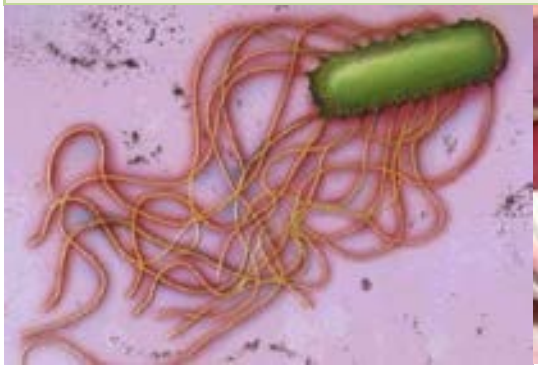
A risk profile requires gathering relevant information on an issue and may take a number of forms. Its main purpose is to assist risk managers in taking further action. The extent of the information gathered can vary from case to case but should always be sufficient to guide the risk managers in determining the need for (and if needed, the extent of) a risk assessment. Risk managers are generally unlikely to carry out risk profiling themselves unless the food safety issue is urgent and there is a need for immediate action. Ordinarily, a risk profile is developed primarily by risk assessors and others with specific technical expertise on the issue(s) at hand).

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 risks; and the distribution of possible risks among different segments of the population. By gathering available information on risks, the risk profile should assist risk managers in setting work priorities, deciding how much further scientific information on the risks is needed, and developing a risk assessment policy. By describing current control measures, including those in place in other countries where relevant, the risk profile can also assist risk managers in identifying possible risk management options. In many situations, a risk profile can be thought of as a preliminary risk assessment that summarizes everything the risk managers know about the possible risks at that time.

Examples of step 2: Developing a risk profile

The New Zealand Food Safety Authority (NZFSA) has developed **risk profiles** for a large number of food-borne hazards, and they are posted on the authority's web site (http://www.nzfsa.govt.nz/science/risk-profiles/index.htm).

Profiles for new hazard-food combinations are added to the library year-by-year. Profiles now posted address primarily microbiological contaminants of foods, including Salmonella and Campylobacter in poultry, Listeria in ice cream and ready-to-eat meats, and an array of other hazards. On the chemical side, NZFSA has developed risk profiles on aflatoxins in maize and glyphosate (an herbicide residue) in soy and soy products.



Salmonella (Souce: Buenasalud)

Campylobacter (Source: Over-blog)

A good risk profile provides the basis for commissioning a risk assessment where this is deemed necessary and assists in identifying the questions that need to be answered by the risk assessment. Formulating these questions usually requires significant interaction between risk assessors and risk managers, as well as dialogue with appropriate external parties (e.g. those with relevant information about the potential hazard).

Some types of information that may be included in a risk profile are listed below. The risk profile should be clearly and thoroughly documented, so that risk managers can use it to decide on further action in relation to a specific food safety issue. If links are made between risk profiles for other hazard-food combinations, risk profiles can provide the basis for qualitative ranking of food safety problems for subsequent risk management.

Examples of information that may be included in a risk profile

- 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.
- Nature of values at risk (human health, economic, cultural etc.).
- Distribution of the risk (who produces, benefits from, and/or bears the risk).

- Characteristics of the commodity/hazard that might affect the availability and feasibility of risk management options.
- Current risk management practices relevant to the issue, including any regulatory standards in place.
- Public perception of the possible risks.
- Information about possible risk management (control) measures.
- Preliminary indication of questions that a risk assessment could (and could not) be expected to answer.
- Preliminary identification of questions that a risk assessment could (and could not) be expected to answer.
- Implications of risk management in terms of international (e.g. SPS Agreement).

2.4.3. Step 3: Establish broad risk management goals

Following development of the risk profile, risk managers need to decide on the broader risk management goals. This is likely to occur in conjunction with a decision on whether or not a risk assessment is feasible or necessary. Delineating risk management goals must precede commissioning of a risk assessment and determines at least some of the questions to be asked of, and possibly answered by, the risk assessment.

Assess the food risks together (Source: Futura-Sciences)

2.4.4. Step 4: Decide whether a risk assessment is necessary

Deciding whether a risk assessment is necessary is an iterative decision for risk managers and risk assessors and may be part of establishing broader risk management goals. Questions such as how a risk assessment might be approached, what questions it might try to answer, what methods might yield useful answers, and where data gaps or uncertainties might likely preclude clear-cut answers, are significant issues.

There are important issues, for example:

• how should a risk assessment be considered?

• to what question should it reply ?

• what methods should be able to provide useful answers?

• what gaps in the data or what uncertainties would have the likely effect of prevent the formulation of questions clearly defined?

(Source: Enricopanai)

If the risk managers decide to progress to commissioning a risk assessment to support their risk management objectives, addressing such matters is essential. Identifying key data gaps at the outset also facilitates essential information being gathered to the extent possible before and during the risk assessment.

These activities usually require **the cooperation of scientific institutions, research-oriented bodies and the industry concerned**.

A risk assessment is likely to be especially desirable when the nature and magnitude of the risk are not well characterized, when a risk brings multiple societal values into conflict or is a pressing public concern, or when risk management has major trade implications. A risk assessment also can guide research by facilitating the ranking of risks of most importance

Examples of generic risk management goals that may require a risk assessment to resolve a food safety issue

- 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).
- Developing specific regulatory standards or other risk management measures for a veterinary drug that leaves residues in foods to ensure that exposure to the residue is limited to levels that do not exceed the acceptable daily intake.
- Ranking risks associated with different hazard-food combinations to establish priorities for risk management (e.g. *Listeria monocytogenes* in different food categories).
- Analyzing the economic costs and benefits (risk reduction impacts) of different risk management options for a particular food safety issue, so as to choose the most suitable controls.
- Estimating 'benchmark' levels of risk for certain priority hazards so that progress toward specific public-health goals can be measured (e.g. a 50 percent reduction in food-borne disease caused by enteric pathogens over a 10-year period).
- Demonstrating that no significant increase in risk to consumers is associated with the introduction of a new food production method or food processing technology.
- Demonstrating that no significant increase in risk to consumers is associated with the use by an exporting country of a control system or process to manage a risk, that is different from the control system or process used in an importing country (i.e. demonstrating equivalence); e.g. different pasteurization regimes.

Practical issues that impact on the decision as to whether a risk assessment is needed are: time and resources available; how urgently a risk management response is needed; consistency with responses to other similar issues; and availability of scientific information. If the risk profile indicates that food-borne risks are significant and immediate, the regulator may decide to impose interim regulatory control measures while a risk assessment is undertaken. On the other hand, some issues can be resolved simply and rapidly without need for a risk assessment. In some situations, a specific regulatory response will be deemed unnecessary because of the limited nature of possible risks. The box here below offers some examples of cases in which a risk assessment is or is not likely to be needed.

Examples of step 4: Deciding whether a risk assessment is needed

Shards of metal are detected in canned peaches from a particular cannery. The source is identified as fragile blades on a newly installed slicer. The machine is repaired; a metal detector is installed.

➔ *Problem solved by Good Hygienic Practice (GHP); no risk assessment needed.*

National food safety authorities are trying to decide whether to ban the use of certain antibiotics in animal feeds to help mitigate antimicrobial resistance. The economic stakes are high, with human health impacts quite uncertain.

➔ *Risk assessment is necessary to help determine the risk contribution of food-animal related uses of antimicrobials compared to that from use in human medicine.*

Listeria monocytogenes produces a serious food-borne illness with a very high fatality rate. The pathogen can contaminate dozens of foods belonging to more than 20 different food categories. To set risk management priorities, the United States government carries out integrated risk assessments for *L. monocytogenes* in 23 food categories, yielding a clear priority ranking.

➔ *Food safety issue managed based on a risk assessment.*

2.4.5. Step 5: Establish a risk assessment policy

Many subjective judgements and choices arise in the course of a risk assessment, and some of those choices will affect the utility of the assessment's results for decision making. Other choices may involve scientific values and preferences, such as how to deal with uncertainty and what assumptions to use when the available data are inconsistent, or how much caution to apply when recommending acceptable exposures[4].

A policy is often developed to provide an agreed framework for the conduct of risk assessment. Risk assessment policy is defined in the 15th Edition of the Codex Alimentarius Commission Procedural Manual as: *"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".* While establishing risk assessment policy is a responsibility of risk managers, it should be carried out in full collaboration with risk assessors, through an open and transparent process that allows appropriate inputs from relevant stakeholders. Risk assessment policy should be documented to ensure consistency, clarity and transparency.

[4] FAO, *Food Safety: Science and Ethics*, Report of an Expert Consultation, Rome, 3-5 September 2002, FAO Readings in Ethics 1, 2003.

Example of Step 5: Establishing a risk assessment policy

In the United States in 1996, Congress, acting as risk managers, established a new policy directing risk assessments by the United States Environmental Protection Agency (EPA) **for pesticide residues in the diet**.

Legislation now requires the EPA to ensure that pesticide residue limits protect the most sensitive populations (infants and children); to apply an additional uncertainty factor when the evidence is insufficient to be reasonably certain that the standard uncertainty factors would ensure safety; and to consider the cumulative effects of multiple residues that share a common mechanism of toxic action, as well as exposures from water and home pesticide use, when defining tolerable exposure from food.

A risk assessment policy underpins a clear understanding of the scope of the risk assessment and the manner in which it will be conducted. It often defines the parts of the food system, the populations, geographic areas and the time period to be covered. A risk assessment policy may include criteria for ranking risks (where, for example, the assessment covers different risks posed by the same contaminant, or risks posed by the contaminant in different foods) and procedures for applying uncertainty factors.

(*Source: Process alimentaire)*

Establishing a risk assessment policy provides guidance as to the appropriate level of protection and the scope of the risk assessment.

2.4.6. Step 6: Commission the risk assessment

Once a decision is made that a risk assessment is required, risk managers must arrange to get the risk assessment done. The nature of the risk assessment and the method by which it is commissioned may vary, depending on the nature of the risk, the institutional context and resources available and other factors. In general, risk managers must assemble an appropriate team of experts to carry out the task, and then interact with the risk assessors extensively enough to instruct them clearly on the work to be performed, while maintaining a 'functional separation' between risk assessment and risk management activities.

Functional separation means separating out the tasks that are carried out as part of risk assessment or risk management at the time when they are being performed. While developed countries may have separate bodies and personnel to carry out risk assessment and risk management, in developing countries the same individuals may be responsible for both. What is important is that conditions are in place to ensure that the tasks are carried out separately of each other (even if they are performed by the same individuals) using existing structures and resources.

Functional separation need not require the establishment of different bodies and personnel for risk management and risk assessment.

When ample time and resources are available, assembling an independent multidisciplinary team of scientists to conduct a risk assessment is often appropriate. In other cases, regulators may call on in-house expert resources or those available from dedicated external science providers, such as academic institutes. The most effective risk assessment teams are interdisciplinary; for instance, when dealing with a microbial hazard, the team may include food technologists, epidemiologists, microbiologists and biostatisticians.

Risk assessments carried out by the joint FAO/WHO expert bodies (JECFA, JMPR or JEMRA) are primarily intended to inform and assist the Codex Alimentarius Commission and governments in their choice of risk management measures for particular hazard-food combinations[5]. Historically, many governments have directly used international risk assessment work by adopting Codex standards for chemical hazards in foods. In other cases, international risk assessments have been used as a starting point for further, nationally specific risk assessments and establishing national standards for chemical hazards. In the case of microbial hazards, few international risk assessments are available but those that are provide an important aid in the establishment of standards at the national level.

National risk managers must ensure that a risk assessment is appropriately commissioned and carried out. Whatever the scope and nature of a risk assessment and regardless of the identity of the risk assessors and risk managers, certain principles should govern this critical step. Box below provides examples of how specific risk assessments were commissioned.

Responsibilities of risk managers in commissioning and supporting a risk assessment

- Ensure that all aspects of the commissioning and conduct of the risk assessment are documented and transparent.
- Clearly communicate the purposes and scope of the risk assessment, the risk assessment policy, and the form of the desired outputs, to the risk assessors.
- Provide sufficient resources and set a realistic timetable.
- Maintain ‘functional separation’ between risk assessment and risk management to the extent practicable.
- Ensure that the risk assessment team has an appropriate balance of expertise and is free from conflicts of interests and undue biases.
- Facilitate effective and iterative communication with the risk assessors during the entire process.

In practice, ‘functional separation’ means that risk managers and risk assessors have different jobs to do, and they each need to do their own jobs. Risk managers must avoid

[5] Information about risk assessments carried out by JECFA, JEMRA and JMPR is available on the Internet.
JEFCA : www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en;
JEMRA : www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/ and www.who.int/foodsafety/micro/jemra/en/index.html ;
JMPR : www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en.

the temptation to 'guide' the risk assessment so that it supports a preferred risk management decision, and risk assessors must assemble and assess the evidence objectively, without being influenced by risk management concerns such as economic benefits of an activity, costs of reducing exposure or consumer perceptions of risks.

In some situations, where resources and legal frameworks permit or require it, risk assessments may be carried out by an independent scientific institution, distinct from a food control authority.

In other cases, particularly in smaller countries or countries with limited, resources, officials may of necessity serve in multiple roles with the same individuals carrying out both risk management and risk assessment tasks. Nevertheless, by striving to keep the two functions separate, and by following the principles outlined in Box above, national risk managers can generally ensure that a risk assessment they commission is soundly conducted, objective and unbiased.

2.4.7. Step 7: Consider the results of the risk assessment

The risk assessment should clearly and fully answer the questions asked by the risk managers as far as possible given the availability of data and, where appropriate, identify and quantify sources of uncertainties in risk estimates. In judging the risk assessment complete, risk managers need to:

- be fully informed about the strengths and weaknesses of the risk assessment and its outputs;
- be sufficiently familiar with the risk assessment techniques used, so that they can explain it adequately to external stakeholders;
- understand the nature, sources and extent of uncertainties and variability in risk estimates ;
- be aware of and acknowledge all important assumptions made during the risk assessment and their impact on the results.

A collateral value of many risk assessments is identification of research needs to fill key gaps in scientific knowledge on a particular risk or risks associated with a given hazard-food combination.

At this point in the preliminary risk management phase, when the risk assessment is complete and can be reviewed and discussed with interested parties, effective communication among risk managers, risk assessors and others with a stake in the issue is essential.

Communicate on the risks (Source: Cunning concept)

2.4.8. Step 8: Rank food safety issues and set priorities for risk management[6]

National food safety authorities must deal with numerous food safety issues, often simultaneously. Resources inevitably are insufficient to manage all issues at any given time and ranking of issues in priority for risk management, as well as ranking risks for assessment, are important activities for food safety regulators.

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 applied to reduce overall food-borne public health risks. Issues may also be prioritized based on other factors, including serious restrictions in international trade resulting from different food safety control measures; the relative ease or difficulty of resolving the issues; and, sometimes, pressing public or political demand that attention be paid to a particular problem or issue. The risk ranking exercise with Listeria in food in the United States illustrates a case in which the relative risk per food category was totally different from the absolute risk.

Examples of Step 8: Commissioning a risk assessment

Case study 1: Total aflatoxins in peanuts

When aflatoxins were evaluated for the first time by the 31st session of JECFA in 1987, sufficient information was unavailable to establish a figure for a tolerable level of intake. At its 46th session, JECFA considered potency evaluations and population estimates and recommended that these analyses be completed and presented in an updated toxicological review.

Concurrently, the Codex Committee on Food Additives and Contaminants had been considering the establishment of a maximum level for aflatoxins in peanuts for further processing for several sessions but could not reach consensus on a proposed maximum level of 15µg/kg. The 29th session of CCFAC (1997) asked JECFA, in the framework of its re-evaluation of aflatoxins, to consider the public health implications of a level of 15µg/kg, as compared to 10µg/kg, as these were the two levels under discussion.

The 49th JECFA session (1997) completed the toxicological evaluation of aflatoxins and concluded that the potency of aflatoxins in individuals who carry the hepatitis B virus (HBsAg+) was substantially higher than in individuals who do not carry the virus. Reduction of the intake of aflatoxins in populations with a high prevalence of HBsAg+ individuals would therefore have greater impact on reducing liver cancer rates. The analysis of the application of hypothetical levels (10 µg/kg and 20 µg/kg aflatoxin in food) to model populations indicated that: i) populations with a low prevalence of HBsAg+ individuals and/or with a low mean intake are unlikely to exhibit demonstrable differences in population risks for levels in the range of the hypothetical cases; and ii) populations with a high prevalence of HBsAg+ individuals and high mean intake of Aflatoxins would benefit from reductions in aflatoxin intake.

As regards the two aflatoxin levels proposed, JECFA concluded that the higher level would yield almost identical liver cancer risks as the lower level. It indicated that *"when*

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

a substantial fraction of the food supply is heavily contaminated, reducing the aflatoxin contamination levels may detectably lower cancer rates. Conversely, when only a small fraction of the food supply is heavily contaminated, reducing the level by an apparently substantial amount may have little appreciable effect of public health".

Taking into account the results of the JECFA evaluation, the CCFAC agreed on a maximum level of 15 µg/kg for total aflatoxins in peanuts for further processing, that was adopted, with the corresponding sampling plan, by the *Codex Alimentarius* Commission in1999.

➢ ***Case study 2: Residues of nitrofurans* in prawns in Australia***

In 1993 JECFA withdrew the acceptable daily intake for four nitrofuran* chemicals (furazolidone, furaltadone, nitrofurantoine and nitrofurazone) due to the incomplete nature of the toxicological database and concerns about carcinogenicity in animal studies. As a result, several countries, including Australia, restricted, or prohibited, the use of nitrofurans in food-producing animals and subsequently, detectable residues in food products were not permitted. In October 2003, data became available indicating that very low levels of a furazolidone metabolite, 3-aminooxazolidinone, had been found in certain imported prawns. Where residues had been detected, they were at a few parts per billion (g/kg). However, in the absence of a specific maximum residue level in the Australian Food Standards Code, these residues were not permitted.

As a result of these test findings, Food Standards Australia New Zealand (FSANZ) undertook a risk assessment to establish the level of food safety risk to consumers from the levels of residue being detected in prawns. The risk assessment was undertaken to help inform enforcement agencies as to whether any risk managements actions should be taken to protect consumer health, such as testing of prawns and/or recalls of batches of prawns containing detectable residues.

The dietary exposure assessment component of the risk assessment utilized the residue concentrations found in an industry survey, and the hazard identification and characterization was based on a re-evaluation of the data summarized in the JECFA monographs.

** Nitrofurans are synthetic broad-spectrum antimicrobial agents used in some countries in human and veterinary medicine. This example has been reproduced from a case study prepared by FSANZ (available at: www.fao.org/docrep/meeting/006/j1985e/j1985e00.htm)*

2.5. Selection of risk management options

The second major phase of the generic RMF involves the identification, evaluation and selection of risk management options. Although this step ordinarily cannot be fully undertaken until a risk assessment has been completed, as a practical matter, it begins very early in a risk analysis, and is reiterated as information about the risk grows more complete and quantitative. A risk profile may contain some information about possible risk management measures, and when risk managers commission a risk assessment, they may ask specific questions, the answers to which may guide the choice among risk management options. Also, in urgent food safety situations, it may be necessary to choose and implement at least some preliminary risk management measures before a risk assessment can be carried out.

As was true for the first phase of risk management, this phase also consists of several distinct sub steps. The exact order in which these activities are carried out is less important than the fact that they each take place.

Examples of generic approaches to identify risk management options

- Eliminate potential for risks (e.g. ban sales of an imported food with a history of high levels of microbial contamination, prohibit use of a carcinogenic food additive).
- Identify those points between production and consumption where food safety measures could be implemented to:
  - prevent or limit initial levels of hazards in raw materials (e.g. select ingredients that have been pasteurized, ensure good veterinary practice (GVP) in use of veterinary drugs in food animals);
  - reduce potential for environmental contamination, cross-contamination and/or growth (e.g. mandate environmental hygiene controls, food processing controls, storage temperature controls)
  - reduce hazard levels in foods (e.g. physical inspection regimes, pasteurization standards, decontamination processes, use of preservatives).
- Apply standardized pre-market toxicological evaluation and regulatory approval processes for chemical hazards (e.g. food additives, pesticide residues and veterinary drug residues) and set monitoring standards (MRLs) based on GAP, GMP, GVP.
- Require labelling to inform consumer groups who may be especially susceptible, e.g. people allergic to nuts, or pregnant women exposed to methylmercury in fish.
- Identify non-regulatory measures when risk is generated largely outside of regulatory jurisdictions, e.g. industry-led quality assurance programmes at the producer level, consumer education for handling foods in the home.

2.5.1. Step 1: Identify available management options

Bearing in mind the risk management goals already established and the outcome of the risk assessment, risk managers will generally identify a range of risk management options with the capacity to resolve the food safety issue at hand. The risk managers are responsible for the process that identifies appropriate measures, but need not always perform all the work themselves. Often risk assessors, scientists from food industry, economists and other stakeholders also play important roles in identifying options based on their expertise and knowledge. Examples of generic options for managing food-related risks (whether the hazards involved are chemical or microbiological) are illustrated in Box above.

Scientist working on behalf of the agri-food industry (Source: Agriculture Canada)

The process of identifying options is conceptually simple but is often restricted by limits on food safety risk managers' ability to implement selected options. While risk managers should try to take into account the entire continuum from production to consumption when identifying possible control measures, in many cases a particular regulatory agency has jurisdiction over only a segment of that continuum. In other situations, a risk assessment may be restricted to a small part of the food production chain and only measures within the scope of the risk assessment may be identified for possible implementation.

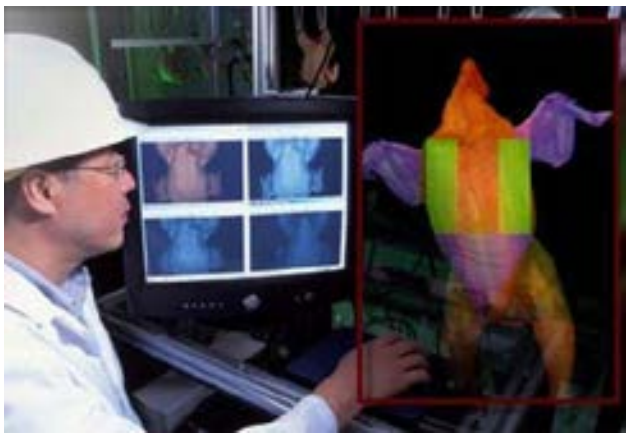
The production-to-consumption approach to risk management

Food safety regulators in many countries are adopting a 'production-to-consumption' approach to food safety. This approach strives to apply risk-based regulatory and non-regulatory control measures at appropriate points in the food production chain to achieve risk management goals in the most efficient and cost-effective manner. The approach assumes that basic good hygienic practices and good manufacturing practices are in place all along the food production chain and that opportunities exist to identify and implement targeted risk-reducing measures at relevant points along the continuum. Ideally, benefit-cost analysis and risk assessment are both conducted to inform risk management choices.

The complexity of food production systems and the ever-changing nature of international trade in foods make it impractical to realize this approach fully in many situations. Certain inputs to food production, such as hazard profiles of animal feeds in different countries may change rapidly. Further, the administrative framework for national food control systems may not be integrated throughout the entire food production continuum.

When risks are generated in one country, as during primary production of a food, but managed in another country, such as when specific characteristics of a high-susceptibility population subgroup in the importing country must be managed, basing risk-management decisions on benefit-cost analysis is often impractical.

In some cases, a single measure may have the potential to successfully manage the risks associated with a particular food safety issue. In other cases, a combination of measures may be necessary. In some cases, a very limited range of risk management options may be available, over and above what is in place as good hygienic practice. In general, to the extent practicable, it is valuable to consider initially a relatively broad range of possible options, then to select the most promising alternatives for more detailed evaluation.



Inspecting carcasses
(Source: Defending food safety)

It is also important at this stage to seek input from a variety of interested parties with knowledge of the food safety issue in question.

In some situations, effective control of a hazard in a particular part of a food production chain will require a systems approach, for example, control of fecal contamination of the carcass during the many steps in slaughter and dressing of red meat and poultry carcasses where this type of contamination can occur.

Where a risk assessment process has identified the level of control required at the end of such a process, the risk management options may be integrated into a complete 'food safety plan' based on a generic system such as HACCP, rather than described as distinct, narrower control measures.

'Risk-based' food safety measures

Food safety measures based on risk assessments are generally designed to reduce risks to a target level, and risk managers must determine the degree of health protection they are aiming to achieve. Through good communication with risk managers, risk assessors will likely have examined the relative impacts of different controls on reducing risks, providing the risk managers with objective data that supports decisions on the most appropriate controls. The overriding objective of risk management is to maximize risk reduction while ensuring that the measures employed are efficient and effective and not overly restrictive. In this context, 'risk-based' controls are formulated according to current knowledge about the human health risks associated with a food-borne hazard, whether expressed quantitatively or qualitatively. Control measures are aimed at achieving an established level of human health protection (which also may be expressed quantitatively or qualitatively) and should be explained and validated on those terms. For foods in international trade, the established level of consumer protection in the importing country is called the 'appropriate level of protection' (ALOP).

2.5.2. Step 2: Evaluate the identified management options

The evaluation of identified risk management options is sometimes straightforward, for instance if the solution is obvious and relatively easy to implement, or if only a single option is under consideration. On the other hand, many food safety problems involve complex processes, and many potential risk management measures vary in feasibility, practicality and the degree of food safety they can achieve, and may require cost-benefit analysis and evaluating trade-offs among competing societal values.

One of the most critical elements in evaluating and selecting food safety measures is to recognize that a clear link must be established between the risk management option being evaluated and the level of risk reduction and/or consumer protection that is provided.

There are no strict rules about how to select the best options; rather, there are a variety of possibilities based on the food safety issue at hand and the risk management goals that apply. In the ideal situation, the following information should be available for evaluating individual or groups of possible risk management options:

- a 'menu' of estimates of risk that would result from application of potential risk management measures (either singly or in combination), expressed either qualitatively or quantitatively;
- estimates of the relative impact of different potential risk management measures (either singly or in combination) on risk estimates;
- technical information on the feasibility and practicality of implementing different options;
- benefit-cost analysis of different potential measures, including both magnitude and distribution (i.e. who benefits, who pays the costs);
- WTO SPS implications of different options in international trade situations.

Any stakeholder group, including risk managers and risk assessors, may participate in this process by providing some of the needed information, commenting on the relative weight to be given to the different considerations, or offering other appropriate inputs.

Benefit-cost analysis is often difficult, even though it is a mandatory element of food safety policy decisions in some countries. Estimating the magnitude and distribution of benefits and costs of particular risk management options may require addressing such concerns as: changes in the availability or nutritional quality of foods; impacts on access to international food markets; impacts on consumer confidence in the safety of the food supply or in the food regulatory system; and other societal costs and consequences of both food safety risks and choices made in managing them. Many of these variables may be difficult to predict or quantify.

Economic estimates often have considerable uncertainty associated with them; for instance, it is difficult to predict how market participants will react to a risk-based regulation and how future markets may change. Rapid advances in science and technology add to the uncertainty in predicting benefits and costs. Thus benefit-cost analysis by itself cannot determine the best risk management choices, but as a systematic discipline for collecting and evaluating data and data gaps, it informs the

decision-making process. Preferences and perceptions of those most affected by the decisions, typically, industry and consumers also need to be considered. Risk managers need to assess critically the quality of information they receive at this stage, and often must make subjective judgments as to how much weight particular considerations, and the data on which they are based, should be given.

Risk management options also often have important ethical dimensions, although they are most typically implied, rather than explicit. For example, ethical principles that underlie specific options might include the view that industry has the responsibility to provide safe food; that consumers have a right to be informed about risks associated with the foods they eat; or that government needs to act to protect those who cannot protect themselves. It may seem easier for risk managers to explain and defend food safety decisions based on scientific and economic analysis, which provide a more objective basis than ethics. But the ethical choices embedded in risk management decisions need to be openly examined to facilitate transparency and good communication.[7]

Industry has the responsibility to provide healthy food. (Source: Innovaltech)

The process used for evaluating risk management options may vary from one risk to the next within any given country, as well as from country to country and between the national and the international levels. A desirable characteristic at all levels is an open process that provides opportunities for industry, consumers and other interested parties to provide information, to comment on proposals, and to suggest criteria for choosing preferred options. Balancing the advantages and disadvantages of multiple risk management options is already a challenging task; expanding communication with stakeholders can make this stage of the process more difficult to manage, and may lengthen the time required to complete it. Nevertheless, risk managers will find that an extensive and inclusive consultation process generally improves both the quality and the public acceptability of the ultimate decision as to the preferred risk management options.

When evaluating risk management options for microbial hazards in food, regulators should provide as much flexibility as possible in regulatory standards for the industry that is implementing them, as long as the outcome in terms of consumer protection is achieved.

(Source: Public Works and Government Services Canada)

[7] FAO, “Food Safety: Science and Ethics”, *op. cit*.

The HACCP system fits nicely into this flexible and outcome-driven approach.

In recent years, this principle has led to the concept of risk-based targets for control of hazards at particular steps in the food production chain. Development of specific quantitative microbiological metrics – such as food safety objectives (FSOs), performance objectives (POs) and performance criteria (PCs) – that can be incorporated in regulation is discussed below.

Codex* definitions of quantitative microbiological food safety metrics

1. **Food safety objective (FSO):** The maximum frequency and/or concentration of a hazard in a food at the point of consumption that provides, or contributes to, achievement of the ALOP.

2. **Performance objective (PO):** The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain that provides, or contributes to, achievement of the ALOP.

3. **Performance criterion (PC):** The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective.

* *Metrics are described as: "quantitative expressions that indicate a level of control at a specific step in a food safety risk management system. For the purpose of this report the term 'metric' is used as a collective for the new risk management terms of food safety objective, performance objective and performance criteria, but it also refers to existing microbiological criteria". FAO/WHO. 2006. The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to improve food safety. Report of a Joint FAO/WHO meeting in collaboration with the German Federal Ministry of Food, Agriculture and Consumer Protection. Kiel, Germany, 3-7 April 2006*

Risk management options for chemical hazards in foods are often generic, such as ensuring that use of a pesticide or veterinary drug according to GAP will not result in harmful residues in food (and establishing an MRL for monitoring purposes). Where chemicals are not intentionally used in food production settings (e.g. environmental contaminants such as dioxins or methylmercury), more specific risk management options often are evaluated (e.g. imposing conditions on harvesting, providing information to consumers so that they can voluntarily limit exposure). Exposure guidelines such as Provisional Tolerable Weekly Intakes (PTWIs) can then provide a reference point for maximum safe intake, and risk management measures can be put in place that aim to prevent consumers from exceeding that safe upper limit of exposure.

Risk management options for many chemical hazards rely on approaches that estimate an acceptable exposure level for avoiding chronic adverse health effects, such as an NOAEL or RfD methodology. When other risk modelling approaches are used, such as linear modelling for carcinogenic effects, different risk management options may be identified and evaluated, such as banning or severely restricting the use of the chemical.

2.5.3. Step 3: Select a risk management option(s)

Various approaches and decision-making frameworks can be used to select risk management options. There is no one preferred approach, and different ways of reaching decisions may be appropriate for different risks and in different contexts. In essence, the risk management decision on appropriate options is arrived at by considering and integrating all of the evaluation information described above.

Using quantitative microbiological metrics as risk management options

Quantitative microbiological metrics based on risk assessments can be useful in risk management. At the international level, Codex recognizes the desirability of using POs and/or PCs as a basis for establishing practical standards, such as risk-based microbiological criteria (MC), process criteria or product criteria, but methods for doing so are still being developed.

An FSO established at the point of consumption of the food provides a reference for developing microbiological targets at other points in the food production chain. One or more POs or PCs may be necessary at different stages along the chain to specify the required level of microbiological control at a particular step in food production; setting a standard on this basis (e.g. requiring a process that reduces Salmonella levels by one-million-fold when cooking ground beef) may be a risk-based regulatory option.

A process criterion is a physical control measure (e.g. time, temperature) at a step, or combination of steps, that can be applied to achieve a PO. Process criteria should be validated to determine that they are achieving the required level of microbiological control on a consistent basis before being set as standards. A product criterion (pH, water activity/a_w) similarly serves as a physical control measure.

Process and product criteria should be risk-based to the extent possible and criteria should not be set that represent unnecessary levels of pathogen control; for instance, current processing standards for pasteurization of milk may be more severe than necessary to deliver an acceptable level of consumer protection.

Methods for translating POs and PCs into risk-based MCs are still being developed. While the former specify the maximum levels of particular micro-organisms allowable in food, a risk-based MC must incorporate sampling plans of sufficient stringency that they can assure risk managers that the probability of exceeding maximum allowable limits is very low. Decisions as to where along the food production chain to apply standards based on POs may be influenced by overarching risk management goals.

For example, the primary source of contamination of the food may be at the farm level (such as Campylobacter in poultry) and risk managers may be able to most effectively reduce consumer risk by setting a PO at an early point in the production chain. Alternatively, when the primary source of contamination is inadequate control at a late stage of processing (such as Listeria in cold-smoked salmon), the risk manager can exert the greatest influence on poor hygienic practice by setting a PO for a later point in the food production chain.

Although there are some cases where risk reduction is not the primary objective, for example when judging the equivalence of different measures in their ability to protect

human health, the foremost objective in most risk management decision-making is to reduce food-borne risks to human health.

Contacting food safety authorities to reduce food-borne risks (Source: FAO)

Risk managers should focus on selecting those measures that have the greatest risk-reducing impact and weigh those impacts against other factors that influence decision-making, including the feasibility and practicality of potential measures, cost-benefit considerations, stakeholder equity, ethical considerations, and creation of countervailing risks such as decreases in the availability or nutritional quality of foods.

This weighting process is essentially qualitative because of the obviously different nature of the values involved. Risk managers must decide how much weight to give each value considered. Thus the selection of the 'best' risk management option is fundamentally a political and social process. Given that, the options chosen should always be in proportion to the actual public health risks involved.

❑ Identify a desired level of consumer health protection

The level of consumer health protection provided by a decision on risk management measures is often called the 'Appropriate Level of Protection' (ALOP) or 'acceptable level of risk'.

ALOP is defined in the WTO SPS Agreement as *"the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory".*

Application of Sanitary and Phytosanitary Measures (SPS Agreement) (Source: NP DIGITAL)

It is important to note that the ALOP is an expression of the level of protection achieved in relation to food safety at the current time. However, because the currently achieved level of consumer health protection may change (for example, new technologies may change the level of a contaminant in a food), an ALOP may be revised over time. Future objectives or goals in terms of consumer health protection may also be established. Once achieved these objectives or public health goals/targets will lead to a revision of the ALOP.

ALOPs may range from general to specific, depending upon the level of information available with regard to the source of hazards and risks. An example of a general ALOP could be the current level of Salmonella infections in a country (an example of an ALOP was the incidence of Salmonella in Finland and Sweden when they joined the European Union). An example of a specific ALOP was the background level of cryptosporidiosis in the United States as a basis for establishing levels of treatment for drinking water.

Expression of public health goals may range from the general to the specific, depending upon the level of source attribution. For example, a general public health goal would be to reduce the incidence of human Salmonella Enteritidis infections. A specific public health goal would be to reduce the incidence of human cases of Salmonella Enteritidis associated with consumption of eggs. Goals may be set either in absolute terms (e.g. number of cases per 100,000 population) or in terms of relative improvement (e.g. a percentage reduction in the number of cases).

Expression of the ALOP or a future goal with regard to the level of consumer health protection for a specific food-borne public health risk is obviously a core risk management function and, in most cases, is tied to the feasibility and practicality of available risk management options. In considering and integrating all of the evaluation information described above, a measure or measures linked to a specific level of consumer protection will be selected.

The concept of ALOP or similar future targets is essential in establishing the linkage between risk management actions and the level of consumer health protection achieved. A range of tools or approaches are available to the risk manager in bridging between practical control measures and level of consumer health protection. Some examples of these approaches are provided in Box below.

For chemical contaminants, the output of the risk assessment generally includes an estimate of a tolerable intake, such as a tolerable daily intake (TDI) or PTWI

(Source: Verstegen)

For food additives, pesticide residues and residues of veterinary drugs, the risk assessors normally determine an acceptable daily intake (ADI). A TDI, PTWI or ADI is generally based on an estimate made by the risk assessors of a dose level that is reasonably certain to have no adverse health effects. It thus provides an ALOP that is pre-determined by public policy to be 'notional zero risk'. A range of risk management measures that should achieve the required ALOP can be then selected for implementation; for example, enforcing GAP at farm level to minimize pesticide residues, setting MRLs for residues in specific foods, and using the MRLs to monitor the food supply.

Examples of approaches to setting an Appropriate Level of Protection that are used in selecting risk management options

- ***Notional zero risk approach:*** Hazards are kept at levels that equate to a pre-determined 'negligible' or 'notional zero' risk, based on a risk assessment indicating that such low exposure levels are reasonably certain not to cause harm. Used in setting ADIs for chemical hazards in food. For example, the insecticide chlorpyrifos

can potentially disrupt brain development in young children. To protect against this risk, the JMPR has established an ADI for chlorpyrifos and based on this the Codex Committee on Pesticide Residues (CCPR) has set MRLs for its residue on a variety of foods on which it may be used.

- ***ALARA ("as low as reasonably achievable") approach:*** Hazard levels are limited by risk management measures to the lowest level technically possible and/or economically feasible under the circumstances. Some residual risk to consumer typically remains; for example for enteric pathogens of animal origin in fresh or undercooked meat products, or for levels of unavoidable environmental contaminants in otherwise wholesome foods.

- ***'Threshold' approach:*** Risks must be kept below a specific numerical level as pre-determined by public policy; this approach may be used for chemical hazards, particularly carcinogens. For example, in the United States, certain food colorings that pose estimated risks greater than one additional expected cancer case above background incidence per 100,000 consumers exposed for a lifetime have been banned.

- ***Benefit-cost approach:*** Both a risk assessment and a benefit-cost analysis are carried out and risk managers then weigh risk reduction units against monetary costs of achieving reductions when choosing measures. An example is selecting risk-based measures to control Campylobacter in chickens in the Netherlands. According to a qualitative benefit-cost approach, sodium nitrite, a preservative that may pose a cancer risk but also prevents botulism, is restricted in many countries to a maximum level of 100 parts per million in specified food.

- ***Comparative risk approach:*** Benefits of reducing a particular risk are compared with countervailing risks that may be generated as a consequence of the decision; e.g. possible loss of nutritional benefits if people eat less fish in order to avoid methylmercury, possible increase in cancer risks where chlorinated water is used to minimize pathogens in food during processing.

- ***Precautionary approach:*** Where information exists to suggest that a hazard in food may pose significant risks to human health, but the scientific data are not sufficient to estimate actual risks, interim measures may be put in place to limit the risk while steps are taken to make possible and carry out a more definitive risk assessment; e.g. bans on feed additives of animal origin and on trade in beef during the early stages of the BSE epidemic in Europe.

In some countries, quantitative probabilistic approaches to risk assessment of chemical hazards are changing the way decisions are made on selecting risk management options. These methods estimate changes in risks associated with changes in chemical exposure levels. A level of risk that is judged acceptable can be defined by public policy, and risk management measures can then be chosen to keep risk below that 'threshold', sometimes referred to as a 'virtually safe dose'. Box above includes examples of approaches to determining an ALOP for a chemical hazard in food.

❑ Reaching a decision on the preferred risk management option(s)

Risk managers must consider both the desired level of consumer protection and the availability and efficacy of risk management options when making this decision. Some

examples have been presented in the discussion above. In general, most decision frameworks for selection of risk management options have as their primary purpose 'optimization' of outcomes. That is, the decision-makers aim to achieve the 'best' level of consumer protection in a manner that is as cost-effective, technically feasible, and sensitive to the rights of consumers and other stakeholders, as possible. Cost-risk-benefit analysis generally requires large amounts of information on both risks and the consequences of different risk management options. As noted, no single approach to decision-making is best for all cases, and more than one approach can be appropriate for any given food safety decision.

Examples of voluntary / non-regulatory risk management measures

- Reduction of lead levels in canned foods through the phase-out of lead-soldered cans by food processing industries.
- Reliance on good veterinary practices and Codex guidelines to minimize and contain antimicrobial resistance associated with antibiotic use in food animals.
- Selection of consumer education approaches for reducing exposure to methylmercury from certain fish and seafood.

A systematic, rigorous evaluation of options, in an open process where affected parties can participate and communicate with decision-makers, is most likely to produce a sound, widely accepted decision. Given the importance of non-scientific values in the resolution of food safety problems, participation by external stakeholders is appropriate and can be critical to the successful completion of this stage.

Where possible, risk management should consider the entire continuum from production to consumption, regardless of the number of authorities involved and their respective responsibilities, in order to develop the best management solutions. Any regulatory measures must be able to be enforced on the basis of the national framework of legal and regulatory authorities.

However, in some countries, good results have been achieved by adopting measures that are voluntary rather than legally binding. Finally, in today's global food marketplace, regulatory measures must take into account international trade agreements and the additional obligations they impose on national authorities.

❑ Dealing with uncertainty

Uncertainty is an inescapable element in risk assessments and in efforts to project the impacts of risk management measures. When making risk management decisions, national food safety authorities need to take into account uncertainty, as transparently as they can. In predicting the outcome of a risk-based measure, the risk assessor should preferably use probability to express the uncertainty related to the estimate.

From the risk manager's perspective, uncertainty must be well enough characterized that the decision-maker *"knows when he knows enough to act".* In this context, risk managers can test their interim decisions by requesting:

- a sensitivity analysis to determine how perturbations in model inputs affect the results;
- an uncertainty analysis to determine the consequences of all the uncertainty.

In most situations, despite the acknowledged uncertainties, a preferred risk management option or options will emerge from the decision-making process. Occasionally, when uncertainties are judged to be large enough to impede a definitive choice, interim measures may be adopted while additional data are gathered to support a better-informed decision, after an additional cycle of application of the RMF.

2.6. Implementation of the risk management decision

Risk management decisions are implemented by a variety of parties, including government officials, the food industry and consumers. The type of implementation varies according to the food safety issue, the specific circumstances and the parties involved.

To effectively execute control measures, food producers and processors generally implement complete food control systems using comprehensive approaches such as GMP, GHP and HACCP systems. These approaches provide a platform for specific food safety risk management options as identified and selected by risk managers.

Industry has the primary responsibility to implement food safety controls (both regulatory and voluntary); many different national legislative arrangements provide for this allocation of food safety responsibility. Government agencies can use a variety of verification activities to ensure compliance with standards by industry. Some governments or regulatory bodies implement control measures such as physical inspection and product testing themselves, which places the primary cost of verifying compliance with standards by industry on the regulatory authority.

The controls can ensure that the product is fit for consumption (Source: Processalimentaire)

For some hazards, it may not be practical or cost-effective for industry to implement food control measures at each individual location at which they operate, for example testing for chemical residues of one sort or another. National chemical residue programmes can provide the data necessary to assure that appropriate control of hazards is being achieved in such circumstances. Programmes of this sort may be implemented by government, industry or both acting jointly.

In recent years, new approaches to the organization of national food safety authorities have emerged in different countries. Integrating all nationally-mandated food inspection systems under a single authority may have several advantages, such as reducing duplication of efforts and overlap of responsibilities, and improving the implementation of

governmental food controls. A consolidation of multiple legislative and functional activities previously spread over several legislative jurisdictions gives practical meaning to multidisciplinary approaches to food safety and implementation of a risk-based 'production-to-consumption' approach.

Quality Manager in an abattoir (Source: Charente Libre)

In parallel, food safety systems today depend increasingly on an integrated systems approach that shares responsibility for implementing food safety decisions. Innovative partnerships across the production-to-consumption continuum provide flexibility, which may be lacking in less integrated regulatory systems. For example, quality assurance systems can be extended in the case of ante- and post-mortem inspection of slaughtered animals to co-regulatory systems that include industry and veterinary service activities.

For instance, in Australia, the official veterinary service is now responsible for the broad design of the inspection system and its audits and sanctions, while industry is responsible for further developing, implementing and maintaining the system. The veterinarian responsible for a specific slaughterhouse ensures that the quality assurance programme implemented by industry meets regulatory requirements on an ongoing basis.

2.7. Monitoring and review

Risk management does not end when a decision has been taken and implemented. Risk managers are responsible for verifying that the risk mitigation measures are achieving the intended results, that there are no unintended consequences associated with the measures, and that risk management goals can be sustained in the longer term. Risk management decisions should be reviewed periodically when new scientific data or insights become available, as well as when experience, such as data gathered during inspection and monitoring, warrants a review. This phase of risk management includes gathering and analyzing data on human health, and on food-borne hazards that pose risks of interest, to provide an overview of food safety and consumer health.

Surveillance of public health (which is a component of monitoring in a broad sense) is usually carried out by national public health authorities. It offers evidence of changes in food-borne illness rates that may follow implementation of risk management measures, as well as the potential for identifying new food safety problems as they emerge. When surveillance yields evidence that required food safety goals are not being achieved, redesign of food safety controls by government and industry is needed.

The box here below illustrates some kinds of information that are useful for monitoring the effects of risk management measures.

Examples of information that can be used for monitoring the effects of risk management measures

- National surveillance databases for notifiable diseases.
- Disease registries, death certificate databases, and time-series data derived from these.
- Targeted human surveys (active surveillance) and analytical epidemiological studies where specific risks and risk factors are being investigated.
- Outbreak data for food-borne illness events, blended with sporadic food-borne illness statistics, for food source attribution purposes.
- Frequency and levels of occurrence of chemical or microbiological contaminants in foods at various points from production to consumption.
- Frequency of persistent organic pollutants (POPs) in human breast milk.
- Frequency of occurrence and levels of contaminants in blood, urine or other tissues gathered from representative samples of the population(s) at risk, such as mercury levels in hair and blood.
- Food consumption survey data, updated periodically, and to the extent possible, for specific subpopulations that may be at risk because of dietary preferences.
- Microbiological ‘fingerprinting’ methods to trace specific genotypic strains of pathogens causing illness in humans through the food chain (e.g. multilocus gene sequence typing).

Most food safety authorities apply regulatory programmes at various points in the food production chain to monitor the presence of specific hazards; for example, national

residue surveys, national monitoring programmes for microbial pathogens in fresh meat. Even though these programmes may not be integrated into an overall food control system, they provide valuable information on the changing prevalence of hazards over time and the level of regulatory compliance.

Monitoring the presence of certain hazards (Source: L'Express)

Human health surveillance to complete the RMF process is ordinarily outside of the jurisdiction of many food safety authorities but may be a responsibility of an overarching government authority. Monitoring and review activities should be specifically designed to support management of food-borne risks and provide the opportunity for multidisciplinary inputs in a risk-based food safety system. Food-borne disease investigations, analytical epidemiological studies such as food source attribution, case-control investigations and strain typing of bacterial hazards to genotype level can provide a valuable adjunct to human health surveillance.

In some cases, monitoring might result in a request for a new risk assessment, perhaps reducing previous uncertainties, or updating the analysis with new or additional research findings. Revised risk assessment results could lead to reiteration of the risk management process, with possible changes in risk management goals and the risk management option chosen. Changes in broad-based public health goals, changing societal values and technological innovations all can provide reasons to revisit risk management decisions previously taken.

Appendices: Glossary and case studies

A.1. Case Study of Methylmercury in Fish

❑ Background

Mercury alert in carnivorous fish (Source: Le Figaro)

Mercury is released into the environment as inorganic mercury compounds from a variety of natural and human-made sources. Inorganic mercury can be converted to an organic form, methylmercury, by microbial action in soils and sediments. Methylmercury is taken up by aquatic organisms and is bio-magnified in the food web; long-lived, predatory species high in the aquatic food chain can accumulate high levels.

The toxic effects of methylmercury in people were first documented among individuals who consumed heavily contaminated fish from Minamata Bay, Japan, which was polluted by industrial mercury sources, in the 1950s.[8] Children born to women who had consumed contaminated fish were most severely affected, exhibiting devastating damage to the central nervous system, which is especially vulnerable during prenatal development.

In the decades since Minamata, several epidemiological studies of populations with a diet either high in fish or in fish and marine mammals have provided evidence that typical levels of methylmercury in some types of fish, not unusually high levels associated with pollution, pose some health hazards, again with a focus on the developing brain[9]. There is some evidence that methylmercury exposure from a diet rich in fish and seafood may adversely affect cognitive function in adults[10]. Nevertheless, damage associated with prenatal exposure is considered the most sensitive effect and is the central concern of risk management. Evidence that these potential health risks may be associated with

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8 N. Huddle, M. Reich and N. Stisman, *Island of Dreams: Environmental Crisis in Japan*, 2nd ed., Rochester, Schenkman Books Inc., 1987.

9 P. Grandjean *et al*., "Cognitive deficit in 7-year-old children with prenatal exposure to methyl mercury", *Neurotoxicol Teratol*, No. 19, 2000, pp. 417-428. National Research Council, *Toxicological Effects of Methylmercury*, Washington, National Academy Press, 1997.

10 See, e.g., E.M. Yokoo *et al*., "Low level methylmercury exposure affects neuropsychological function in adults", *Environmental Health: A Global Access Science Source*, No. 2, 2003, p. 8; also C.M. Newland and E.B. Rasmussen, "Behavior in Adulthood and During Aging Is Affected by Contaminant Exposure *in utero*", in *Current Directions in Psychological Science*, vol. 12, No. 6, 2003, pp. 212-217.

'normal' levels of fish consumption has led to both national and international efforts to assess the risks from methylmercury in fish, and to establish guidelines for safe maximum exposure.

Methylmercury risks may be a concern for any national or subnational population that consumes large amounts of fish. Different fish species tend to accumulate methylmercury to different degrees, and the degree of exposure to methylmercury will vary depending on which fish species are important in a population's diet, and how much methylmercury is present in the specific fish species consumed locally. Risk assessments, in particular the exposure assessment part, must therefore be population-specific. If excessive methylmercury exposure is found, risk management can be challenging. Fish consumption has many nutritional benefits, and fish is the main source of dietary protein for some populations. Reducing fish consumption to avoid methylmercury exposure might therefore damage public health in the broader sense. Risk communication, in particular educating consumers so that they can choose low-mercury fish species, is an important risk management tool for managing methylmercury risks.

This case study briefly reviews two examples of risk analyses for methylmercury in fish.

The United States Environmental Protection Agency (EPA) has established a Reference Dose (RfD), which is a safe upper intake limit, similar to a Tolerable Daily Intake. The United States has also established an Action Level, which is a guideline for a maximum acceptable mercury level in fish, and has issued fish consumption advice. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established a safe upper intake limit, called a Provisional Tolerable Weekly Intake (PTWI), based on a scientific review and risk assessment, and the Codex Alimentarius Commission (CAC) has established Guideline Levels for Methylmercury in Fish (CAC/GL 7-1991).

❑ Risk management of methylmercury in fish

The cases described in this Annex illustrate how previously completed risk analyses were reviewed and updated in the United States and at the international level. Methylmercury in fish has been a recognized hazard for several decades, and these cases illustrate the ongoing, iterative nature of risk analysis in which scientific understanding of, and risk management responses to, a problem are updated as necessary and as new scientific data become available. Despite this inherently cyclic process, steps in the risk analyses for methylmercury are described here in the sequence laid out in the generic RMF presented here.

❑ Risk management, phase 1: Preliminary risk management activities

➢ *Step 1: Identify the problem*

This risk arises when a population consumes fish that have absorbed potentially harmful levels of methylmercury from the environment. The focus of this case study is on methylmercury in commercially caught fish consumed by the general population. Problems also exist with methylmercury in fish caught by sport fishermen from locally polluted waters, but that narrower situation is outside the scope of this analysis.

➢ ***Step 2: Develop a risk profile***

The extent of the problem varies depending on several factors:

- the quantity of fish consumed by the population;
- the kinds of fish eaten;
- the amount of methylmercury contained in those particular fish species;
- the amounts of particular methylmercury accumulating species consumed by the population;
- the characteristics of the population (such as being female and of childbearing age); and, sometimes,
- particular genetic or cultural attributes of the population that may enhance or reduce risk.

The population group most often considered at risk from methylmercury exposure are women of childbearing age because damage to the developing fetal brain is currently considered to be the health risk of greatest concern, i.e. the most sensitive endpoint. However, methylmercury has other toxic effects (e.g. it affects the nervous system in adults).[11]

Therefore, concern is not strictly limited to potential effects on the fetal brain; people who eat a great deal of fish may also be at some risk for as yet sparsely documented effects. In some countries, only a small subset of the total population consumes enough fish to warrant any health concerns, while in other countries, where fish is the primary source of dietary protein, 'high-end' consumers may include much of the general population.

The risk profile developed by the EPA focuses on women who are or may become pregnant, and on a handful of particular fish species that accumulate fairly high levels of methylmercury. The JECFA/*Codex* approach recognizes that methylmercury in fish may be a public health concern for many member countries, and also that a specific risk profile needs to be developed for each individual country contemplating action, since fish consumption patterns and thus the associated risk vary from country to country. These risk profiles were developed primarily by risk assessors (JECFA for FAO/WHO and *Codex*; government scientists in the USA), who were working and communicating with the risk managers in each case.

➢ **Step *3: Establish risk management goals***

At both the national and the international levels, the general goal of risk management was to reduce consumer exposure to methylmercury from fish consumption in order to prevent adverse effects on public health. Risk managers at both levels had in mind a number of alternative risk management options that might be applied (see discussion in later sections of this Annex), and in each case a collateral goal was to try to reduce risk without losing the nutritional benefits of fish consumption. The risk managers in these cases (United States government agencies, FAO/WHO and Codex) did not require a risk assessment to help them choose among risk management options so much as they

[11] For a review of the relevant literature, see National Research Council, 2000. Also see "Safety evaluation of certain food additives and contaminants", JECFA's 2003 assessment, WHO Food Additives Series, No. 52, prepared by the 61st meeting of the Joint FAO/WHO Expert Committee on Food Additives, International Programme on Chemical Safety, World Health Organization, Geneva, 2004, pp. 565-623, Methylmercury.

needed an updated and more precise definition of a 'safe' level of exposure to methylmercury to support their determinations of the appropriate level(s) of protection for exposed populations.

➢ ***Step 4: Decide whether a risk assessment is needed***

At both the national and international levels, risk assessments for methylmercury in fish have been carried out many times in the past. However, as new scientific evidence continues to become available, risk assessments require updating. In the United States, the EPA determined that a new risk assessment for methylmercury was needed in the late 1990s. The EPA sought to establish an RfD, a term the EPA uses for a safe upper exposure limit, for methylmercury, and needed a safety/risk assessment to support that policy decision. The EPA conducted its own internal risk assessment and asked the United States National Academy of Sciences/National Research Council (NAS/NRC) to serve as a peer-review and advisory expert group.

At the international level, JECFA has reviewed methylmercury on several occasions during the period from 1972 to 2006. At its 2000 session, and at the request of the CAC, JECFA noted that evidence was accruing from two major ongoing epidemiological studies, and agreed that an additional review be conducted, specifically to advise on whether the existing PTWI should be revised in light of recent evidence, when additional data became available. That review occurred at the 61st JECFA meeting, in 2003. Thus, in the United States, the need for a risk assessment was driven primarily by risk managers planning a policy action, while internationally, risk assessors, monitoring emerging scientific evidence, determined that the time had come to update the risk assessment, knowing that risk managers were prepared to review the related risk management decisions.

➢ ***Step 5: Establish a risk assessment policy***

In neither case examined here was establishing risk assessment policy a formal, clearly defined step. This step has not yet become a routine part of risk analysis as practiced either within *Codex* or by most member governments. Most risk assessors and risk managers have at least a general sense of principles that would be part of a formal risk assessment policy if one were developed, but as a rule those principles have been neither transparently documented nor formally applied.

➢ ***Step 6: Commission a risk assessment***

Good communication between risk assessors and risk managers is essential when a risk assessment is commissioned. In the case of the NAS/NRC review, the EPA provided a detailed set of questions it needed answered by the committee (and which it presumably also sought to answer in carrying out its own internal risk assessment). Communication between risk managers in the government and risk assessors within federal agencies and at the NAS/NRC was also extensive and ongoing after the NAS/NRC risk assessment was completed.

At the international level, JECFA communicates closely with CCFAC, the risk managers who apply the PTWI in managing risks of methylmercury in fish. Since CCFAC and JECFA each meet once a year at different times and in different countries, communication between them mostly occurs through the JECFA Secretariat. Subsequent

to the 2003 JECFA review, CCFAC posed some specific questions to JECFA, which were taken up at the JECFA session in 2006. The discussion at CCFAC is continuing and further interaction with JECFA may occur as the process moves forward.

A key step in commissioning a risk assessment is to assemble the risk assessment team. Finding qualified experts who are knowledgeable about the specific problem but are not committed to a predetermined point of view can be a challenging task for risk managers. The EPA put together a group of scientists drawn from its health effects research staff. The NAS/NRC assembled a group of experts from the national scientific community, following procedures (described on the NAS web site)[12] to ensure appropriate expertise, to balance viewpoints and to exclude those with possible biases or conflicts of interest. Internationally, the JECFA Secretariat assembled an expert group from FAO and WHO rosters of experts, drawn from the worldwide scientific community, in accordance with FAO/WHO procedures to balance expertise and screen out potential conflicts of interest.[13]

➢ ***Step 7: Consider the results of the risk assessment***

To avoid repetition this step will be discussed below after the description of the risk assessments that were conducted.

➢ ***Step 8: Rank risks***

This step is useful when risk managers are confronted with multiple food safety problems that all need to be managed, and have limited resources. However, enough knowledge already exists to establish that methylmercury is a serious public health concern, and it has been a priority for risk management for many years. The risk ranking step therefore was not necessary either in the United States or internationally in this case.

❑ **Risk assessment**

The initial step reiterates two preliminary risk management activities, identify the problem and develop a risk profile, described above. The primary focus of the risk assessments in both examples here was on updating previous assessments to take into account results of recent research.

➢ ***Step 1: Hazard identification***

The hazard in this case was clearly identified as the organic mercury compound, methylmercury, which is more toxic than inorganic mercury, and also accounts for the vast majority of the total mercury in fish.

➢ ***Step 2: Hazard characterization***

This step requires qualitative and, to the extent practical, quantitative evaluation of the adverse effects of exposure to methylmercury, ideally with the development of dose-response relationships that permit defining a safe level of exposure. The main focus of

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[12] See www.nationalacademies.org/onpi/brochures/studyprocess.pdf.

[13] Further information about FAO/WHO rosters of experts is available in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries) as well as on the JECFA web site at www.who.int/ipcs/food/jecfa/experts/en/index.html.

the risk assessments examined here (also called 'safety assessments' by many practitioners) remained on the potential damage to the developing brain. The risk assessors agreed that methylmercury may also have other adverse health effects, but found the data on those other effects insufficient to establish a cause-effect relationship and to characterize dose-response relationships.[14]

Unlike the examples presented above, which describe how changes in risk associated with given increases or decreases in exposure are quantified and used to determine an Appropriate Level of Protection, the risk assessors in these methylmercury cases used a somewhat different approach. In each case, the (limited) available dose response data were used to calculate a Benchmark Dose Lower Confidence Limit (BMDL) or to estimate a No-Observed Effect Level (NOEL). Uncertainty factors were then applied to estimate the nominally 'safe' dose (RfD by the EPA, PTWI by JECFA).

The EPA and NAS/NRC each concluded, after reviewing the new epidemiological evidence, that a long-term study in the Faeroe Islands, testing for methylmercury effects in children born to women with a diet rich in fish and whale meat,[15] provided the best available evidence on potential adverse health effects.

(Source: NRC)

The Faeroe Islands study has associated prenatal methylmercury exposure with observed effects on brain nerve signal transmission and on several indices of cognitive development. Neither of the risk assessments in the United States relied on a similar study of a population with a high-fish diet in the Seychelles Islands[16], which has examined children for effects comparable to those studied in the Faeroe Islands, but has to date not identified statistically significant adverse effects, and thus was not deemed suitable for the risk assessment EPA wished to perform. JECFA, on the other hand, relied on both studies to derive an average dose from a BMDL (Faeroe Islands) and the NOEL (Seychelles).

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14 For a description of the EPA risk assessment, see D.C. Rice, R. Schoeny and K. Mahaffey, "Methods and rationale for derivation of a reference dose for methylmercury by the US EPA", in *Risk Analysis*, vol. 23, No. 1, 2003, pp. 107-115. For a description of the NAS/NRC risk assessment, see National Research Council, 2000 (*cf. supra*). For a description of the JECFA risk assessment, see WHO Food Additives Series, 52, Safety evaluation of certain food additives and contaminants, prepared by the 61st session of the Joint FAO/WHO Expert Committee on Food Additives. International Programme on Chemical Safety, World Health Organization, Geneva, 2004, pp. 565-623, Methylmercury.

15 P. Grandjean *et al*., "Cognitive deficit in 7-year-old children with prenatal exposure to methyl mercury", *op. cit*., pp. 417-428; K. Murata *et al*., "Delayed Brainstem Auditory Evoked Potential Latencies in 14-year-old Children Exposed to methylmercury", in *J. Pediatr.*, No. 144, 2004, pp. 177-183.

16 G.J. Myers *et al*., "Prenatal methylmercury exposure from ocean fish consumption in the Seychelles child development study", *The Lancet*, No. 361, 2003, pp. 1686-1692.

The EPA next estimated a variety of BMDLs using several models and associations between methylmercury doses and neurological developmental outcomes from the Faeroe Islands study. One BMDL was then selected and a ten-fold default uncertainty factor was applied to account for the variability in individual sensitivity, and an RfD of 0.1 µg/kg of body weight (µg/kg-bw) per day, or 0.7 µg/kg-bw per week was established which corresponds to a blood mercury level of 5.8 µg/liter.[17] JECFA, relying on the same evidence, used a slightly different approach. The committee calculated a steady-state intake of methylmercury of 1.5 µg/kg-bw per day from a maternal hair mercury level of 14 mg/kg, which is the average dose from the two studies. It was the lower confidence limit of the benchmark dose from the Faeroe Islands study, and the calculated NOEL from the Seychelles study. JECFA then applied a data derived, 6.4-fold uncertainty factor to calculate a PTWI for exposure of pregnant women of 1.6 µg/kg-bw per week[18]. This value is slightly lower than the previous JECFA PTWI of 3.3 µg/kg-bw per week, which was derived based on the lowest effect levels noted in earlier studies of populations exposed to methylmercury contamination via food.

The recommendations reached by experts in the USA and JECFA cases described here differed by approximately a factor of two. However, in view of the uncertainties in the scientific evidence and the different approaches taken by the two groups of risk assessors who made those determinations, these recommendations are actually quite close.

➢ ***Step 3: Exposure assessment***

The EPA and the United States Food and Drug Administration (FDA) assembled detailed information from which exposures could be characterized. Food consumption surveys indicate that a few percent of Americans consume more than 12 ounces (340 grams) of fish per week, considered 'high consumption' in the USA.[19]

Extensive data on mercury in fish, collected by the FDA and other agencies, show that several species consumed in the USA contain relatively high methylmercury levels. A national survey that examines a representative sample of the United States population for a variety of health and nutritional indices each year was expanded to include tests for blood mercury levels, beginning in 1999; data collected over a four-year period indicate that about 6 percent of women of childbearing age have blood Hg values above the EPA reference level of 5.8 µg/l.[20] Several independent studies of subgroups of the United States population who consume unusually high amounts of fish have also reported

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17 See Rice *et al.*, *cf. supra*.

18 JECFA report, cited in footnote 14 above, p. 615.

19 C.D. Carrington and P.M. Bolger, "An exposure assessment for methylmercury from seafood for consumers in the United States", *Risk Anal.*, No. 22, 2002, pp. 689-699.

20 K.R. Mahaffey, R.P. Clickner and C.C. Bodurow, "Blood Organic Mercury and Dietary Mercury Intake: National Health and Nutrition Examination Survey (NHANES), 1999 and 2000", *Environ. Health Perspect.*, No. 112, 2004, pp. 562-570; S.E. Schober *et al.*, "Blood Mercury Levels in US Children and Women of Childbearing Age, 1999-2000", *JAMA*, vol. 289, No. 13, 2003, pp. 1667-1674 ; R.L. Jones *et al.*, "Blood Mercury Levels in Young Children and Childbearing-Aged Women – United States, 1999-2002", *Morbidity and Mortality Weekly Reports*, vol. 53, No. 43, 2004, pp. 1018-1020.

evidence of exposure well above the EPA RfD in at least some members of these subgroups.[21]

JECFA assembled data from five national exposure studies, and calculated possible methylmercury intake associated with the five WHO GEMS/Food-regional diets, using estimated average fish intake and data on the average mercury content of fish submitted by various member governments. JECFA estimated that high-end fish consumers in most of the countries for which it had data were exposed to methylmercury doses greater than the PTWI. The highest estimate for the average methylmercury dose from the five GEMS/Food-regional diets (JECFA did not say which regional diet was highest) was 1.5 µg/kg-bw per week, just below the new PTWI of 1.6 µg/kg-bw per week, indicating that almost half the people with that diet would exceed the tolerable level of methylmercury intake.[22]

➢ ***Step 4: Risk characterization***

As indicated above in the United States, according to the National Health and Nutrition Examination Survey (NHANES) reports, about 6 percent of the study population had body burdens of mercury that slightly exceeded the blood level which is equivalent to the RfD.

JECFA did not characterize the risk for particular regions or countries, but clearly suggested that exposure to methylmercury doses above the PTWI is relatively commonplace in countries where fish is important in the diet, and that national governments may now need to carry out population-specific exposure assessments.

Risk characterizations of the type developed for methylmercury are relatively imprecise; risk is not quantitatively characterized in terms of the probability and severity of adverse health effects relative to defined levels of exposure, but rather, presumptively 'safe' exposure levels are estimated. Such 'safety assessments' can nonetheless provide a basis for risk management decisions.

❑ **Risk communication aspects**

The EPA, the NAS/NRC and JECFA have each published detailed reports on their methylmercury risk assessments, which explain the scientific evidence considered, the interpretations and judgments made by the risk assessors, conclusions and recommendations of the expert groups, uncertainties and data gaps that remain, and steps taken to address uncertainties in the risk assessments.[23] Publication of a risk assessment offers an important opportunity for risk communication and in the USA, extensive communication took place among the interested government agencies, the scientific community, and a variety of stakeholders, ranging from fishing industry interests to NGOs concerned about methylmercury hazards in foods.

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[21] For a review of this evidence, see K.R. Mahaffey, "Update on Mercury", presentation at Fish Forum 2005, 19 September 2005, epa.gov/waterscience/fish/forum/2005/presentations/Monday%20Slides%200919/afternoon/Mahaffey_Fis h%20Forum%202005%20-%20Mahaffey%20Final.ppt.

[22] See JECFA report ((*op. cit., cf. supra*) pp. 607-609.

[23] These reports are cited in footnote 14 above.

As attention returned to risk management aspects, the process in the United States was open to participation by stakeholders.[24] Some of those stakeholders have communicated aggressively, both with the government and with the public at large. For example, fishing interests, especially the United States tuna industry, have criticized the EPA risk assessment and RfD as excessively precautionary, denied that methylmercury in fish poses risks to public health, and spent millions of dollars on public relations and advertising campaigns to persuade people to ignore methylmercury risks and eat more fish.[25] Public health, environmental and consumer organizations have concluded, in contrast, that methylmercury risks are a significant public health concern, and sought in their own ways to inform the public and persuade policy-makers of their view.[26] There has been so much risk communication on the methylmercury problem in the United States that an intense public controversy exists.

Communication about the JECFA risk assessment has been somewhat less intense. When CCFAC received the JECFA recommendation for a lowered PTWI, the committee initiated are view of the Codex guidelines for methylmercury in fish. Some CCFAC members had questions, seeking clarification of JECFA's reasoning on certain points.[27] In particular, some members were uncertain whether JECFA intended that the new, lower PTWI should be applied to everyone in the general population, or whether it applied only to women who were or might become pregnant. JECFA considered this request in 2006 and clarified that the previous PTWI of 3.3 µg/kg-bw had, in fact, been withdrawn in 2003. JECFA confirmed the existing PTWI of 1.6 µg/kg-bw, set in 2003, based on the most sensitive toxicological endpoint (developmental neurotoxicity) in the most susceptible species (humans). However, the Committee noted that life-stages other than the embryo and fetus may be less sensitive to the adverse effects of methylmercury. In the case of adults (with the exception of women of childbearing age for protection of the developing fetus), JECFA considered that intakes of up to about two times higher than the existing PTWI of 1.6 µg/kg-bw would not pose any risk of neurotoxicity. For infants and children JECFA could not identify a level of intake higher than the existing PTWI that would not pose a risk of developmental neurotoxicity for infants and children, hence for this age group the new PTWI applies.

❑ Risk management, Phase 2: Identification and selection of risk management options

Once the findings of the risk assessment are available, risk managers can proceed to manage the risk. At the international level, WHO and CCFAC each have distinct roles as risk managers with respect to methylmercury in fish. Since neither WHO nor Codex

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[24] Mercury in fish was discussed extensively at a December 10, 2003 meeting of the FDA's Food Advisory Committee (transcript available at www.fda.gov/ohrms/dockets/ac/cfsan03.html). It was addressed in written comments submitted by industry groups and by Consumers Union among others.

[25] Many examples of denial of the evidence of mercury risks and promotion of increased fish (and specifically, tuna) consumption are accessible on the United States Tuna Foundation web site. For example, see www.fishscam.com, an industry funded web site created by a public relations firm in an effort to discredit mercury risk concerns.

[26] For example, see E. Groth, *Risks and Benefits of Fish Consumption: Yes, Mercury is a Problem*, Report prepared for Oceana and the Mercury Policy Project, December 2005, oceana.org/sites/default/files/reports/RisksandBenefitsofFishConsumptionFinal_Report_12-5.pdf.

[27] See the report of the 2005 CCFAC meeting, ALINORM 05/28/12, §§ 201-205.

committees implement risk management measures, the international bodies' actions serve primarily as guidance for national risk managers.

The CCFAC, based on the new JECFA PTWI, is now considering further appropriate actions it might pursue. At its 2004 meeting, CCFAC asked a drafting group to prepare a discussion paper, outlining possible risk management options that national governments might consider. The paper, prepared with the leadership of the European Commission, focused on both the Codex Guideline Levels for Methylmercury in Fish, and on providing information to stakeholders, especially consumers, as a risk management option. It was discussed at the 2005 CCFAC session[28] which agreed to organize a workshop on risk communication as a risk management tool. This workshop was held in conjunction with the CCFAC session in April 2006.

WHO is also currently drafting a document to provide advice to member governments on how to conduct risk analysis for methylmercury in fish. International advice on this subject will be drawn from national experiences. The rest of this section, therefore, examines the national aspect of this case study, the experience in the United States.

➢ ***Step 1: Identify risk management options***

(Source : Unep)

Several risk management options can be identified which might help reduce methylmercury risks at the national level. A general option, important for addressing local pollution problems that may put specific fish-eating populations at risk, is to control industrial mercury emission sources; however, this approach will have negligible short-term impact on the methylmercury levels in migratory oceanic fish species. Furthermore, pollution control is generally outside the authority of food safety agencies, which have the primary risk management responsibility for food-borne contaminants such as methylmercury.

Among actions that can be taken by national food safety authorities, the following are some risk management options that could be considered:

- The sale of certain fish species that are very high in methylmercury could be banned.
- A maximum contaminant level could be set for mercury or methylmercury in fish, and used to restrict sale and consumption of fish that exceed the established limit.
- The fishing industry and fish processors and retailers could be required to implement a code of Good Hygienic Practice or a HACCP system designed to prevent fish with potentially harmful levels of methylmercury from reaching consumers.

Consumers can be educated and informed about methylmercury levels in fish and the associated risks, so that they can manage their own methylmercury exposure.

[28] See Report of 2005 CCFAC session (cited above).

➢ ***Step 2: Evaluate the options***

The pros and cons of these options have been examined in several cycles of risk analysis on methylmercury in the United States. The United States government has not been willing to ban the sale or consumption of any fish species, even those with very high methylmercury levels, such as swordfish or marlin. High-mercury fish still has nutritional benefits, and most high-mercury species are eaten only infrequently by the vast majority of consumers, so bans have been viewed as unjustified, as well as impractical to enforce. Social and economic concerns, such as the possibility of putting fishermen out of work, have also been considerations weighed in evaluating this option.

The United States adopted an 'Action Level', a guideline value for the acceptable upper limit of methylmercury concentrations in fish, in 1969. Originally set at 0.5 parts per million (ppm), the Action Level was raised to 1.0 ppm in 1979, after the fishing industry successfully sued the FDA. The court ruled that FDA's exposure assessment and resulting safety assessment which it used as the justification for the 0.5 ppm level were unnecessarily conservative and inappropriate. Many other national governments, and CCFAC, have issued similar guidelines, generally set either at 0.5 or 1.0 ppm.[29]

In the United States, the Action Level is rarely if ever enforced; FDA concedes, for instance, that a significant portion of swordfish sold in national markets contains more than 1.0 ppm of mercury. While such a limit can, in theory, be used to prevent sale of fish that exceed it, in practice the United States Action Level has proved difficult and costly to enforce, and if strictly enforced, it could have negative socioeconomic effects similar to those discussed for a ban, above. Also, since the level of mercury in fish is just one of several factors that determine risk, efforts to keep high-mercury fish off the market cannot, by themselves, effectively reduce exposure and the associated risk. Someone who ate a great deal of fish with, for example, 0.25 ppm mercury could exceed the safe intake limit by a wide margin, while someone else who ate swordfish once or twice a year, for instance, might not be particularly at risk. Since the Action Level cannot be adjusted to take into account other factors that determine risk, enforcing it has not been a high priority. In sum, while it is seen as a useful guideline, the United States Action Level for mercury in fish has not significantly reduced exposure.

GHP or HACCP approaches that could help fish and seafood industries reduce the amount of methylmercury in products they sell appear to have significant potential for mitigating the problem, but this approach has not been pursued to date in the USA.

A few other private-sector initiatives have had modest effects. Some retail grocery chains are working with state governments and NGOs in the United States to provide information on the mercury content of different fish at the point of sale (e.g. at supermarket fish counters). Other sellers of fish, including chefs at famous restaurants, have promised to stop offering certain high-mercury species.

Information-based options have been the recent focus of risk management for methylmercury in the USA. Because the risk depends on multiple factors (including who is consuming the fish, which fish they choose to consume, how much of each fish species they eat, and how much methylmercury the fish in question contain) education and risk

[29] CCFAC has adopted a two-tiered system, with a list of species that should not exceed 1 ppm, i.e. large predatory fish that tend to accumulate relatively high mercury levels, and a second list that should not exceed 0.5 ppm, i.e. fish that tend to accumulate moderate but still relatively significant amounts of mercury.

communication have attracted great interest as risk management options. These approaches can address the complexity of the problem, do not require costly and impractical enforcement efforts, can be implemented relatively quickly and at relatively minimal cost, and hold at least the potential for reducing methylmercury exposure substantially, without adverse nutritional or economic consequences.

➢ ***Step 3: Select the preferred option(s)***

As should be clear from the discussion above, the currently preferred risk management option and main focus of risk managers in the United States is providing information to consumers.

❑ **Risk management, Phase 3: Implementation**

Once the preferred risk management option has been selected, governments and other stakeholders need to implement the chosen option. In the United States, the FDA issued a national 'advisory' on methylmercury and fish consumption in 2001, targeting women of childbearing age, telling them to avoid four species with high mercury levels, *i.e*. swordfish, tilefish, shark and king mackerel. In 2004, the FDA and EPA issued a joint, updated, expanded 'advisory', which emphasized the nutritional benefits of fish consumption, urged women to consume a variety of low-mercury fish, listed several widely available low-mercury fish and seafood choices, listed the same four species that should be avoided, advised limiting consumption of canned albacore tuna, and said that children's fish consumption should follow similar guidelines. The 'advisory' has been published on the government's web sites[30] and was publicized heavily when it was initially issued. FDA has taken steps within its modest resources to promote awareness of the advisory and to work with industry, professional (medical and nutritional) societies, and other interested parties to educate consumers on how to manage their own methylmercury exposure.

Several State Health Departments within the United States have also issued consumer advice on methylmercury in fish, as have some professional organizations and numerous NGOs. American consumers have no shortage of advice and 'educational' information on this topic; in fact, one concern has been that differences in the advice from different sources may be confusing consumers. The 2004 joint FDA/EPA 'advisory' was in part undertaken as an effort to get the federal government, at least, to speak with a single voice on this subject.

Since implementation is a responsibility of national authorities, there is no section on this phase of risk management in the JECFA/*Codex* risk analysis for methylmercury

❑ **Risk management, Phase 4: Monitoring and review**

The 'final' stage of risk analysis occurs when risk managers assess how well the risk management options implemented are working and weigh the need to examine new evidence and update risk assessments and management strategies. Since each of the risk analysis cases described in this Annex were to a large extent reviews and updates, or reiterations, of previous efforts, they essentially began at this point. In the case of the United States risk analysis documented here, relevant government agencies continue to monitor of the effects of risk management actions.

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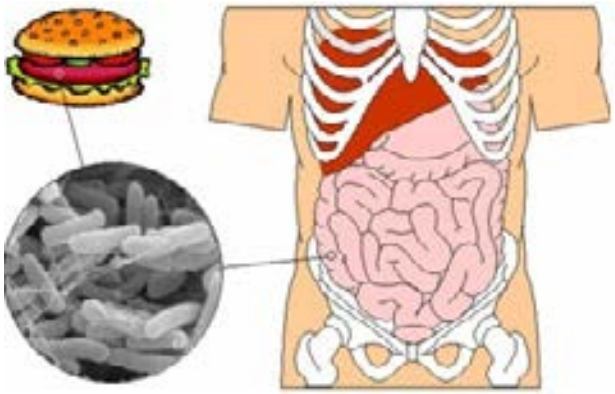
[30] The current *advisory* EPA/FDA (2004) is called "What You Need to Know About Mercury in Fish and Shellfish", available at epa.gov/waterscience/fishadvice/advice.html.

The 'advisory' option being pursued now in the USA was implemented in 2004, and there has not been enough time to determine most of its expected effects. For example, a key indicator of effectiveness of the EPA/FDA 'advisory' will be whether national surveys show that a decreasing percentage of women have blood mercury levels above the EPA reference level, but such data are not expected to be available for several years.

Nevertheless, some efforts to assess the effects of the informational approach in the USA are now under way. Before it issued the 2004 advisory, the government conducted sessions with consumers ('focus groups') to assess how they would understand and respond to both the information and the advice provided. Since the advisory was issued, a concern has arisen that warnings about contaminants like methylmercury in fish may make consumers afraid to eat fish, and cause them to lose important nutritional benefits associated with fish in the diet. Whether this is true or not is far from clear at this point,[31] but the question has attracted a great deal of attention from academic researchers, state and federal governments, and interested stakeholders. Investigations now under way may lead to fine-tuning the advice offered to consumers, so that they can continue to consume low-mercury fish for their nutritional benefits, while minimizing their mercury exposure.

A.2. Case study of Listeria monocytogenes in ready-to-eat foods

❑ Background



Listeria monocytogenes is a food-borne bacterial pathogen that can cause listeriosis, a severe disease that can result in septicemia, meningitis and spontaneous abortion. Given the importance of this disease, the 'USA Healthy People 2010' goals for national health promotion and disease prevention called on federal food safety agencies to reduce food-borne listeriosis by 50 percent by the end of the year 2005.

While increased government and industry attention to general aspects of *L. monocytogenes* control would result in some decrease in incidence, specific risk management actions were needed.

This case study illustrates application of the generic RMF.

[31] See Groth, 2005 (above) for discussion.

❑ Risk management, Phase 1: Preliminary risk management activities

➢ *Step 1: Identify the problem*

Listeriosis typically occurs in susceptible individuals including the elderly, pregnant women and immunocompromised people (e.g. patients undergoing cancer therapy, transplant recipients and people with AIDS). Although the total number of cases in any population is relatively low (about 2,500 cases per year in the United States), listeriosis has an estimated case fatality rate of 20 to 40%.

L. monocytogenes is widespread in the environment but the predominant food-borne disease pathway is via ready-to-eat.[32] In addressing the *L. monocytogenes* problem in the United States, risk managers made an early decision to only evaluate risks associated with ready-to-eat foods because the organism is destroyed in other types of foods that are cooked or further processed before consumption.

In addition to good hygienic practice (GHP), a 'zero tolerance' regulatory standard of no *L. monocytogenes* cells being detected in the food sample tested is maintained in the United States. A typical food test for *L. monocytogenes* is two samples at 25 grams each, which equates to a standard of less than 0.04 cfu/g. The existing regulatory standards are not achieving the level of public health protection required and better 'risk-based' control measures are needed.

➢ *Step 2: Develop the risk profile*

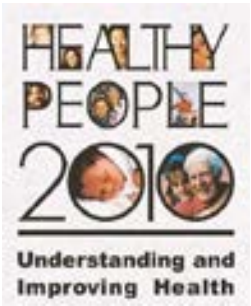
The concerned government agencies gathered all relevant information on *L. monocytogenes* in foods to inform further action. Different types of ready-to-eat foods were considered including meat products, seafood, dairy products, fruits, vegetables and delicatessen salads.

Preliminary data collection activities identified many gaps in the scientific information available on *L. monocytogenes* in ready-to-eat foods. In particular, exposure data was deficient for a number of ready-to-eat food types and a specific survey was commissioned to fill this data gap. While most samples were found to be negative for *L. monocytogenes*, those that were positive typically contained less than 1.0 cfu/g, with almost all foods containing less than 100 cfu/g.

➢ *Step 3: Establish risk management goals*

The primary risk management goal was to estimate relative risks associated with different types of ready-to-eat foods and develop targeted food control measures that would significantly reduce the overall incidence of food-borne listeriosis in line with 'USA Healthy People 2010'. The relative risk ranking would identify priority food categories for risk management.

(Source: FAQS)



[32] Products that may be consumed without any further cooking or reheating.

A subsidiary goal was to estimate the relative risks of serious illness and death for three age based subpopulations:

- prenatal/perinatal (16 weeks after conception to 30 days after birth);
- the elderly (60 years of age or more);
- an intermediate age population.

Interventions in the ready-to-eat food chains that presented the greatest relative risks would be evaluated for their individual ability to reduce risks.

➢ ***Step 4: Decide whether a risk assessment is needed***

In the United States, government agencies are required to do risk assessments when making major food safety policy decisions. In this case, the risk managers decided that the most value would be gained from estimating relative risks from a wide range of ready-to-eat food categories. The decision to base control measures on estimates of relative risk was predicated by limitations in data availability.

➢ ***Step 5: Establish risk assessment policy***

While this is a formal step in the generic RMF developed in this handbook, establishment of risk assessment policy was not conducted as a discrete exercise in this case study. However, there were a number of situations where a standardized approach to dealing with scientific data was agreed. A policy decision was made that data sets that were more recent and/or came from peer-reviewed publications would be given a higher weighting than others, and data collected outside the United States could be used if the product was imported. Exposure data would be represented as presence/absence data rather than actual numbers of *L. monocytogenes* in foods and this allowed all the available exposure data to be utilized in some form.

For the dose-response assessment, a policy decision was made to use a non-threshold model rather than a threshold model. A non-threshold model assumes that there is a small but finite probability of illness even if only a single organism is consumed.

➢ ***Step 6: Commission the risk assessment***

Before commissioning, a public meeting was held to invite comment on the planned assessment and a request was made for scientific data and information to be submitted for use in the assessment. The advice and recommendations of the National Advisory Committee on Microbiological Criteria for Foods were sought on the assumptions therein and the model structure to be used.

The risk assessment was carried out by the Food Safety and Inspection Service (FSIS) in the United States Department of Agriculture (USDA), the United States Department of Health and Human Services (HHS), the United States Food and Drug Administration (FDA) and the United States Centers for Disease Control and Prevention (CDC) over a period from 1999 to 2003. The risk assessment team was a multidisciplinary group of government scientists including food microbiologists, epidemiologists and mathematicians.

A total of 23 separate assessments were undertaken, which allowed an analysis of the relative risks of serious illness and death associated with a wide range of ready-to-eat

food categories. Primary considerations were: consumption by susceptible persons; types of contaminated foods; foods that support growth; storage time; and storage temperature.

Risk communication included presentations at scientific meetings and public meetings, the latter being held for the purpose of soliciting feedback and peer review. An initial draft risk assessment was released in 2001 to allow public comment and input from the scientific community before the assessment was finalized. This generated additional data for risk assessment and was an effective method for communicating with all stakeholders before the assessment was finalized.

- ***Step 7: Consider the results of the risk assessment***

The primary output of the risk assessment is shown in Figure A3-1 as estimated cases of listeriosis associated with different ready-to-eat food categories for the total United States population on a per serving basis. In the United States, delicatessen meats, frankfurters (not reheated), pâté and meat spreads pose a much greater risk (about 1 case of listeriosis per 107 servings is predicted) than hard cheeses, cultured milk products and processed cheeses, where the predicted level of illness is approximately 1 case of listeriosis per 10 servings. The main reason for this is that the former group of foods supports the growth of *L. monocytogenes* to high numbers even during refrigerated storage, while the latter group does not.

The risk assessment generated risks per serving to an individual consumer and risks per annum to various populations; the latter representing total disease burden. Ready-to-eat foods ranked as very high risk, both risk per serving and per annum, included delicatessen meats and frankfurters (not reheated). This is due to high consumption, high rates of contamination and rapid growth to high numbers in stored products. Ready-to-eat foods ranked as high risk included pâté and meat spreads, smoked seafood, pasteurized and unpasteurized fluid milk, and soft unripened cheeses. Here, high relative risks are generated either from high contamination but low consumption rates or low contamination but high consumption rates e.g. pasteurized fluid milk. Ready-to-eat foods ranked as moderate risk (e.g. dry/semi-dry fermented sausages and frankfurters (reheated)) include a bactericidal step or inhibitors, so that growth to high numbers is prevented or retarded. Ready-to-eat foods ranked as low risk (e.g. preserved fish and raw seafood) have both low contamination rates and low consumption rates, and may have natural barriers to growth. Ready-to-eat foods ranked as very low risk (e.g. hard cheese) do not support growth.

The dose-response curves show that elderly and perinatal populations are more likely to contract listeriosis than the general population. The dose-response curves also suggest that the relative risk of contracting listeriosis from low dose exposures is less than previously estimated, even for susceptible populations.

Summary of elements of the risk assessment of L. monocytogenes in ready-to-eat foods

- Hazard characterization: Severe illness or death in three age-based populations were considered: prenatal/perinatal; the elderly; and an intermediate age population. Dose-response relationships were estimated by using contamination and growth data to predict levels of *L. monocytogenes* at the time of consumption for all ready-to-eat foods. These data were combined with epidemiology data to derive a dose-response model for each population group. The shape of the dose-

response curve was based on mouse lethality data for *L. monocytogenes* but the position of the dose response curve was fixed by 'anchoring' the curve to annual disease statistics for the United States. Mild non-invasive listeria gastroenteritis was not considered in the risk assessment.

- Exposure assessment: Exposure assessments were based on estimates of the frequency of contamination of foods, the numbers of cells on ready-to-eat foods, the amount of growth before consumption, the amount of each food type consumed at a typical serving and the number of servings consumed per year. Servings per year of each ready-to-eat food category varied considerably, as did the amount of food eaten at each serving. As examples for the whole United States population, there were 8.7 *10 servings of pasteurized milk per year at 244 g, 2.1*10 servings of delicatessen meats at 56 g, and 2*10 servings of smoked seafood at 57 g. Initially 'expert opinion' was used to fill a significant data gap on the length of time for which foods were stored by consumers and its effect on *L. monocytogenes* numbers. Later, a survey of consumer practices was commissioned by the meat industry to obtain data to allow better estimates to be made for hot dogs and delicatessen meats.

  Most (1,300) contaminated servings of food per person per year contained less than one organism per serving; 19 servings contained between 1.0 and 1,000 cfu/g; and 2.4 servings contained between 1,000 and 1,000,000. Less than one serving per person per year contained more than one million *L. monocytogenes*.

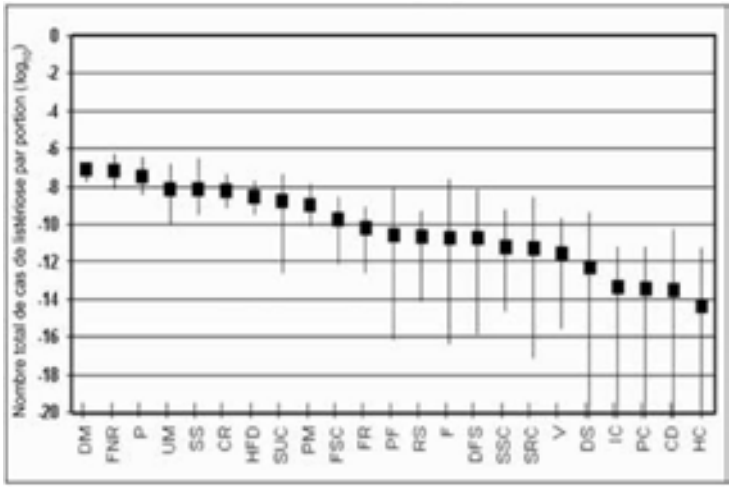
- Risk characterization: Individual food category data and the dose-response model were used to estimate the number of cases of illness per serving and per year for each food category and each population group. This allowed foods to be ranked according to two different measures of relative risk. An uncertainty analysis was performed and results were compared with existing epidemiological knowledge to validate the outputs of the risk assessment. The ability of a food to support growth of *L. monocytogenes* to high numbers and the opportunity for growth is a key risk factor in food-borne listeriosis. The model indicates that it is the few servings with very high levels of contamination that are responsible for most of the illnesses and deaths.

- ***Step 8: Rank risks***

Ranking of risks associated with the 23 ready-to-eat food types was a key design element of this case study and provided the platform for the risk management options subsequently chosen. Relative risk rankings are shown below.

Once the risk assessment was finalized, a series of reports were released. The first report was a short executive summary of the findings. The second report was an interpretive summary, with a more detailed review of the findings. The third report was the risk assessment. A fact sheet with questions and answers was also released. By providing the information in many formats, different audiences were properly addressed.

Estimated cases of listeriosis associated with different food categories for the total United States population on a per serving basis



The box indicates the median predicted number of cases of listeriosis (log scale) and the bar indicates the lower and upper bounds (i.e. the 5th and 95th percentiles). The y-axis values are presented on a log scale. For example a log of –6 is equivalent to 1 case of listeriosis in a million servings.

DM = Delicatessen meats; FNR = Frankfurters (not reheated); P= Pâté and Meat Spreads; UM= Unpasteurized Fluid Milk; SS= Smoked Seafood; CR = Cooked Ready-To-Eat Crustaceans; HFD = High Fat and Other Dairy Products; SUC = Soft Unripened Cheese; PM = Pasteurized Fluid Milk; FSC = Fresh Soft Cheese; FR = Frankfurters (reheated); PF = Preserved Fish; RS = Raw Seafood; F = Fruits; DFS= Dry/Semi-dry Fermented Sausages; SSC = Semi-soft Cheese; SRC = Soft Ripened Cheese; V = Vegetables; DS = Delicatessen-type Salads; IC= Ice Cream and Frozen Dairy Products; PC = Processed Cheese; CD = Cultured Milk Products; HC = Hard Cheese.

❑ Risk management, Phase 2: Identification and selection of risk management options

The results of the risk assessment were used in different ways by the different government agencies. HHS used the risk assessment to develop a risk management action plan for *L. monocytogenes* whereas USDA FSIS used the risk assessment primarily as a basis for new regulatory measures.

➢ *United States Department of Health and Human Services (HHS)*

FDA and CDC developed a risk management action plan to target the products and practices that generate the greatest risks of food-borne listeriosis. The action plan included the following objectives:

- Develop and revise guidance for processors, retail outlets, food service and institutional establishments that manufacture or prepare ready-to-eat foods.

- Develop and deliver training for industry and food safety regulatory employees.
- Enhance consumer and health care provider information and education efforts.
- Review, redirect and revise enforcement and regulatory strategies including microbial product sampling.

In evaluating different risk management options, risk managers worked with risk assessors to change one or more input parameters in the risk model and measure the change in relative risk outputs. These 'what if' scenarios included:

- Refrigerator temperature scenario, where the impact of ensuring home refrigerators do not operate above 45 °F was evaluated. Here, the predicted number of cases of listeriosis would be reduced by approximately 69 percent. At 41 °F or less, the predicted number of cases would be reduced by approximately 98%.
- Storage time scenario, where maximum storage time scenarios were evaluated. Limiting the storage time for delicatessen meat, for example, from a maximum 28 days to 14 days, reduces the median number of estimated cases in the elderly population by 13.6%. Shortening storage time to ten days results in a 32.5% reduction.

Other scenarios included modelling of different contamination level scenarios in retail foods and specifically modelling fresh soft cheese made from unpasteurized milk. Risk assessment outputs and modelling of 'what if' scenarios resulted in development of new published guidance for processors on prevention of post-processing contamination with *L. monocytogenes*, including improved sanitation practices and environmental sampling for ready-to-eat foods, and improved distribution practices. This includes updated guidance on enhancing the safety of milk and milk products and fresh-cut produce. Existing training programmes and long-distance teaching instruments were also updated.

Additional messages to consumers and health care providers on the prevention of listeriosis were developed. These include advice on safely selecting, storing, and handling foods with special emphasis on short storage times in combination with minimizing storage temperatures to as cold as necessary (and not exceeding 40 °F). Educational programmes aimed at pregnant women, older adults, and people with weakened immune systems were also updated. As examples, these population groups are advised not to eat hot dogs and luncheon meats unless they are reheated until steaming hot, soft cheese unless it is labelled as made with pasteurized milk, refrigerated smoked seafood unless it is contained in a cooked dish, and raw (unpasteurized) milk.

Regulatory risk management options include increased inspection of regulated food processing facilities that produce ready-to-eat foods ranked moderate to high risk in the risk assessment. This focuses inspection efforts on post-process contamination potential, sanitation practices, and environmental testing programmes.

➢ ***Food Safety and Inspection Service, United States Department of Agriculture (FSIS, USDA)***

During the development of the HHS/USDA risk assessment, FSIS initiated several regulatory actions based on current scientific knowledge with the aim of reducing food-borne listeriosis associated with meat products. When the first draft of the risk model was released in 2001, it showed that

delicatessen meats (such as cooked ready-to-eat turkey or ham) presented a relatively high risk for listeriosis.

As a consequence FSIS decided to focus risk management activities on delicatessen meats and initiated a further risk assessment specific to the product group. 'What if' scenarios showed that combinations of interventions (e.g. sanitation/testing of food contact surfaces, pre- and post-packaging lethality interventions, and growth inhibitors) were much more effective than any single intervention in reducing estimated risks from deli meats.[33]

As a consequence, FSIS amended its regulations to require that official establishments that produce certain ready-to-eat meat and poultry products put in place specific controls to prevent contamination with *L. monocytogenes* if those products are exposed to the environment after lethality treatments. So as to provide flexibility to industry, the regulatory rule allows establishments to incorporate one of three strategies: i) employ both a post lethality treatment and a growth inhibitor for *L. monocytogenes* on ready-to-eat products; ii) employ either a post-lethality treatment or a growth inhibitor; or iii) employ sanitation measures only. These in-plant requirements are underpinned by new compliance guidelines and FSIS inspection procedures (see below).

Regulatory change was accompanied by education and outreach programmes. These risk communication activities were harmonized with those of FDA to ensure that consumer messages on listeriosis remained consistent.

❑ **Risk management – Phase 3: Implementation**

➢ ***United States Department of Health and Human Services (HHS)***

FDA and CDC continue to work on implementation activities, including disseminating guidance for processors. Technical assistance is provided to small and very small establishments (e.g. dairy facilities) on an ongoing basis.

Consumer information and education efforts continue, including specific education packages for highly susceptible population groups and medical guidance for health care professionals. An example of a targeted education programme is that to Hispanic women of child-bearing age to only eat fresh soft cheeses made with pasteurized milk.

Regulatory risk management options that focus on increased inspection of establishments that produce 'high risk' ready-to-eat foods have also been implemented. FDA is also working with states to eliminate the unlawful production and sale of raw milk soft cheeses.

➢ ***Food Safety and Inspection Service, United States Department of Agriculture (FSIS, USDA)***

A specific aspect of implementation of the new FSIS regulations is the matching of FSIS verification activities to the specific control strategy chosen by the processor. Establishments that chose sanitary measures alone have the highest frequency of inspection whereas establishments that chose both a post-lethality treatment and a growth inhibitor for *L. monocytogenes* on ready-to-eat products are subject to FSIS activity that only focuses on verification of post-lethality treatment effectiveness. This way,

[33] www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf.

establishments are encouraged to select the most effective strategies to control for *L. monocytogenes*. FSIS also places increased scrutiny on operations that produce hotdogs and delicatessen meats. Compliance guidelines to control *L. monocytogenes* in post-lethality exposed ready-to-eat meat and poultry products were published in the United States Federal Register in May 2006.[34]

FSIS is currently working on a risk-based *L. monocytogenes* verification algorithm that rewards highly-performing establishments by reducing inspection frequency.

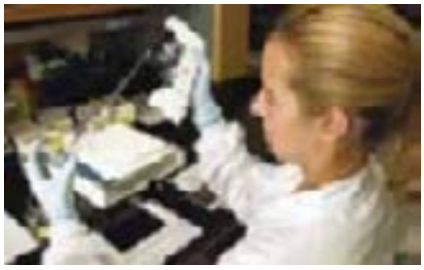
❑ **Risk management, Phase 4: Monitoring and review**

➢ ***United States Department of Health and Human Services (HHS)***

The risk management action plan developed by FDA and CDC also includes the objectives of:

- Enhance disease surveillance and outbreak response.
- Coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

Monitoring of both domestically-produced and imported food is focused on 'high-risk' ready-to-eat foods.



To detect illness outbreaks more quickly and accurately, CDC is continuing to increase the number of laboratories capable of *L. monocytogenes* analysis through CDC's 'PulseNet' laboratory network and will evaluate additional methods for rapid subtyping of pathogenic strains. A CDC comprehensive case-control study to gather additional information about food-borne listeriosis is also being undertaken.

Source: Medscape news

Risk managers identified a number of future research needs to refine the existing risk assessment so as to facilitate review the risk management options chosen. These include scientific evaluation of: the effectiveness of post-packaging pasteurization; use of bacteriocins, irradiation, high pressure processing, and inhibitory compounds to eliminate or prevent the growth of *L. monocytogenes*; and development of improved epidemiological methods for food source attribution.

➢ ***Food Safety and Inspection Service, United States Department of Agriculture (FSIS, USDA)***

Establishments must share data and information relevant to their controls for *L. monocytogenes* with FSIS. Additionally, FSIS carries out its own random testing of ready-to-eat meat and poultry products and this is used to rank establishments for verification purposes. These data are subject to ongoing evaluation, with review of regulation if

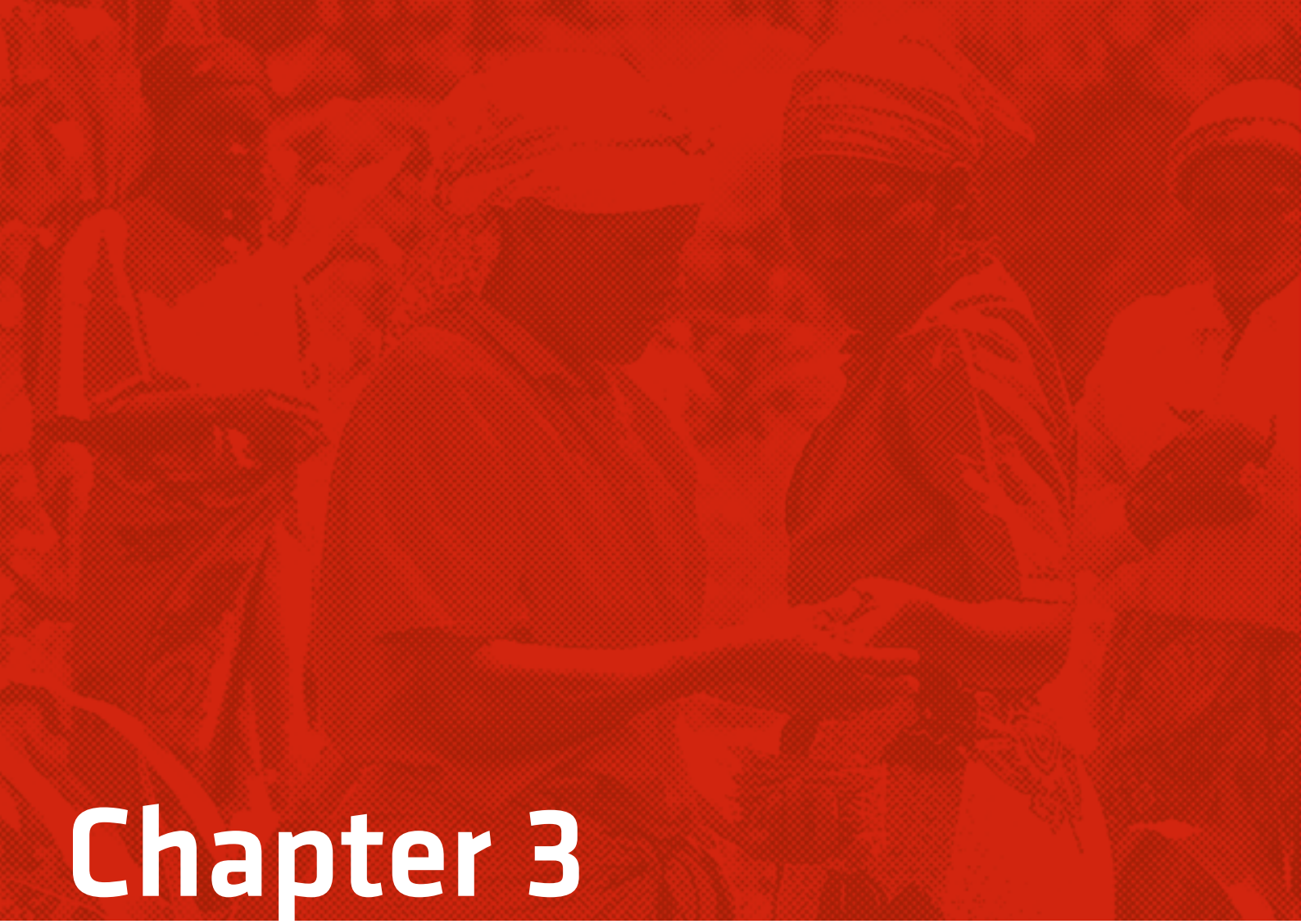
[34] www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf.

necessary. It should be noted that human health surveillance as a specific 'monitoring and review' activity is not within the jurisdiction of USDA.

❑ Risk communication

Risk communication was incorporated at various points throughout the risk analysis as indicated in the above discussion. Different approaches were used to communicate with external stakeholders about the nature and effects of the specific food safety risks faced. These included public meetings and calls for scientific data and information before the risk assessment was commissioned, public meetings to seek feedback from interested groups (including the scientific community) and peer review an initial draft risk assessment, and complementary activities to enhance knowledge among consumers and health care providers about the prevention of listeriosis.

In the case of proposed risk management options for ready-to-eat meat and poultry products, FSIS published proposals for interim regulatory requirements in the Federal Register and are continuing to engage with industry on practical aspects of their implementation.



Chapter 3

Risk assessment

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3.1. Introduction

Risk assessment is the central scientific component of risk analysis and has evolved primarily because of the need to make decisions to protect health in the face of scientific uncertainty. Risk assessment can be generally described as characterizing the potential adverse effects to life and health resulting from exposure to hazards over a specified time period.

Risk management and risk assessment are separate but closely linked activities, and ongoing, effective communication between those carrying out the separate functions is essential. Risk managers applying the RMF must decide whether a risk assessment is possible and necessary. If this decision is affirmative, risk managers commission and manage the risk assessment, carrying out tasks such as describing the purpose of risk assessment and the food safety questions to be answered, establishing risk assessment policy, setting time schedules and providing the resources necessary to carry out the work.

This chapter describes the substantive content of the food safety risk assessment process and explains how risk assessment fits into application of the RMF. While the main focus is on application of risk assessment methodology as defined by *Codex*, a broader view of risk assessment is also taken. All methods for assessing risks described here use the best scientific knowledge available support risk-based standards or other risk management options.

Individual risk assessments should be 'fit-for-purpose' and can generate estimates of risks in various forms. Where they are feasible, quantitative risk assessments have the additional advantage of being able to model the effects of different interventions and this probably is their greatest strength. Scientific approaches that combine risk assessment, epidemiology[1] and economics are likely to be most useful to risk managers trying to integrate and balance risks and benefits.

3.1.1. Risk assessment and the WTO SPS Agreement

WTO members are bound by the provisions of the SPS Agreement, which places risk assessment within a coherent SPS system for developing and applying standards for food in international trade. The scope of the SPS Agreement in the context of this handbook covers risks to human life and health, and requires that WTO members:

- shall ensure that any measure is applied only to the extent necessary to protect human life and health;
- shall base their measures on risk assessment, taking into account the techniques developed by the relevant international organizations;
- may implement a measure that differs from international norms where a higher 'appropriate level of health protection' is a legitimate goal;

[1] Epidemiology data are important for risk assessment. Epidemiology, as a tool, can also be used independently of risk assessment, for example in food source attribution.

- shall apply the principles of equivalency where a different measure in an exporting country achieves their appropriate level of protection n.

Risk assessment (Source: Science et avenir)

These provisions reflect the notion that the scientific conclusions of a risk assessment must reasonably support the SPS measure in question, and this in turn underpins the explanation of a 'risk-based standard'. However, case law resulting from disputes between countries is still limited and certain aspects of the WTO SPS provisions and obligations in regard to risk assessment methodology remain open to interpretation, for example, when evaluating the proportionality between the level of risk and the SPS measure,[2] when deciding how rigorous a risk assessment should be in low-risk situations, and when judging the sufficiency of scientific evidence. Nevertheless, the scientific robustness and quality of the risk assessment in question primarily drive decisions of this type.

3.1.2. Relative positions of risk assessment and risk management

Although risk managers commission and guide the production of a risk assessment and evaluate its outputs, the risk assessment itself is generally an external product, independently produced by scientists.

[2] 'Proportionality' means that control measures should be in proportion to the risk; e.g. if the risk assessment identifies negligible risks it is unreasonable to introduce an SPS measure that requires a stringent and costly regulatory regime.

3.2. Scientific approaches for assessing risks

When addressing a particular food safety issue, an early risk management decision concerns the scientific approach that will be taken. While this handbook is focused on risk assessment as an input to the RMF, there are many situations at the national level where no risk assessment of any form is available or feasible. In other situations, an active decision may be taken to use a scientific approach that does not include risk assessment. Obviously the advantages that flow from using risk assessment to set food safety control measures cannot be realized in such scenarios; nevertheless, choices to apply other scientific approaches are likely to be reasonable and appropriate in their own right.

This chapter takes the broad view that several approaches to risk assessment can be used to establish an association of sufficient strength between food-borne hazards, control measures and risks to consumers, such that controls can be genuinely described as 'risk-based'. Often, a combination of approaches may contribute to the risk assessment as a whole. This perspective shifts the focus from prescription of risk assessment methodology (as in Codex) to the outcome, and encourages food regulators to use methods best suited to the task. Where resources are limited, this handbook also may provide regulators with simpler methods that still lead to standards that can reasonably be described as risk-based, *i.e.* based on a scientific assessment of risk. Recognition that a range of approaches can lead to a risk-based standard also brings flexibility to the issue of the level of risk assessment rigor needed in low-risk situations.

In promulgating a flexible approach to use of risk assessment methodology, this handbook advocates that the RMF process should always include a risk profile of some sort. In applying the RMF, risk managers may *directly* use the information in the risk profile to identify and select food standards. Box here below and Box on page 5 present examples illustrating the direct use of a risk profile as a basis for risk management decisions in cases where it was either unnecessary or not feasible to carry out a risk assessment. While basing risk management decisions on a risk profile may be fully justifiable in particular circumstances, the resulting standards are not ordinarily considered to be risk-based.

(Source: Eufic)

Examples of direct use of a risk profile to establish food safety standards

In the 1990s, microbial resistance to a range of antibiotics used in both animal health and human medicine was found to be widespread. Risk profiles indicated the proportion of resistant pathogens in surveys of food animal and human populations, and identified the unique value of certain individual antibiotics in treating human infections as well as the availability of substitute antibiotics. As a result, some countries took steps to deregister certain antibiotics for animal health uses, even though as yet no measurable change in the incidence of human disease has convincingly been linked to those uses.

The recent discovery in Sweden that acrylamide, a substance known to cause cancer in laboratory animals, is formed through normal heat-treatment of baked and fried starchy foods, led to widespread recognition of significant exposure of consumers via a range of food types. Scientific studies showed that reducing cooking temperatures and/or times can lower consumer exposure levels. Modification of commercial food processes was instituted on this basis, even though the actual risk and the impact of process changes on risk reduction are still not fully known.

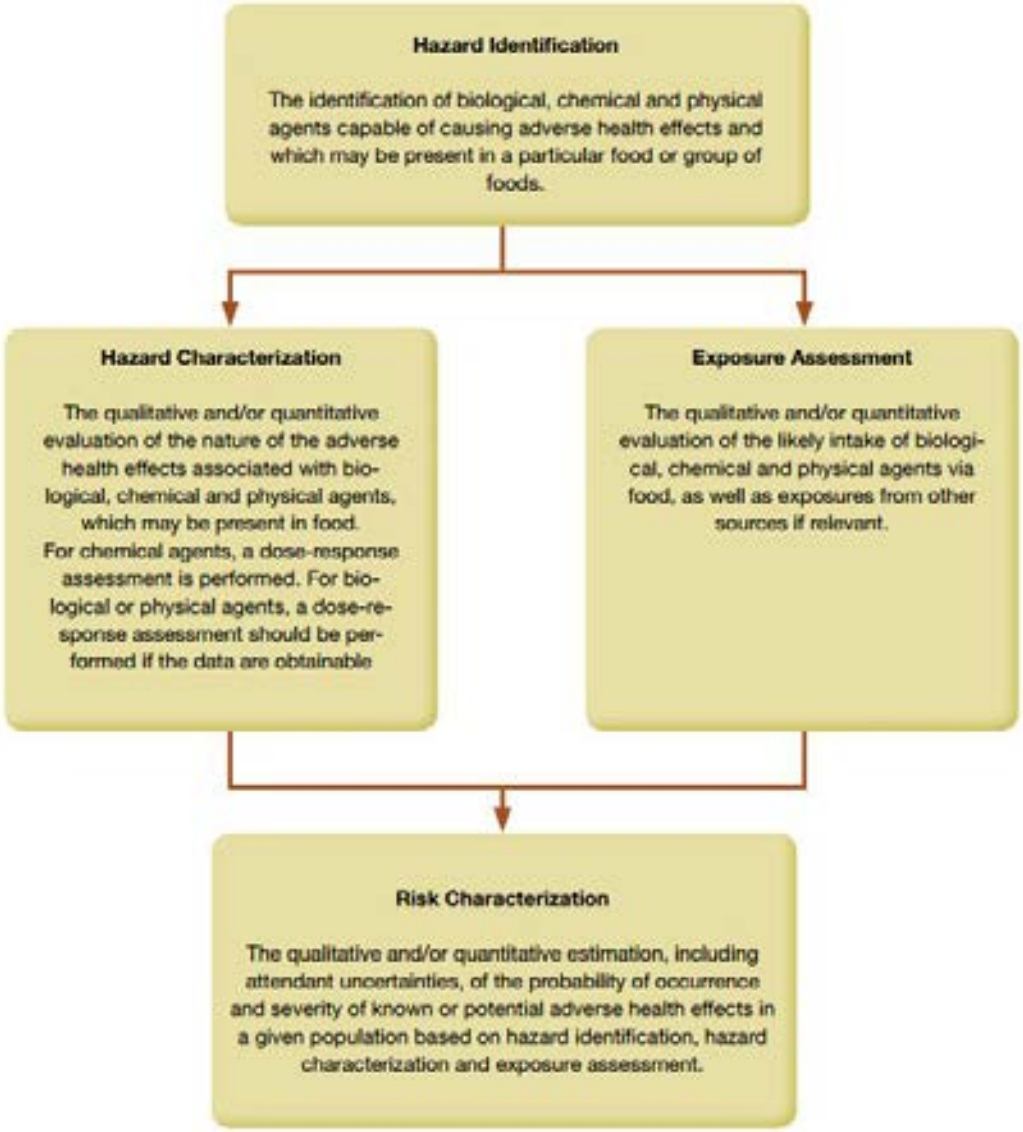
3.2.1. Risk assessment

Risk assessment incorporating, in one way or another, the four analytical steps described by *Codex* is the main focus here. The way those steps are applied differs somewhat for microbiological and chemical hazards.

(Source: FAO)

For microbiological hazards, the occurrence and transmission of the hazard at various stages from food production to consumption is evaluated, thus moving “forward” through the various stages of the food chain to arrive at an estimate of risk. While the accuracy of estimated risks is often limited by uncertain dose-response information, the greatest strength of such risk assessments arguably lies in their ability to model the relative impacts of different food control measures on risk estimates.

Generic* Codex *description of the components of risk assessment



The Canadian approach to regulating Listeria monocytogenes in ready-to-eat foods

When the Canadian government did a risk profile of this problem they recognized that contamination by *L. monocytogenes* could be reduced, but not eliminated from the final product or the environment. Risk management policy focuses inspection, testing and compliance action on ready-to-eat foods that are capable of supporting growth of *L. monocytogenes*. Specific attention is paid to those foods that have been linked to food-borne illness, and those with more than a ten day shelf life. In this approach, ready-to-eat foods are placed in one of three categories:

– Category 1: foods have been causally linked to human illness and are most intensively regulated. The presence of any Listeria in Category 1 foods results in a Class I recall that may include a public alert.

– Category 2: foods are capable of supporting Listeria growth and have a shelf life of more than 10 days; presence of Listeria in Category 2 foods requires a Class II recall with possible consideration of a public alert. Category 2 foods also have second highest priority in inspection and compliance activity.

– Category 3: contains two types of ready-to-eat products: those supporting growth with less than a ten day shelf life, and those not supporting growth. These products receive the lowest priority in terms of inspection and compliance, and the action level for presence of the hazard in food is 100 organisms per gram.

Note: The Canadian Food Inspection Agency assigns numerical designations to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. Class I is "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death". Class II is "a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote". See www.hc-sc.gc.ca/fn-an/securit/eval/reports-rapports/fers-siua_08_e.html for further information.

In contrast, for chemical hazards, 'safety evaluation' is a standard risk assessment methodology.[3] In that approach, maximum exposure levels are identified to fit a 'notional zero risk' outcome (a dose level that is reasonably certain to pose no appreciable risk to the consumer). This approach does not produce precise estimates of risk versus dose and cannot model the impact of various interventions in terms of risk reduction. These differences are explored further.

Examples of risk ranking tools

The *Business Food Safety Classification Tool* developed by the Australian Government Department of Health and Aging is a software programme that incorporates a decision tree to assess the potential public health risk from different types of food businesses and food producers. This tool identifies those food industry sectors/businesses that are candidates for priority regulatory control and verification.

The Risk Categorizing Model for Food Retail/Food Service Establishments developed by the Canadian Federal Provincial Territorial Food Safety Policy Committee categorizes food establishments so that the competent authority can give greater attention to those where a failure of regulatory controls would cause the greatest potential risks to consumers.

The Food Safety Research Consortium in the United States is developing a model to produce rankings by pathogens, by food, and by pathogen/food combination, using

[3] The term 'safety evaluation' is often used in regard to chemical hazards because the chief output is a definition of a presumptive 'safe' exposure level, without detailed assessment of how risk varies with exposure to differing doses.

five criteria for ranking impact on public health: number of cases of illness, number of hospitalizations, number of deaths, monetary valuations of health outcomes, and loss of Quality Adjusted Life Years.

The National Institute for Public Health and the Environment in the Netherlands applied a quantitative methodology (developed by WHO) to calculate disease burden using Disability Adjusted Life Years and cost-of-illness in monetary terms in order to assist risk managers in prioritizing regulatory activities according to pathogen.

Risk Ranger, a software programme developed at the University of Hobart, Australia, extends the above risk ranking tools to allow risk ranking of hazard-food combinations in national settings. Categories used in the tool include rankings for hazard severity and susceptibility of the consumer, probability of exposure to the food and probability of the food containing an infectious dose. Comparative risk in the population of interest is expressed as a relative ranking between zero and 100.

3.2.2. Use of ranking tools

Risk ranking, using tools that rely on knowledge of risk factors to rank risks and prioritize regulatory controls, is often commissioned by risk managers. Such rankings may or may not be based on risk assessments. Some tools categorize a food business against specified risk factors, e.g. by type of food, type of food preparation, type of business, compliance record, food user subpopulation. Other tools are used to rank hazard-food combinations in a national context by deriving a “comparative risk” scoring system. While risk ranking methods not based on risk assessments assist risk-based food regulation, their use of scoring systems (which inevitably have subjective, arbitrary elements) to derive regulatory standards has inherent shortcomings. Thus they are not a good substitute for ranking methodologies that do incorporate risk assessment.

3.2.3. Epidemiology

Epidemiology is increasingly being used in food safety to study the links between the frequency and distribution of adverse health effects in specific populations and specific foodborne hazards. This includes observational studies of human illness such as case-control, analysis of surveillance data, and focused research. The usefulness of epidemiology depends on the availability of data.

(*Source: Epidemio56)*

Epidemiology is probably the most reliable approach to assess the current burden of illness, follow trends over time and attribute risks to sources. It is an important source of information for risk assessment, particularly the hazard identification and hazard characterization steps. As a stand-alone tool, epidemiology uses human illness data and works “backwards” to attribute risks and risk factors to foods; therefore it cannot generally be used to investigate the effects of different food safety control measures in reducing risk. However, risk assessment incorporating epidemiological data can be used to evaluate the impact of various changes or interventions in the food chain in terms of reducing risks. In other words, the risk assessment approach works forward from the

relevant points in the food chain to estimate the risk to human health normally associated with a particular hazard-food combination.

Food source attribution is particularly valuable in food safety risk management. Risk assessments often address only a single hazard or, in the microbiological field, a single hazard-food combination, whereas at some stage risk managers need to have good scientific information on all transmission pathways and their relative contributions to the aggregate risk from the hazard. Risk assessments can be designed to answer this question, but other food source attribution approaches are more commonly used, such as analysis of outbreak data, or genotyping of human microbial isolates from multiple outbreak situations where it is known that some genotypes occur predominantly in a single animal reservoir or food type. However, food source attribution often proves difficult as sporadic cases of illness are rarely represented in the available surveillance data and these may collectively cause many more cases than the outbreaks that are primarily recorded.

The use of analytical epidemiology to support development of risk-based standards depends on the availability of sufficient surveillance data on food-borne illness. Many governments are currently strengthening surveillance systems so they can better apply analytical epidemiological techniques, as well as validate microbiological risk assessment models. A detailed description of the application of epidemiological techniques is beyond the scope of this chapter.

Examples of food source attribution supporting the development of risk-based standards for microbiological hazards in foods

- Many shellfish toxins have been identified and regulatory interventions initiated only after epidemiological studies linked shellfish with outbreaks of human illness; e.g. domoic acid in shellfish in Canada, azaspiracids in shellfish in Ireland.
- Case-control studies carried out by the United States Centers for Disease Control and Prevention (CDC) have implicated ground beef as an important risk factor in E. coli O157:H7 infection in humans, and outbreak reports continue to be associated with this pathogen. Control efforts have focused on both slaughterhouse/processing plant hygiene and educating consumers as to proper preventive food handling and cooking methods.
- New Zealand does not have the recognized antibiotic multi-resistant Salmonella serotypes in food animals that can cause severe disease in humans. However, there are similar levels of antibiotic susceptible serotypes to those in other countries. Faced with applications for importation of foods from countries with multi-resistant serotypes, a source attribution model was used to apportion any potential increase in risks from imported foods against risks introduced via other transmission pathways (e.g. domestically-produced food, travelers, imported live animals, migratory birds, pet food). This model allows decisions to be made on import health standards that are proportional to risks and non-discriminatory to trade.
- Denmark has an integrated system in which data from public health surveillance and pathogen monitoring of foods of animal origin and animals at primary production and processing are routinely collected, collated and analyzed by a single coordinating body. Cultures collected from infected persons, animals and retail food sources are subtyped, allowing the direct comparison of surveillance and monitoring data and the identification of public health outcomes by food

source. The basic premise for this model is the predominance of at least one "distinctive" Salmonella subtype in each main animal reservoir; human infections of distinctive subtypes are assumed to have originated from that reservoir. The model has proven valuable for identifying pathogen reservoirs in animal populations, tracking trends of human salmonellosis and guiding interventions.

3.2.4. Combinations of approaches

Distinctions are drawn here between risk assessment approaches based on the four analytical steps described by *Codex*, the use of ranking tools and the use of analytical epidemiological techniques. However, as a practical matter these various approaches are often used in combination or feed into each other (e.g. epidemiological data feed into hazard identification and hazard characterization steps of any risk assessment). Ways in which they can be integrated vary widely on a case-by-case basis, but all are subject to the general principles and guidelines described in the sections that follow.

(Source: La curieuse histoire du monde)

The remainder is focused on risk assessment conducted according to the *Codex* methodology.

3.3. Responsibilities of risk managers in commissioning and administering a risk assessment

The decision to proceed with a risk assessment depends on factors such as the health risk priority ranking, urgency, regulatory needs and availability of resources and data.

It is likely that a risk assessment will not be commissioned when:

- the risk is well described by definitive data;
- the food safety issue is relatively simple;
- the food safety issue is not of regulatory concern or not subject to regulatory mandate;
- an urgent regulatory response is required.

It is likely that a risk assessment will be commissioned when:

- the hazard exposure pathway is complex;
- data on the hazard(s) and/or health impacts are incomplete;
- the issue is of significant regulatory and/or stakeholder concern;
- there is a mandatory regulatory requirement for a risk assessment;
- there is a need to verify that an interim (or precautionary) regulatory response to an urgent food safety problem is scientifically justified.

Risk managers, in consultation with risk assessors, should fulfill several tasks when commissioning a risk assessment and seeing it through to completion. While risk managers do not need to know all the details of how a risk assessment is carried out, they do need a general understanding of risk assessment methodologies and what the outcomes mean. This understanding is both acquired through, and contributes to, successful risk communication.

3.3.1. Forming the risk assessment team

A risk assessment team should be appropriate to the circumstances. When strategic and large scale risk assessments are undertaken, the general criteria described below relating to risk assessment teams apply. However, small-scale and straightforward risk assessments may be undertaken by very small teams or even by individuals, especially where a primary risk assessment is already available and the scientific work involves mostly adaptation using local data.

General responsibilities of risk managers in commissioning and administering a risk assessment

- Risk managers should request the relevant scientific bodies to assemble the risk assessment team or, where this is not possible, establish the risk assessment team.
- Risk managers, in consultation with risk assessors, should establish and document the:
  - purpose and scope of the risk assessment;
  - questions that need to be addressed by the risk assessment;
  - risk assessment policy;
  - form of the outputs of the risk assessment.
- Risk managers should ensure that sufficient time and resources are available to complete the risk assessment according to specifications.

A large-scale risk assessment generally requires a multidisciplinary team that may include experts with biological, chemical, food technology, epidemiological, medical, statistical and modelling skills, among others.

Finding scientists with the required knowledge and expertise can be a challenging task for risk managers.

Source: Festival des sciences

Where government food safety agencies do not have a large scientific staff of their own upon which to draw, risk assessors are generally recruited from the national scientific community.

In some countries, national science academies may organize expert committees to carry out risk assessments for the government, and private companies that conduct risk assessments on a contract basis are also becoming more widespread.

Risk managers need to take care to ensure that the assembled team is objective, balanced in terms of scientific perspectives, and free from undue biases and conflicts of interest. It is also crucial to elicit information about potential financial or personal conflicts of interest that could bias an individual's scientific judgement. Typically, this information is solicited by a questionnaire before appointments are made to a risk assessment team. Exceptions are sometimes made if an individual has essential, unique expertise; transparency is essential when any such decisions on inclusion are made. The FAO/WHO framework for the provision of scientific advice on food safety and nutrition may provide guidance in this area. [4]

[4] FAO/WHO, Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries). Final draft for public comments, 2006.

Examples of questions to be addressed by risk assessors

In the example of *Campylobacter* in broiler chickens, risk assessors could be asked to address any of the following questions:

- Quantify relative impacts of specified food safety controls for *Campylobacter* in broiler chickens, either alone or in combination, on levels of consumer risk.
- Quantify influence of different levels of hazard control at specified steps in the food production chain (including prevalence at the farm level) on risk estimates (e.g. what is the impact on risk to consumers if flock prevalence is reduced by 50%?).
- Estimate the likely proportions of human campylobacteriosis transmitted by broiler chickens compared to other food transmission pathways.

In the case of aflatoxin contamination of a particular crop, risk assessors could be asked to address any of the following questions:

- Quantify the comparative lifetime cancer risk from consumption of the crop where the mean concentration of aflatoxin was reduced from 10 ppb to 1 ppb.
- Quantify the comparative lifetime cancer risk from consumption of the crop in the same scenario but for an exposed population with a significant level of liver damage from hepatitis A.
- Assess the proportionate lifetime cancer risk from current aflatoxin levels in the crop compared with other significant sources of aflatoxin in the diet (e.g. other types of crops and nuts).

3.3.2. Specification of purpose and scope

Risk managers should prepare a “purpose statement” for a risk assessment, which should identify the specific risk or risks to be estimated and the broad risk management goal(s). For example, a risk assessment might be designed to provide quantitative estimates of food-borne risks due to *Campylobacter* in broiler chickens on an annual basis for the national population, and the risk assessment might be primarily used to evaluate risk management options at various points from production to consumption of broiler chickens, to maximize reduction in risk. The purpose statement generally flows directly from the risk management goal(s) agreed on when the risk assessment is commissioned.

In some situations, an initial exercise may be to set up a risk assessment framework model, to identify data gaps and establish the research programme required to generate the scientific inputs needed to complete a risk assessment at a later date. Where a risk assessment can be completed using currently available scientific knowledge, the model can still identify further research that will allow later refinement of the outputs.

The ‘scope’ portion of the risk assessment description should identify the parts of the food production chain that are to be evaluated and should establish boundaries for risk assessors with regard to the nature and extent of scientific information to be considered. Risk managers addressing specific food safety issues at the national level should also be aware of international risk assessments and other pre-existing scientific efforts on relevant subjects before they commission new work. By considering existing risk assessments in consultation with their risk assessors, risk managers may be able to substantially narrow the scope of the work and the data needed.

3.3.3. Questions to be addressed by risk assessors

Risk managers, in consultation with risk assessors, should formulate the specific questions that need to be answered by the risk assessment. Depending on the scope of the risk assessment needed and the resources available, considerable discussion may be required to arrive at clear and realizable questions which will yield answers to guide risk management decisions.

As with the statement on purpose and scope, questions to be addressed by the risk assessment often flow from the broad risk management goal(s) agreed on when the risk assessment is commissioned.

The questions asked by the risk managers can have an important influence on the choice of risk assessment methodologies used to answer them.

3.3.4. Establishing risk assessment policy

While risk assessment is fundamentally an objective, scientific activity, it inevitably contains some elements of policy and subjective scientific judgement. For example, when scientific uncertainty is encountered in the risk assessment, inferential bridges are needed to allow the process to continue.

The judgements made by the scientists or risk assessors often entail a **choice among several scientifically plausible options**, and policy considerations inevitably affect, and perhaps determine, some of the choices.

Thus gaps in scientific knowledge are bridged through a set of inferences and ‘default assumptions’. At other points in a risk assessment, assumptions may be required that are driven by values-based, social consensus, often developed through long experience with how such issues should be handled.

Documentation of all such default assumptions contributes to the consistency and transparency of risk assessments. These policy decisions are spelled out in a risk assessment policy, which should be developed by risk managers and risk assessors in active collaboration in advance of the risk assessment. Policies governing values-based choices and judgements should be decided primarily by risk managers, whereas policies governing science-based choices and judgements should be decided primarily by risk assessors, with active communication between the two functional groups in each case.

Pre-determining risk assessment policy for scientific aspects of a risk assessment is especially difficult when it concerns sufficiency of scientific evidence. Often, only limited data sets are available at a particular step and scientific judgements are required if risk assessment is to proceed. While risk assessment policy in a broad sense may be able to guide these judgements, they are more likely to be made on a ‘case-by-case’ basis. Different national legal contexts also influence the way sufficiency of evidence and scientific uncertainty are addressed.

3.3.5. Specification of form of the outputs

Source: EJPS

Outputs of a risk assessment may be sought in non-numerical (qualitative) or numerical (quantitative) form. Non-numerical risk estimates provide a less definitive basis for decisions but are adequate for several purposes, such as establishing relative risks or evaluating relative impacts on risk reduction of different control measures. Numeric estimates of risk can take one of two formats:

- point estimate which is a single numerical value representing for example the risk in a worst-case scenario;
- probabilistic risk estimates, which include variability and uncertainty and are presented as a distribution reflecting more real-life situations.

Examples of choices that might be part of a risk assessment policy

➢ ***Policies governing values-based choices:***

- where a chemical hazard may be deliberately introduced into the food supply (e.g. as a food additive or technological aid) use should be limited to levels where there is 'notionally zero risk' to consumers, *i.e.* the amount permitted should be without any appreciable human health risk;
- hazard characterization in microbiological risk assessment should include description of the type and severity of adverse health effects and categorize these in risk estimates;
- when calculating an acceptable daily intake for a chemical hazard, it is appropriate to start with the dose at which no adverse effect is observed in appropriate animal tests for the most sensitive relevant end-point (toxic effect), and to apply a 100-fold safety factor: a ten-fold factor to account for possible differences between humans and test animals in sensitivity to toxic effects, and a second ten-fold factor to account for variability in susceptibility of individuals or subgroups of the population to the toxic effect.

➢ ***Policies governing science-based choices:***

- when animal test data are available from relatively high-dose exposures to carcinogenic chemicals but these are considered insufficient to define the shape of the dose-response curve in the low-dose region and extrapolation is needed, a linear model may be deemed appropriate for public health protection purposes;
- microbiological risk assessments should be constructed in modular form so that food chain parameters can be changed, or new modules added, to estimate the impact on risk;
- toxicological reference values for carcinogenic chemicals should be based on a combination of epidemiological and animal data where available.

To date, point estimates have been more common outputs of chemical risk assessments while probabilistic outputs are the usual product of microbiological risk assessments.

3.3.6. Time and resources

While it is desirable to maximize scientific inputs and commission specific research to fill data gaps when conducting a risk assessment, all risk assessments are inevitably constrained in some ways. In commissioning a risk assessment, risk managers must ensure that sufficient resources (e.g. time, money, personnel and expertise) are available relative to the purpose and scope, and establish a realistic timetable for completion of the work.

(Source: Sergey Ilin Fotdia.com)

3.4. General characteristics of risk assessment

Irrespective of the context, risk assessments generally share a number of basic characteristics. While these attributes are described comprehensively in the sections that follow, in some situations a specific risk assessment is a relatively simple and straightforward exercise. In such cases, the general characteristics can be substantially modified; for instance, it may sometimes be possible for experts within a government food safety agency to conduct an adequate risk assessment quickly and efficiently, without the need to assemble a multidisciplinary risk assessment team.

3.4.1. Objectivity and transparency

A risk assessment should be objective and unbiased. Opinions or value judgements on issues other than science (for instance on economic, political, legal or environmental aspects of the risk) should not be allowed to influence the outcome and risk assessors should explicitly identify and discuss any judgements on the sufficiency of the science that was relied on.

(Source: Wikimemoires)

A participatory process should be used in initiating, performing and finalizing a risk assessment and reporting should be in a style that allows risk managers and other stakeholders to properly understand the process. Above all, a risk assessment must be transparent and in documenting the process the risk managers should:

- describe the scientific rationale;
- reveal any biases that may affect the conduct or results of the risk assessment;
- identify clearly and concisely all scientific inputs;
- clearly state all assumptions;
- provide an interpretive summary for lay readers;
- where possible, make assessments available to the public for comment.

3.4.2. Functional separation of risk assessment and risk management

In general, the functions of risk assessment and risk management should be carried out separately to the extent practicable, so that the science remains independent from regulatory policy and values. However, delineating the functional boundaries between risk assessors, risk managers and risk communicators in all situations is a significant challenge. Functional separation may be more obvious when different bodies or officials are responsible for risk assessment and risk management tasks. However, functional separation can also be achieved in countries with limited resources and personnel where risk assessments are undertaken by people who act as both risk assessors and risk managers. What is important in these cases is to have conditions in place which ensure

that risk assessment tasks are carried out separately from risk management tasks. In such cases, particular attention should be devoted to ensuring that the risk assessment meets the criteria. Whatever the functional separation arrangements, a highly interactive, iterative process is essential for risk analysis as a whole to be effective. Communication between risk assessors and risk managers is also a critical element in the process.

3.4.3. Structured process

Risk assessments should follow a structured and systematic process; see section 5 on risk assessment methodology.

3.4.4. Basis in science

It is a primary tenet that risk assessment be soundly based on scientific data. Data of sufficient quality, detail and representativeness must be located from appropriate sources and assembled in a systematic manner. Descriptive and computational elements should be supported with scientific references and accepted scientific methodologies, as appropriate.

(Source: Claytowne)

When a risk assessment is commissioned, there often are insufficient data available to complete the assignment. Scientific information to support many food safety risk assessments is available from a variety of sources, both national and international. Risk assessments carried out at the national level are rapidly increasing in number and many of them can be accessed through web-based portals. For instance, microbiological risk assessments carried out by the United States Food Safety and Inspection Service are available at www.fsis.usda.gov/Science/Risk_Assessments/index.asp.

Sources of scientific information for risk assessments

- Published scientific studies.
- Specific research studies carried out (by the government agency or external contractors) in order to fill data gaps.
- Unpublished studies and surveys carried out by industry, such as data on the identity and purity of a chemical under consideration as well as toxicity and residue studies carried out by the chemical's manufacturer*.
- National food monitoring data.
- National human health surveillance and laboratory diagnostic data.
- Disease outbreak investigations.
- National food consumption surveys, and regional diets e.g. those constructed by FAO/WHO.
- Use of panels to elicit expert opinion where specific data sets are not available.
- Risk assessments carried out by other governments.
- International risk assessments carried out by JECFA, JMPR and JEMRA.

- International food safety databases.

** Manufacturers often may agree to supply data only if it remains confidential. Risk managers must judge the need to trade off transparency so as to obtain relevant and sufficient data.*

FAO and WHO manage international expert groups on chemical hazards (JECFA and JMPR) and microbiological hazards (JEMRA) to provide risk assessments as a basis for *Codex* standards. These assessments are also used by national risk assessors and managers.

While risk assessors conducting a given risk assessment may try to fill data gaps and to obtain adequate input data, inevitably default assumptions will need to be made at some steps during risk assessment. These assumptions must remain as objective, biologically realistic and consistent as possible. Risk assessment policy provides broad guidelines but default assumptions specific to a particular problem may have to be made on a case-by-case basis. It is essential that any such assumptions are transparently documented.

Sometimes when data are lacking, expert opinions can be used to address important questions and uncertainties. A variety of knowledge elicitation techniques have been developed for this purpose. Experts may be unaccustomed to describing what they know or how they know it; knowledge elicitation techniques reveal expert knowledge and help to make expert opinions as evidence-based as possible. Approaches that can be used include interviews, the Delphi methods[5], surveys and questionnaires, among others.

Examples of uncertainty and variability in risk assessments

- Methylmercury in fish. The two best-designed large epidemiological studies have yielded results interpreted by some scientists as inconsistent. In the United States, risk assessor relied on only the study yielding stronger evidence to assess the risk, and risk managers adopted a TDI with a 10-fold default uncertainty margin. At the international level, JECFA integrated exposure data from both studies and applied a 6.4-fold data-derived uncertainty factor in recommending a somewhat higher PTWI. The uncertainty factors applied in each case were in response to the known variability of individuals in susceptibility to harm from methylmercury.

- *Listeria* in ready-to-eat foods. A preliminary risk assessment in the United States revealed substantial uncertainties regarding the relative risks posed by Listeria monocytogenes in different foods. Risk managers chose to collect more data and carry out a much more detailed risk assessment, which suggested substantially clearer regulatory priorities. Variability in hazard levels, food consumption and human susceptibility to harm were included and accounted for in the detailed assessment.

[5] The Delphi method is a technique for eliciting and refining group judgements. The objective is generally the reliable and creative exploration of ideas or the production of suitable information for decision-making.

3.4.5. Dealing with uncertainty and variability

Definitive data needed to derive quantitative risk estimates are often lacking, and sometimes there are significant uncertainties inherent in biological or other models used to represent the processes that contribute to risk. Uncertainty about the available scientific information is often addressed in a risk assessment by using a range of possible data values.

Two distinct characteristics of scientific information are relevant in this context. *Variability* is a characteristic of phenomena that differ from one observation to the next; for example, people eat different amounts of a food, and the level of a particular hazard present in a food also can vary widely from one serving of food to another. *Uncertainty* is the quality of being unknown, for example because inadequate data exist, or because the biological phenomena involved are not well understood. For instance, in assessing a chemical hazard scientists may need to rely on data from toxicity tests in rodents because insufficient human epidemiological data exist.

Risk assessors must ensure that risk managers understand the impacts of limitations of available data on the results of the risk assessment. Risk assessors should provide an explicit description of uncertainties in the risk estimate and their origins. The risk assessment should also describe how default assumptions may have influenced the degree of uncertainty in the outputs. As necessary or appropriate, the degree of uncertainty in the results of a risk assessment should be described separately from the effects of variability inherent in any biological system.

(Source: FSDL)

Deterministic chemical risk assessments for chronic adverse health effects use point estimates to represent data and typically do not explicitly quantify uncertainty or variability in outcomes.

3.4.6. Peer review

Peer review reinforces transparency and allows wider scientific opinion to be canvassed in relation to a specific food safety issue. External review is especially important where new scientific approaches are being applied. Open comparison of the outcomes of similar risk assessments where different scientific defaults and other judgements have been used can yield useful insights.

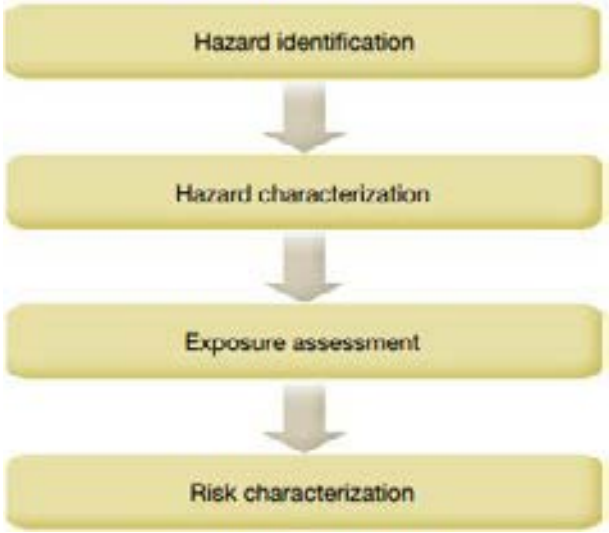
3.5. Risk assessment methodology

Different risk assessment methods are used in different countries and within countries, and different methods may be used to assess different kinds of food safety problems. Methods vary according to the class of hazard (*i.e.* chemical, biological or physical hazard), the food safety scenario (e.g. concerning known hazards, emerging hazards, new technologies such as biotechnology, complex hazard pathways such as for antimicrobial resistance) and the time and resources available. This section provides only a brief overview of methods.

Differences in risk assessment methodology are most apparent for chemical compared with microbiological hazards. This is partly due to intrinsic differences between the two classes of hazards. The differences also reflect the fact that for many chemical hazards, a choice can be made as to how much of the chemical may enter the food supply, e.g. for food additives, residues of veterinary drugs and pesticides used on crops. Use of these chemicals can be regulated or restricted so that residues at the point of consumption do not result in risks to human health. Microbial hazards, in contrast, are ubiquitous in the food chain, they grow and die, and despite control efforts, they often can exist at the point of consumption at levels that do present obvious risks to human health.

3.5.1. Basic components of a risk assessment

The risk assessment process is generally represented as consisting of four steps, described by Codex. Following identification of the hazard(s), the order in which these tasks can be carried out is not fixed; the process is normally highly iterative, with steps repeated as data and assumptions are refined.



❑ Hazard identification

Specific identification of the hazard(s) of concern is a key step in risk assessment and begins a process of estimation of risks specifically due to that hazard(s). Hazard identification may have already been carried out to a sufficient level during risk profiling; this generally is the case for risks due to chemical hazards. For microbial hazards, the risk profile may have identified specific risk factors associated with different strains of pathogens, and subsequent risk assessment may focus on particular subtypes. Risk managers are the primary arbiters of such decisions.

❑ Hazard characterization

During hazard characterization, risk assessors describe the nature and extent of the adverse health effects known to be associated with the specific hazard. If possible, a dose-response relationship is established between different levels of exposure to the hazard in food at the point of consumption and the likelihood of different adverse health effects. Types of data that can be used to establish dose-response relationships include animal toxicity studies, clinical human exposure studies and epidemiological data from investigations of illness.

Some characteristics of microbial and chemical hazards that influence the choice of risk assessment methodology

Microbial hazard	Chemical hazard
Hazards can enter foods at many points from production to consumption.	Hazards usually enter foods in the raw food or ingredients, or through certain processing steps (e.g. acrylamide or packaging migrants).
The prevalence and concentration of hazard changes markedly at different points along the food production chain.	The level of hazard present in a food after the point of introduction often does not significantly change.
Health risks are usually acute and result from a single edible portion of food.	Health risks may be acute but are generally chronic.
Individuals show a wide variability in health response to different levels of hazard.	Types of toxic effects are generally similar from person to person, but individual sensitivity may differ.

Response parameters may be categorized according to the risk management questions that are asked of risk assessors; for example, for chemical hazards, type of adverse health effects induced by different doses of chemical hazards in animal tests; for microbial hazards, infection, morbidity, hospitalization and death rates associated with different doses. Where economic analyses are undertaken, hazard characterization should include the large impact of food-borne illness that is due to complications following the acute phase, e.g. with hemolytic uremic syndrome with *E. coli* O157:H7, and with Guillain-Barre syndrome with *Campylobacter*.

❑ Exposure assessment

Exposure assessment characterizes the amount of hazard that is consumed by various members of the exposed population(s). The analysis makes use of the levels of hazard in raw materials, in food ingredients added to the primary food and in the general food environment to track changes in levels throughout the food production chain. These data

are combined with the food consumption patterns of the target consumer population to assess exposure to the hazard over a particular period of time in foods as actually consumed.

Characterization of exposure may vary according to whether the focus is on acute or chronic adverse health effects. Risks from chemical hazards are typically assessed against long-term or lifetime chronic exposure to the hazard, often from multiple sources. Acute exposures are also frequently considered for certain contaminants and pesticide and veterinary drug residues. Risks from microbial hazards are typically evaluated in terms of single exposures to a contaminated food.

The level of a hazard in a food at the time of consumption is often very different from that when the food is being produced. Where necessary, exposure assessment can scientifically evaluate changes in levels of hazard throughout the production process to estimate the likely level at the time of consumption. In the case of chemical hazards in foods, there may be relatively little change from levels in raw materials. In the case of microbiological hazards in foods, marked changes in levels can occur due to pathogen growth, and cross-contamination at the time of final preparation for consumption may add to the complexity of the evaluation.

❑ **Risk characterization**

During risk characterization, outputs from the previous three steps are integrated to generate an estimate of risk. Estimates can take a number of forms and uncertainty and variability must also be described if possible. A risk characterization often includes narrative on other aspects of the risk assessment, such as comparative rankings with risks from other foods, impacts on risk of various “what if” scenarios, and further scientific work needed to reduce gaps.

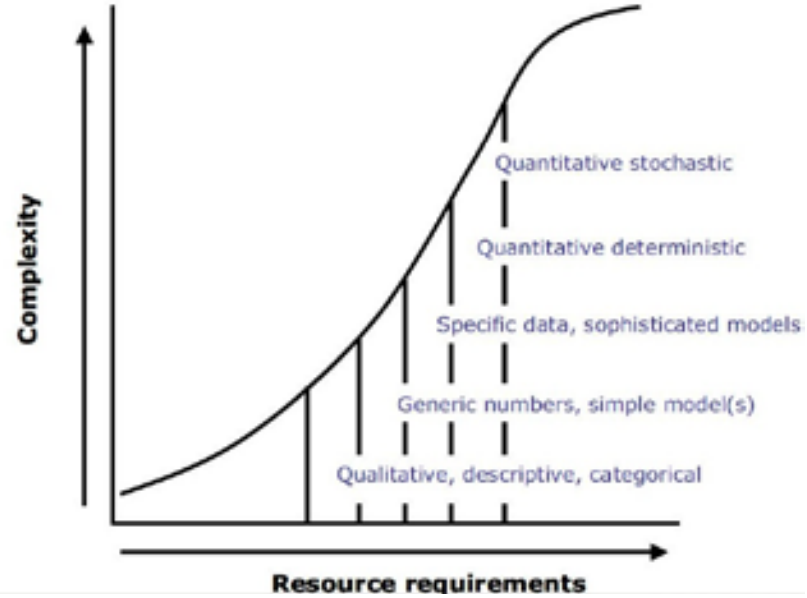
(Source: AtouSanté)

Risk characterization for chronic exposure to chemical hazards does not typically include estimates of the likelihood and severity of adverse health effects associated with different levels of exposure. A “notional zero risk” approach is generally taken and where possible the goal is to limit exposure to levels judged unlikely to have any adverse effects at all.

3.5.2. Qualitative or quantitative evaluation?

Risk assessment outputs can range from qualitative to quantitative with various intermediate formats. The characteristics of risk assessments presented above apply to all types. In qualitative risk assessments, outputs are expressed in descriptive terms such as high, medium or low. In quantitative risk assessments, the outputs are expressed numerically and may include a numerical description of uncertainty. In some cases, intermediate formats are referred to as semi-quantitative risk assessments. For instance, one semi-quantitative approach may be to assign scores at each step in the pathway and express outputs as risk rankings.

Continuum of risk assessment types



❑ Deterministic (point estimate) approaches

The term 'deterministic' describes an approach in which numerical point values are used at each step in the risk assessment; for example, the mean or the 95th percentile value of measured data (such as food intake or residue levels) may be used to generate a single risk estimate. Deterministic approaches are the norm in chemical risk assessment, for instance to determine whether any risk may arise from consumption of a single food containing a chemical residue arising from a use governed by an MRL.

❑ Stochastic (probabilistic) approaches

In stochastic approaches to risk assessment, scientific evidence is used to generate statements of probabilities of individual events, which are combined to determine the probability of an adverse health outcome. This requires mathematical modelling of the variability of the phenomena involved, and the final risk estimate is a probability distribution. Stochastic (probabilistic) models are then used to create and analyze different scenarios of risk. This approach is generally viewed as being most reflective of the real world, but stochastic models are often complex and difficult to generate.

Stochastic models are only now beginning to be used to complement the 'safety evaluation' approaches traditionally used in managing chemical food-borne hazards, in particular for contaminants. On the other hand, probabilistic approaches are the norm in the newer discipline of microbial risk assessment and provide a mathematical description of the dynamics of hazard transmission from production to consumption. Exposure data are combined with dose-response information to generate probabilistic estimates of risk. Even one colony-forming unit of the pathogen in an edible portion of food is assumed to have some probability of causing infection; in this respect, such risk models resemble risk assessment methodology for chemical carcinogens.

3.5.3. Risk assessment for chemical hazards

Chemical hazards in foods include food additives, environmental contaminants such as mercury and dioxins, natural toxicants in food, such as glycoalkaloids in potatoes and aflatoxins in peanuts, acrylamide, and residues of pesticides and veterinary drugs. The scientific rationale for risk assessment of chemical hazards is somewhat different from that for biological hazards. Adverse health effects are usually predicted for long-term exposure to chemicals, whereas biological hazards are generally assessed in terms of a single exposure and an acute health risk.[6] For certain chemicals, such as some mycotoxins, marine toxins, pesticides and veterinary drugs, both acute and chronic health effects need to be considered.

Considerable amounts of data of the types needed to establish standards have been provided by long-standing global data-gathering systems and other information sources specific to the class of chemical hazard under consideration, such as industry registration packages for pesticides and veterinary drugs or for food additives.

On the risk management side, many quantitative standards for chemical hazards in foods have been established by Codex and some national governments over several decades based on the mostly predictive risk assessment processes for chemicals. These generally employ a 'worst case' standard-setting scenario based on a 'notional zero risk' ALOP.

❑ Hazard identification

Hazard identification describes the adverse effects of the substance, the possibility of causing an adverse effect as an inherent property of the chemical, and the type (age group, gender, etc.) and extent of the population that may be at risk. Because sufficient human data from epidemiological studies are often not available, risk assessors frequently rely on results from toxicological studies in experimental animals and *in vitro* studies.

❑ Hazard characterization

Hazard characterization describes and evaluates dose-response relationships for the most sensitive adverse effects reported in the available studies. This includes consideration of mechanistic aspects (e.g. whether the mechanism of action of the chemical observed in often high-dose experimental studies is also relevant to human exposure at lower levels.

In cases where the toxic effect results from a mechanism that has a threshold, hazard characterization usually results in the establishment of a safe level of intake, an acceptable daily intake (ADI), or tolerable daily intake (TDI) for contaminants. For some substances used as food additives the ADI may not need to be specified, i.e. no numerical ADI is considered necessary.

(Source: Le jardin du Bonheur)

[6] Note that many natural toxins such as mycotoxins and marine toxins need insight into biology as well as chemistry for their risk assessment.

This may be the case when a substance is assessed to be of very low toxicity, based on the biological and toxicological data, and the total dietary intake of the substance, arising from the levels permitted in foods to achieve the desired function does not represent a hazard.

Estimation[7] of the ADI or TDI (PTWI) includes the application of default 'uncertainty factors' to a no-effect-level or low-effect level observed in experimental or epidemiological studies, to account for uncertainties inherent in extrapolating from an animal model to humans and to account for inter-individual variability (see Box 3.7). An ADI or TDI therefore represents a crude but conservative approximation of an actual chronic safe daily intake; both the estimate of risk and the inherent uncertainties remain unquantified. If sufficient data are available, the default uncertainty factors can be replaced by data-derived chemical-specific extrapolation factors. The term tolerable daily intake (TDI) or provisional tolerable weekly intake (PTWI), as opposed to an ADI, is used for contaminants and established by applying the same methods and principles.

The conservatism considered to be inherent in such a safety evaluation is generally thought to ensure sufficient protection of human health

Methods have also been developed for calculating reference doses for acute exposures to toxic chemicals when such potential adverse health effects are plausible, even if rare. For example, an acute reference dose (ARfD) may be calculated for a pesticide to take into account the possibility of occasional intake of residues that far exceed the MRL.

Toxicological reference values used by different authorities for (genotoxic) carcinogenic chemicals vary. Some are based on a combination of epidemiological and animal data, some may be based on animal data alone, and different mathematical models may be used to extrapolate risk estimates to low doses. These differences can lead to significant variability in cancer risk estimates for the same chemical.

❑ Exposure assessment

Exposure assessment describes the exposure pathway or pathways for a chemical hazard and estimates total intake. For some chemicals, intake may be associated with a single food, while for others the residue may be present in multiple foods, as well as in drinking water, and sometimes in household products, such that food accounts for only a portion of total exposure. For chemicals, exposure assessment often uses values at certain points on the continuum of exposure, such as the mean or the 97.5th percentile.

(Source : Le Figaro)

Such point estimates are referred to as deterministic models. Some exposure models are emerging, such as for intake of pesticide residues, that take into account the distribution of food consumption by a population.

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[7] These are toxicological reference values, or also called health-based guidance values.

These models, generally called probabilistic, provide more details on the distribution of exposed consumers, but are not inherently more accurate than deterministic models

The outcome of the exposure assessment is compared to the ADI or TDI in order to determine whether estimated exposures to the chemical in foods are within safe limits.

❑ **Risk characterization**

Risk characterization in chemical risk assessment primarily takes the form of defining a level of exposure presumed to pose a 'notional zero risk'. That is, the ALOP is set below a dose associated with any significant likelihood of harm to health. Standards are then typically based on 'worst case' exposure scenarios in order to keep risk below this ALOP.

Quantitative risk assessment methodologies have only rarely been applied for chemical hazards thought to pose no appreciable risk below certain very low levels of exposure (i.e. those with mechanisms of toxic action believed to exhibit a threshold), probably because the approach described above has generally been considered to provide an adequate margin of safety without a need to further characterize the risk. In contrast, quantitative risk assessment models have been applied by some governments as well as by international expert bodies (JECFA) for effects that are judged to have no threshold, i.e. for genotoxic carcinogens. These models employ biologically-appropriate mathematical extrapolations from observed animal cancer incidence data (usually derived from tests using high doses) to estimate the expected cancer incidence at the low levels typical of ordinary human exposure. If epidemiological cancer data are available, they also can be used in quantitative risk assessment models.

❑ **Application of toxicological guidance values**

For veterinary drug and pesticide residues, maximum residue levels (MRLs) are derived from controlled studies and are generally established so that the theoretical maximum daily intake of residues (calculated by any of several accepted methods) does not exceed the ADI.

For environmental contaminants and other chemicals that appear in food, regulatory standards often define "permissible levels" (or maximum levels (MLs) established by risk managers). In assessing the risks of these hazards it is recognized that as a practical matter it is often neither economically nor technically feasible to apply the same "notional zero risk" model to unavoidable contaminants as to other chemicals in the food supply. MLs are generally set so that the estimated intake does not exceed the TDI or PTWI. Risk managers may ask the risk assessors to compare the health protection impact of different proposed MLs. In such cases, the risk assessors focus on the exposure assessment to provide a more in-depth scientific basis for the risk management choices.

3.5.4. Risk assessment for biological hazards

Biological risk assessments typically use a quantitative model to describe the baseline food safety situation and estimate the level of consumer protection currently afforded.

(Source: Réseau lieu)

Then, some of the inputs into the model are changed, such as the level of the hazard in the raw food at the time of primary production, the conditions of processing, the temperature at which packaged material is held during retail and in the home. Changing inputs in a series of simulations enables the risk assessors to predict the impacts of the various control measures on the level of risk compared to that estimated in the baseline model.

❑ Hazard identification

A wide range of biological hazards can cause food-borne illness. Long-familiar hazards include microbes, viruses, parasites and toxins of biological origin, but new hazards are continually being identified, such as *E. coli O157:H7*, the prion agent of BSE, and multi-antibiotic resistant strains of *Salmonella*. In a given case, a risk profile may have identified specific strains or genotypes of pathogens that pose risks in a particular situation, and assessment may focus on these.

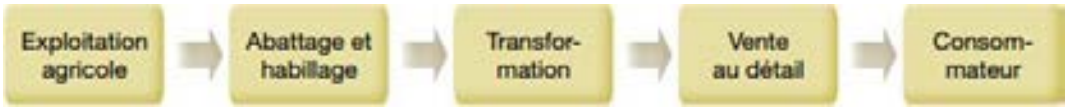
❑ Hazard characterization

A wide range of hazard factors (e.g. infectivity, virulence, antibiotic resistance) and host factors (e.g. physiological susceptibility, immune status, previous exposure history, concurrent illness) affect hazard characterization and its associated variability. Epidemiological information is essential for full hazard characterization.

While dose-response data are essential for quantitative biological risk assessment, such data are often difficult to obtain for specific hazards. Relatively little human data is available to model dose-response curves for specific populations of interest, and assumptions often have to be made in this area, e.g. by using surrogate dose-response data from a different pathogen. However, data from outbreak investigations can be a useful source in establishing the dose-response relationship.

Dose-response relationships can be developed for a range of human responses, e.g. infection, morbidity, hospitalization, and death rates associated with different doses.

Typical modular structure for estimating exposure to microbial hazards from meat product



❑ Exposure assessment

A food-chain exposure pathway model up to the point of consumption is developed for the hazard so that a human dose-response curve can be used to generate estimates of risk. Consideration of the whole food chain, while not always necessary, should be encouraged to the extent required to answer the risk managers' questions. The level of human exposure depends on many factors including: the extent of initial contamination of the raw food, characteristics of the food and the food processes in terms of the hazard organism's survival, multiplication or death, and storage and preparation conditions before eating.

Some transmission pathways, for instance those for Campylobacter in poultry, may involve cross-contamination at retail or in the home.

(Source: Plein champ)

❑ **Risk characterization**

Risk estimates can be qualitative, e.g. high, medium or low rankings for a pathogen, or presented in quantitative terms, e.g. cumulative frequency distributions of risk per serving(s), annual risks for targeted populations, or relative risks for different foods or different pathogens.

Considerable challenges lie ahead in carrying out national quantitative microbial risk assessments for hazard-food combinations that pose significant risks to human health. Codex has stated in its guidelines for microbiological risk assessment that "a microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread".[8] However, biological characteristics of the pathogen/host relationship are often uncertain and modeling the exposure pathway from production to consumption often suffers from substantial data gasps.

Bearing these challenges in mind, risk characterization for microbial hazards may be somewhat inaccurate, but the greater strength of microbial risk assessment lies in its ability to model different food control measures and their impact on estimates of relative risks. Modelling "what-if" scenarios, such as changing the assumed prevalence of infection in the live animal population from which the food is derived, is also an essential part of economic analysis.

3.5.5. Biotechnology risk assessment

(Source: Ecolorama)

Risk analysis principles and food safety assessment guidelines have recently been elaborated by Codex for foods derived from "modern biotechnology", i.e. those containing, derived from or produced using genetically modified organisms. Potential adverse health effects that require assessment include transfer of, or creation of new, toxins or allergens into foods with introduced genetic traits.

[8] FAO/WHO, Principles and Guidelines for the Conduct of Microbiological Risk Assessment. *Codex Alimentarius* Commission, CAC/GL 30-1999, available at www.fao.org/docrep/005/Y1579E/Y1579E00.HTM.

Safety assessment is carried out to identify whether a hazard, nutritional or other safety concern is present, in which case information on its nature and severity should be collected and analyzed. The safety assessment should include a comparison between the whole food derived from modern biotechnology (or component thereof) and its conventional counterpart, taking into account both intended and unintended effects.

If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health, using those testing and risk assessment methods appropriate to the nature of the identified concern. In this context, animal feeding studies may not be suitable as a test system to characterize risks arising from modern biotechnology, and a relatively broad range of other tests may need to be applied to fully assess the potential for risks to human health.

Pre-market safety assessments should be undertaken on a case-by-case basis using a structured and integrated approach.

3.5.6. Sensitivity analysis

Sensitivity analysis is a tool that can help risk managers select those controls that best achieve risk management goals. Sensitivity analysis, as a scientific process, shows the effects of changes in various inputs (data or assumptions) on the outcomes of a risk assessment. One of the most useful insights gained from a sensitivity analysis is estimating how much the uncertainty or variability associated with each input factor contributes to the overall uncertainty and variability in the risk estimate. Input distributions where uncertainty has the greatest impact on the outcome can be identified, and this process also can help set priorities for research to reduce uncertainty.

3.5.7. Validation

Model validation is the process of evaluating a simulation model used in a risk assessment for its accuracy in representing a food safety system, e.g. by comparing model predictions of food-borne disease with human surveillance data, or by comparing model predictions on hazard levels at intermediate steps in the food production chain with actual monitoring data.

While validation of the outputs of a risk assessment is desirable, this activity is not always practical. This is especially true for chemical risk assessments, where chronic adverse health effects in humans may be predicted from animal tests but can rarely be validated with human data.

3.5.8. Establishment of ‘targets’ in the food chain as regulatory standards

The development and evaluation of specific quantitative microbiological parameters, such as performance targets and performance criteria that can be incorporated into regulations, have been described previously.

Risk assessors are involved in developing risk-based microbiological targets by simulating their impacts in risk models. In most cases, the goal of such simulations is to develop practical risk-based metrics than can be directly incorporated (and monitored) in HACCP plans, such as process criteria, product criteria and microbiological criteria. However, considerable methodological challenges remain in this area.

The concept of regulatory targets is equally applicable to chemical hazards. Currently, standards for chemical hazards in foods are often generic, such as requiring use of a pesticide or veterinary drug according to good agricultural practice (GAP) and good veterinary practice (GVP). MRLs developed from this process are not directly related to health outcomes. An appropriate performance target developed from a quantitative risk assessment could be the level of chemical hazard that is permissible at a specified step in the food chain, weighted relative to the ADI.

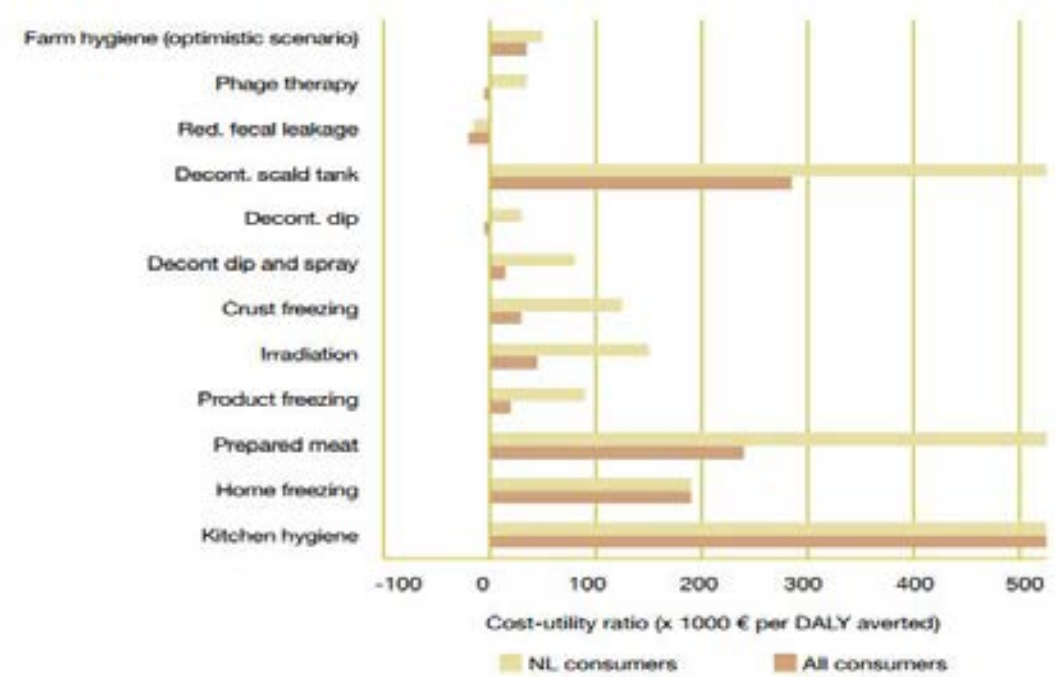
(Source : Maroc Agriculture)

3.6. Integrating risk assessment and economic assessment

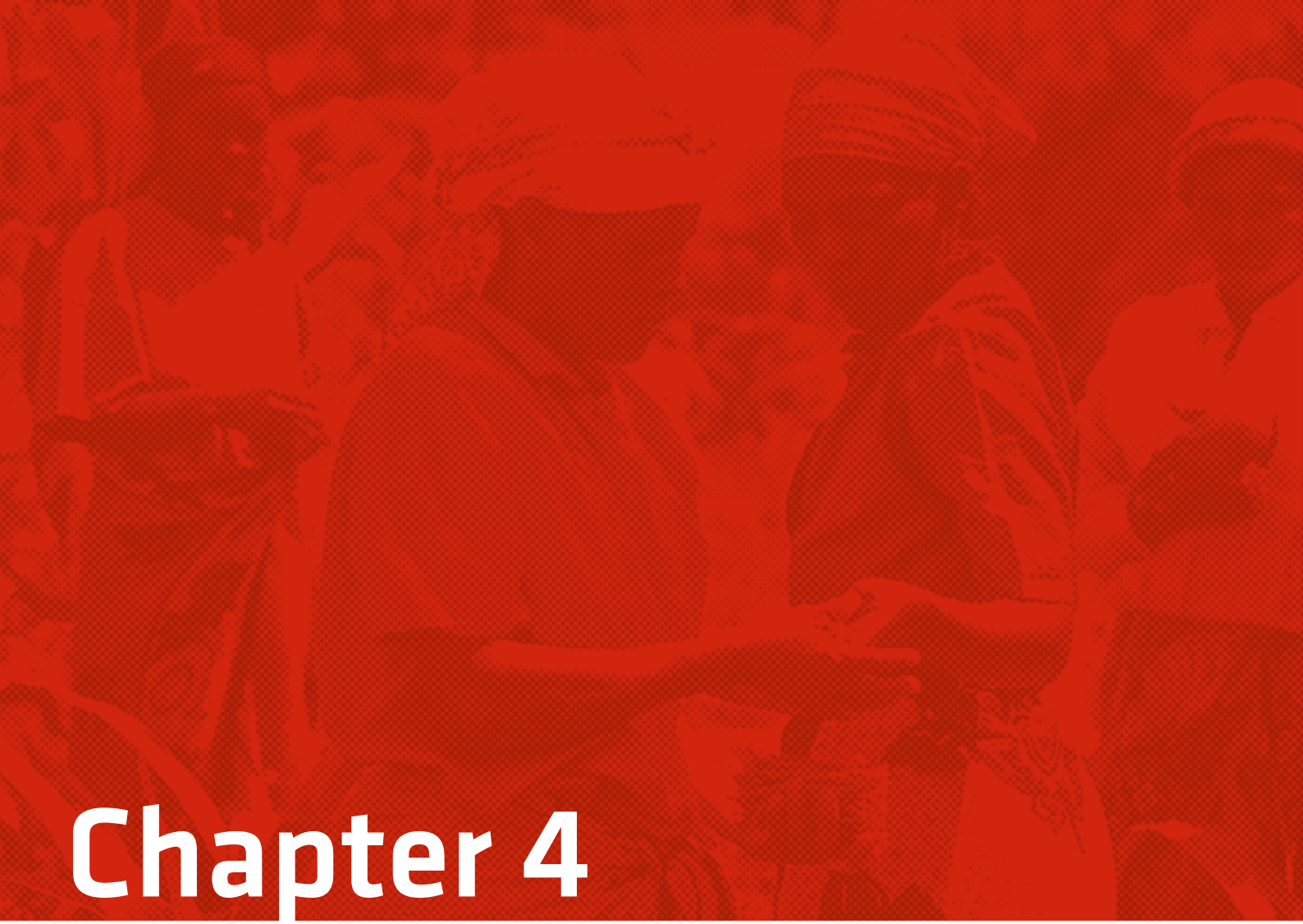
As both risk assessment and economic assessment suffer from uncertainty, there are real benefits in integrating the two disciplines to gain more realistic descriptions of the consequences of decisions that may be made by risk managers. The common element is being able to create a single matrix for decision-making. Typically, such matrices convert all outcomes, health impacts, economic costs and other costs, into units (such as dollars, 'disability-adjusted life years', DALYs, or 'quality-adjusted life years', QALYs) that permit ready comparison. While noting the increasing interest in using such tools, it is beyond the scope of this handbook to examine economic methodologies for estimating costs and benefits of different risk management options.

Nevertheless, one good recent example of integrated risk assessment and economic assessment is the work of Havelaar and others in the Netherlands, who estimated cost-utility ratios for different interventions to reduce contamination of broiler chickens with *Campylobacter*. The figure here below, from their analysis, makes the cost per unit of health risk averted (DALY) very transparent to risk managers making decisions on control measures. It shows that decontamination in the scald tank, cooking (prepared meat) and good kitchen hygiene have by far the greatest cost-utility.

Cost-utility ratios for different interventions to reduce contamination of broiler chickens with* Campylobacter



** Data are presented for effect on Dutch consumers (NL) and for effect on all consumers (including those who consume exports from the Netherlands), from Havelaar and others, 2005.*



Chapter 4

Risk communication

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4.1. Introduction

Risk communication is an integral part of risk analysis and an inseparable element of the RMF. Risk communication helps to provide timely, relevant and accurate information to, and to obtain information from, members of the risk analysis team and external stakeholders, in order to improve knowledge about the nature and effects of a specific food safety risk. Successful risk communication is a prerequisite for effective risk management and risk assessment. It contributes to transparency of the risk analysis process and promotes broader understanding and acceptance of risk management decisions.

Numerous reports in the international literature have described how to communicate about risks. Communicating effectively with different audiences requires considerable knowledge, skill and thoughtful planning, whether one is a scientist (a risk assessor), a government food safety official (a risk manager), a communication specialist, or a spokesperson for one of the many interested parties involved in food safety risk analysis.

This chapter examines the role of risk communication in risk analysis, and describes practical approaches for ensuring that sufficient, appropriate communication takes place at necessary points in application of the RMF. It illustrates some effective methods for fostering essential communication within the risk analysis team and for engaging stakeholders in dialogue about food-related risks and the selection of preferred risk management options. This chapter does not attempt to explain how to communicate about risks, but readers are encouraged to consult the sources listed in the references for this chapter for material on that topic.

The emphasis is on situations where risk communication is a planned and orderly part of application of the RMF and the effective resolution of a food safety issue. However, there may be other situations, such as food safety emergencies, or technical contexts such as developing ‘equivalent’ food standards, in which government risk managers have less opportunity and/or less need, to engage in risk communication in such a comprehensive manner. The guidance offered here should therefore be tailored as appropriate to suit specific needs on a case-by-case basis.

4.2. Understanding risk communication

Risk communication has been defined as an interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.[1]

Risk communication is a powerful yet neglected tool in helping people make more informed choices about risks. Risk communication encompasses a continuous and interactive exchange of information and opinions between risk assessors, risk managers, consumers, industry, academic institutions and other interested stakeholders throughout the risk analysis process. Risk communication should involve a two-way dialogue. Risk communicators must provide external stakeholders with clear and timely information about the food safety risk and measures to manage it; this information should be communicated in a way that stakeholders can easily understand and using a media that they can easily access. In addition, it is essential for risk communicators to solicit feedback from external stakeholders and listen to their opinions in order to refine the key message communicated and to fully and adequately address stakeholder concerns.

Given its value, why is risk communication frequently underutilized? Sometimes food safety officials are simply too overwhelmed with collecting information and trying to make decisions to engage in effective risk communication. Risk communication also can be difficult to do well. It requires specialized skills and training, to which not all food safety officials have had access. It also requires extensive planning, strategic thinking and dedication of resources to carry out. Since risk communication is the newest of the three components of risk analysis to have been conceptualized as a distinct discipline, it often is the least familiar element for risk analysis practitioners. Nevertheless, the great value that communication adds to any risk analysis justifies expanded efforts to ensure that it is an effective part of the process.

Risk communication is fundamentally a two-way process. It involves sharing information, whether between risk managers and risk assessors, or between members of the risk analysis team and external stakeholders. Risk managers sometimes see risk communication as an ‘outgoing’ process, providing the public with clear and timely information about a food safety risk and measures to manage it; and indeed, that is one of its critical functions. But ‘incoming’ communication is equally important. Through risk communication, decision-makers can obtain vital information, data and opinions, and solicit feedback from affected stakeholders. Such inputs can make important contributions to the basis for decisions, and by obtaining them risk managers greatly increase the likelihood that risk assessments and risk management decisions effectively and adequately address stakeholder concerns.

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[1] Definition by the *Codex Alimentarius* Commission, Procedural Manuel, 15th ed.

Everyone involved in a risk analysis is a ‘risk communicator’ at some point in the process. Risk assessors, risk managers, and ‘external’ participants all need risk communication skills and awareness. In this context, some food safety authorities have communication specialists on their staffs. When such a resource is available, integrating the communication function into all phases of a risk analysis at the earliest opportunity is beneficial. For example, when a risk communication specialist can be assigned to the risk assessment team, their presence heightens sensitivity to communication issues and can greatly facilitate communication about the risk assessment that occurs later in the process.

4.3. Key communication elements of food safety risk analysis

While good communication is essential throughout application of the RMF in addressing a food safety issue, effective communication is particularly critical at several key points in the process. Risk managers therefore need to establish procedures to ensure that communication of the required nature(s) occurs at the required times, and that the appropriate participants are involved in each case.

4.3.1. Identifying a food safety issue

During this initial stage of preliminary risk management activities, open communication between all parties with information to be made can be invaluable in defining the problem accurately. As explained below, information from a wide range of sources relating to a particular food safety problem may be brought to the attention of risk managers, who are then responsible for seeking information from other sources, Other sources likely to have knowledge of the problem under consideration, such as the industry that produces or processes the food in question, scientific experts and other interested parties, depending on the circumstances. Given that the definition of the problem is changing, an open process, accompanied by communication through frequent dialectical exchanges among all participants, contributes to both a precise definition and a common perception of the problem that needs to be addressed.

Risk communication and the generic RMF (steps that require effective risk communication are underlined)

4.3.2. Developing a risk profile

At this step, the critical communication is primarily between risk managers, who are directing the process, and risk assessors or other scientists who are developing the risk profile. The quality of the result is likely to be enhanced if the same open and broadly representative communications network described in the previous step is maintained, and used to obtain input and feedback as the profile is developed. During this activity, the experts developing the risk profile need to establish their own communication networks with the external scientific community and industry to build up a sufficient body of scientific information.

4.3.3. Establishing risk management goals

When risk managers establish risk management goals (and decide whether or not a risk assessment is feasible or necessary), communication with risk assessors and external stakeholders is essential; the risk management goals should not be established by risk managers in isolation. The government policy aspects included in the goals will vary on a case-by-case basis. The risk managers have to be comfortable that the risk management questions asked can be reasonably addressed by a risk assessment, and this assurance can come only from risk assessors. Once risk

management goals for resolving a particular food safety issue have been established, they should be communicated to all interested parties.

4.3.4. Developing a risk assessment policy

A risk assessment policy provides essential guidelines for subjective and often value-laden scientific choices and judgements that risk assessors must make in the course of a risk assessment. The central communication process at this step involves risk assessors and risk managers. Often, face-to-face meetings are the most effective mechanism, and a considerable amount of time and effort may be required to complete the process. Usually, a number of complex issues must be considered and resolved, and even when the risk assessors and risk managers have worked with each other for some time, the different terminologies and different 'cultures' of these two groups can require time and patience to agree on a risk assessment policy.

Input from external interested parties with knowledge and points of view on these policy choices is also both appropriate and valuable, at this step. Stakeholders may be invited to comment on a draft or invited to participate in a public meeting where the risk assessment policy is being considered, for example. Risk assessment policies also should be documented and accessible for review by parties who may not have taken part in developing them.

4.3.5. Commissioning a risk assessment

When risk managers form a risk assessment team and ask the risk assessors to carry out a formal risk assessment, the quality of communication at the outset often contributes significantly to the quality of the resulting risk assessment product. Here too, the communication that matters most is that between risk assessors and risk managers. The subjects to be covered include, most centrally, the questions that the assessment should try to answer, the guidance provided by the risk assessment policy, and the form of the outputs. Other practical aspects at this stage are clear and unambiguous communication of the purpose and scope of the risk assessment, and the time and resources available (including availability of scientific resources to fill data gaps that emerge).

As in the step above, face-to-face meetings between the two groups is generally the most effective communication mechanism, and the discussions should be iterated until clarity is achieved by all participants. There is no single approach for ensuring effective communication between risk managers and risk assessors. At the national level, mechanisms may depend on agency structure, legislative mandates and historical practices.

Because of the need to protect the risk assessment process from the influence of 'political' considerations, the role of external stakeholders in discussions between risk assessors and risk managers is generally limited; however, it is possible to obtain useful inputs in a structured manner.

(Source: INRA)

4.3.6. During the conduct of a risk assessment

Traditionally, risk assessment has been a comparatively 'closed' phase of risk analysis, in which risk assessors do their work largely out of the public eye. Ongoing communication with risk managers is essential here, of course, and questions the risk assessment seeks to answer may be refined or revised as information is developed. As explained in Chapter 2, interested parties who have essential data, such as manufacturers of chemicals and food industries whose activities contribute to exposure may also be invited to share scientific information with the risk assessment team. However, in recent years, the general trend towards greater openness and transparency in risk analysis has had an impact on risk communication, encouraging more participation by external stakeholders in processes surrounding successive iterations of a risk assessment. Some national governments and international agencies have recently taken steps to open up the risk assessment process to earlier and wider participation by interested parties (Box below).

4.3.7. When the risk assessment is completed

Once the risk assessment has been done and the report is delivered to risk managers, another period of intense communication generally occurs (see Chapter 2). Risk managers need to make sure they understand the results of the risk assessment, the implications for risk management, and the associated uncertainties. The results also need to be shared with interested parties and the public, and their comments and reactions may be obtained. Since the results of a risk assessment often are complex and technical in nature, the success of communication at this stage may rest to a large extent on a history of effective communication by and among the relevant participants at appropriate earlier points in the risk analysis process.

External stakeholder participation in processes related to the conduct of food safety risk assessments at international (FAO/WHO) and national levels

The Internet has created opportunities for wider participation in the work of the FAO/WHO joint expert bodies. JECFA and JMPR each have web sites (on the FAO and WHO web sites), on which calls for experts, rosters of experts and requests for data are posted. Any interested experts may submit an application to be included on a roster.

Interested parties may submit scientific data for consideration by the expert committees in response to specific calls for data. Increasingly, e.g. when risk assessment methodologies are updated, public input is sought via posting of draft documents on the dedicated Web sites.

When the United States conducted its risk assessment for Listeria monocytogenes in ready-to-eat foods, it solicited extensive inputs from industry, consumer groups and others with an interest in and knowledge of the problem. The government held public meetings with stakeholders to discuss questions to be addressed, to ask for data and to hear suggestions about analytical approaches. A draft of the risk assessment was published and comments were solicited from the public. Extensive additional scientific data and other inputs were received, especially from industry, and the process led to several improvements between the first draft and the final risk assessment.

Because of its central importance as a basis for risk management decisions, the output of a risk assessment is usually published as a written report. Some examples of published risk assessments are cited in the case studies.

In the interests of transparency, other important attributes of the assessment, and thoroughly documented. In the interests of effective communication, they need to be written in clear, straightforward language, readily accessible to the non-specialist.

Assigning a communication expert to the risk assessment team, from the outset if possible, is often helpful for meeting this latter objective.

4.3.8. Ranking risks and setting priorities

When this step is necessary, risk managers should ensure a broadly participatory process that encourages dialogue with relevant stakeholder groups. Priority judgements are inherently value-laden, and ranking risks in priority for risk assessments and risk management attention is fundamentally a political and social process, in which those stakeholder groups affected by the decisions should participate.

Box below presents some examples of national processes that involved such multiparty consultation with external stakeholders. Food safety officials in various contexts have established new communication forums that bring industry, consumer representatives and government officials together to discuss problems, priorities and strategies in collegial, non-adversarial settings.

Such contacts can build bridges and common understandings of issues, such as the value of risk analysis or emerging problems; they are less useful for resolving current specific disputes, although they do improve understanding of each other's general perspectives.

4.3.9. Identifying and selecting risk management options

Decisions on issues such as risk distribution and equity, economics, cost-effectiveness and arriving at an ALOP are often the crux of risk management. Effective risk communication during this stage of the RMF is therefore fundamental to the success of the risk analysis.

Public food safety risk managers with their experience in managing other food-related risks can have a clear idea of the potential risk management options and possibly preliminary to the management of a new food safety problem, but consultation at this stage may alter their views, for example, in situations where there are various risk management options for controlling a hazard at different points of the food production chain.

The extent of this consultation will depend on the food safety issue considered.

Industry experts often have crucial information and views on possible food hygiene control measures, their effectiveness, and their technical and economic feasibility.

Consumers, who typically support foodborne risks and who are usually represented by consumer associations and other NGOs involved in food safety, can also provide important avenues for risk management options, In particular when the options envisaged include information-based measures, such as consumer awareness campaigns or warning labels.

It is essential to consult with consumers on these measures to find out what kind of information the public wants and needs and to understand in what form and on what medium this information is most likely to be noticed and taken into account.

Examples of national and regional experiences with multiparty processes for communication about broad food safety issues

- ***New Zealand Consumer Forum***

In 2003, the New Zealand Food Safety Authority (NZFSA) initiated an on-going biannual forum with representatives of more than two dozen consumer, environmental health and other civil-society groups with an interest in food safety, and invites them to discuss how NZFSA makes decisions, and how civic organizations could productively be involved in that process. Stakeholders also identify their own food safety priorities on an annual basis, and a portion of NZFSA operational research funds is dedicated to investigating the scientific basis of those concerns.

- ***Lebanese National Food Safety Committee***

In 2005, Lebanon's Minister of Agriculture set up an independent national committee for food safety. The committee is advisory and includes representation from a cross section of interested stakeholders, including food producers, processors, retailers, and consumer organizations. The committee began its work by focusing on issues related to pesticides and animal health as each relates to food safety.

- ***UK Stakeholder Forum on BSE***

The Food Standards Agency (FSA) in the UK set up a forum for consultation with stakeholders, to communicate about risks of BSE and measures for managing the risks. The forum was chaired by the chair of the FSA Board and included participants representing all segments of the food production chain, from cattle and feed producers to consumer organizations.

- ***Uruguayan Food Safety Agency***

In Uruguay, Parliament is considering a new food safety law that would establish a national food safety agency. The proposed agency will have an advisory board of stakeholders, which will include industry, consumers and other designated participants. Also under discussion is the possibility of including experts from various stakeholder sectors on the Scientific Board of the new agency.

- ***Latin America: COPAIA***

In 2001, Latin American governments and the Pan American Health Organization established COPAIA, a commission on food safety in the region with 20 appointed members, 10 from government and five each from industry and consumer

organizations. The group serves in an advisory role to the regional council of agricultural and health ministers and has made a variety of consensus policy recommendations, focused mainly on the use of risk analysis and on strategies for involving interested sectors of the public in national food safety decision-making.

➢ ***United States National Academy of Sciences Food Forum***

In the early 1990s, United States federal food safety agencies and the National Academy of Sciences (NAS) set up this forum which brings together experts on food safety and nutrition from government, industry, consumer organizations, academia and professional societies. The group meets several times a year to study issues; it also has organized large public science-and-policy meetings on numerous topics it identified as important and likely to benefit from in-depth discussion. The Food Forum does not make policy recommendations to the government but provides a mechanism to identify priorities and emerging issues, and suggests possibly effective problem-solving strategies. It has also fostered a team approach among differing sectors whose experts have rarely worked together outside this setting.

While government food safety risk managers, based on their experience managing other food related risks, may have a clear idea of potential risk management options, and perhaps some preliminary preferences for managing a new food safety issue, consultation at this stage may well alter these views, for instance where there is a range of possible risk management options for controlling a hazard at different points in the food production chain. The extent of this consultation will depend on the individual food safety issue. Some mechanisms for consultation with stakeholders at the national level are illustrated below.

Some examples of processes for communication with national stakeholders on evaluation and selection of risk management options

The United States Food and Drug Administration (FDA) regularly convenes public meetings to solicit feedback from stakeholders on particular food safety issues including the assessment of particular food safety risks and ways to manage them.

For instance, in 2004, FDA announced a series of public meetings to discuss the proposed rule for prevention of Salmonella enteritidis (SE) in shell eggs during production in follow-up to the publication in the Federal Register of a proposed rule for egg safety national standards.

The purpose of the public meetings was to solicit public comments on the proposed rule and provide the public an opportunity to ask questions. An announcement about the planned public meetings was placed on the Internet along with information on how to register.

Interested parties were encouraged to attend to present their comments, concerns and recommendations regarding the proposed rule. In addition to seeking oral presentations from specific individuals and organizations at the public meeting, the FDA also encouraged the submission of written comments on issues of concern.

In September 2003, the Advisory Committee on the Microbiological Safety of Food (ACMSF) in the UK Food Standards Agency set up an ad hoc group to develop advice

on the potential risk to human health associated with the consumption of chilled or frozen baby foods, particularly in relation to *Clostridium botulinum*.

In June 2005, this Group presented a final draft report of its work to the Committee. At this meeting, the ACMSF agreed to publish the report for public consultation. The consultation took place between September and December 2005. Comments received in response to the consultation were considered by the ad hoc Group and several minor amendments were made to the report.

When risk management options are being evaluated, the risk analysis process sometimes becomes an overtly political one, with different interests within a society each seeking to persuade the government to choose the risk management options they prefer. This can be a useful phase; if managed effectively, it can illuminate the competing values and trade-offs that must be weighed in choosing risk management options, and support transparent decision-making. WTO members are required to implement the SPS Agreement based on transparency as a means to achieve a greater degree of clarity, predictability and information about trade rules and regulations.

In such public debates about food safety controls, industry and consumers often seem to be trying to push the government in opposite directions. While there can be genuine differences and unavoidable conflicts between what consumers want and what industry wants, the differences are sometimes less than they might seem. Food safety officials may find it useful to seek common ground by fostering direct communication between industry and consumer representatives, in addition to the ongoing communication that each sector maintains with the government agencies themselves.

Transparency provisions in the WTO SPS Agreement

Governments are required to notify other countries of any new or changed sanitary requirements which affect trade, and to set up offices (called 'Enquiry Points') to respond to requests for more information on new or existing measures. They also must open to scrutiny how they apply their food safety regulations. The systematic communication of information and exchange of experiences among the WTO's member governments provides a better basis for national standards. Such increased transparency also protects the interests of consumers, as well as of trading partners, from hidden protectionism through unnecessary technical requirements.

A special Committee has been established within the WTO as a forum for the exchange of information among member governments on all aspects related to the implementation of the SPS Agreement.

The SPS Committee reviews compliance with the agreement, discusses matters with potential trade impacts, and maintains close co-operation with the appropriate technical organizations. In a trade dispute regarding a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.

4.3.10. Implementation

To ensure that a chosen risk management option is implemented effectively, government risk managers often need to work closely, in an ongoing process, with those upon whom the burden of implementation falls. When implementation is carried out primarily by industry, government generally works with the industry to develop an agreed plan for putting food safety controls into effect, then monitors progress and compliance through the inspection, verification and audit process. When risk management options include consumer information, outreach programmes are often required, for example to enlist health care providers in disseminating the information.

Surveys, focus groups and other mechanisms also can be pursued to measure how effectively consumers are receiving and following the government's advice. While the emphasis at this stage is on 'outgoing' communication, the government needs to explain to those involved what is expected of them, mechanisms should be built into the process to collect feedback and information about successes or failures of implementation efforts.

4.3.11. Monitoring and review

At this stage, risk managers need to arrange for the collection of relevant data needed to evaluate whether the implemented control measures are having the intended effects. While risk managers take the lead in developing formal criteria and systems for monitoring, other inputs may enhance this determination. Parties other than those designated as responsible for monitoring and review activities may be consulted or may bring information to the attention of the authorities at this stage as well. Risk managers sometimes use a formal risk communication process to decide whether new initiatives are needed to further control risks.

Communication with public health authorities that are not integrated in food safety authorities is especially important during this step. The importance of integrating scientific information from all aspects of monitoring hazards throughout the food chain, risk assessments, and human health surveillance data (including epidemiological studies) is emphasized throughout this chapter.

4.4. Some practical aspects of risk communication

While the advantages of effective risk communication are obvious, communication does not occur automatically and it has not always been easy to achieve. Communication elements of a risk analysis need to be well organized and planned, just as risk assessment and risk management elements are. When resources permit, governments may include specialists in conducting or managing communication aspects of food safety risk analysis among their staff. Whether managing risk communication falls to a specialist or to someone with more general responsibilities, a number of practical questions are inevitably encountered. This section examines some of those questions and suggests some workable approaches for answering them in the national context.

4.4.1. Goals of communication

When planning for communication, an essential first step is to determine what the goal is. For instance, communication has a somewhat different focus. Those planning communication programmes need to establish:

1) what the subject of the communication is (for example, risk assessment policy, understanding outputs of a risk assessment, identifying risk management options);
2) ii) who needs to participate, both generically (i.e. risk assessors, affected industry) and specifically (*i.e*. which individuals) ;
3) when during the risk analysis process each kind of communication should take place. The answer to this last question can be 'often'; that is, some communication processes do not occur once, but may be reiterated, or ongoing, during large portions of or throughout application of the entire RMF.

Some pitfalls to avoid: What risk communication is not good for

Risk communication is not public education.

Public education on food safety requires risk communication skills, but the two endeavors are separate and distinct activities.

'Education' implies a 'teacher/student' relationship, in which the expert authorities have knowledge to pass on to the (largely uninformed) public. The public may in fact already have a great deal of information; effective communication is a two-way exchange of information, not a one-way transfer. In a risk analysis context, gathering information is often as important as conveying it.

Risk communication is not public relations.

Much of the literature on communicating with consumers about risks and control measures conveys the strong message that risk communication is a useful tool for making the public see the issues the way the experts or risk managers see them. But

in fact, ordinary citizens often have an equally rational but fundamentally different perspective on risks.

The essence of good communication is for each group to understand and appreciate the other's perspective, not for the group with greater communication resources to convince the others that their perspective is the correct one.

Telling people a food is safe will not necessarily reassure them. One common, difficult risk communication situation arises when government and industry food safety officials perceive that consumers are unduly frightened about a risk.

In that situation, simply asserting that the available scientific information shows the risk is insignificant generally does not make people worry less. In fact, if consumers perceive that their concerns are being dismissed too lightly, they may trust those in authority less and worry more.

The most effective response to perceived public fears is to engage in dialogue with consumers, to listen and respond to their concerns. Honest discussion of what scientific data about the risk show (including uncertainties) will help put risk in perspective.

It is also important to avoid choosing inappropriate risk communication goals. Communication efforts undertaken without sufficient care as to what they are intended to accomplish often turn out to be counterproductive.

4.4.2. Communication strategies

A great many specific strategies for effective risk communication have been developed for use in various contexts, including food safety, and in different cultures. Some basic components of a risk communication strategy in the context of food safety risk analysis are summarized in Box below.

Strategies for effective communication with external stakeholders during a food safety risk analysis

- Collect, analyze and exchange background information about the food safety risk.
- Determine risk assessors', risk managers' and other stakeholders' perceptions of and knowledge of the food safety risk or risks involved, and their resulting attitudes and risk related behavior.
- Learn from external stakeholders what their risk-related concerns are and what their expectations are for the risk analysis process.
- Identify and be sensitive to related issues that may be more important to some stakeholders than the identified risk itself.
- Identify the types of risk information stakeholders consider important and want to receive, and the types of information they possess and wish to convey.

- Identify types of information needed from external stakeholders, and determine who is likely to have information to contribute.
- Identify the most appropriate methods and media through which to disseminate information to, and obtain information from, different types of stakeholders.
- Explain the process used to assess risk, including how uncertainty is accounted for.
- Ensure openness, transparency and flexibility in all communication activities.
- Identify and use a range of tactics and methods to engage in an interactive dialogue involving risk analysis team members and stakeholders.
- Evaluate the quality of information received from stakeholders and assess its usefulness for the risk analysis.

4.4.3. Identifying 'stakeholders'

While risk managers may agree with the general goal of inviting affected stakeholders to participate at appropriate points in application of a RMF, it is not always a simple matter to know specifically who those parties are, or to get them engaged in a particular risk analysis process. Often, affected stakeholder groups are known to risk managers from the outset, or identify themselves and seek to participate early in the process.

Sometimes, however, some affected stakeholders may be unaware of the need for or the opportunity to participate, and authorities may need to reach out to them.

Most countries have laws and policies about how and when stakeholders can participate in public decision-making processes. Risk managers can work within such frameworks to optimize participation. When risk managers seek to identify appropriate stakeholders, the criteria in other Box below may be useful.

Logo of the French Agency for Food, Environmental and Occupational Heath Safety

Mechanisms have been established in many countries for engaging stakeholders in food safety decision making at the national level in a general, ongoing way. Participation by interested parties in such broader activities may increase their awareness of new food safety issues, and builds the government's familiarity with interested sectors of the society.

For example, some countries have set up a national food safety advisory committee, a national *Codex* committee, a network of industry and civil-society contacts who wish to take part in *Codex*-related activities, and similar organizations.

To the extent that such networks exist, they can be used to ensure appropriate risk communication with relevant stakeholder groups.

Where such mechanisms have not yet been established, the benefits they offer in terms of supporting participation of affected interested parties in risk analysis is only one of many advantages national food authorities may gain by creating them.

Examples of potential stakeholders in a particular food safety risk analysis

- Farmers, ranchers, fishermen and other food producers
- Food processors, manufacturers, distributors and their vendors
- Food wholesalers and retailers
- Consumers and consumer organizations
- Other citizen advocacy groups (environmental, religious etc.)
- Community groups (neighborhood associations, co-operatives etc.)
- Public health community and health care providers
- Universities and research institutions
- Government (local government, state and federal regulatory agencies, elected officials, importing countries etc.)
- Representatives of different geographic regions, cultural, economic or ethnic groups
- Private sector associations
- Businesses
- Labor unions
- Trade associations
- Media

Once stakeholders are identified, their role in a given risk analysis needs to be defined. While potentially valuable inputs from stakeholders in different sectors can occur at most stages of the generic risk management process, constraints may exist in specific cases. For example, in a situation that demands urgent action, time for consultation may be very limited. In some cases stakeholder participation may not have much genuine influence on the decision; if the decision is not really negotiable, stakeholders should be informed so that they do not feel that they are wasting their time.

Criteria for identifying potential stakeholders to participate in a given food safety risk analysis

- Who might be affected by the risk management decision (including groups that already know or believe they are affected, as well as groups that may be affected but as yet do not know it)?
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?
- Who has expressed interest in being involved in similar decisions before?
- Who should rightfully be involved, even if they have not asked to be?

4.4.4. Methods and media for communication

(Source: 123RF)

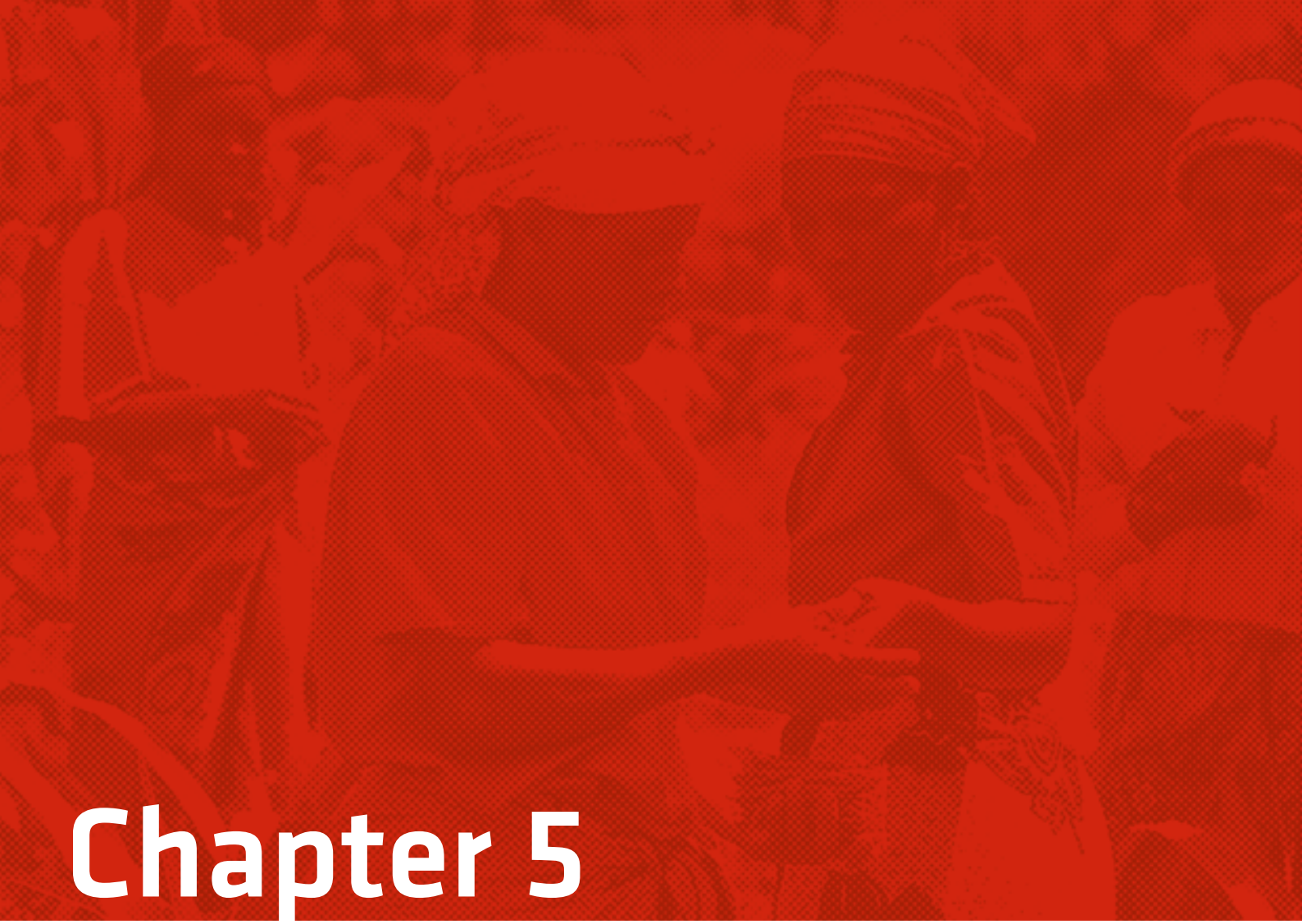
Depending on the nature of the food safety issue, the number and nature of the stakeholder groups involved, and the social context, a great many alternatives may be appropriate for conveying and receiving information at various points in application of the RMF. Box below lists some of the more widely applicable options.

Some tactics for engaging stakeholders in a food safety risk analysis	
Meeting techniques	**Non-meeting techniques**
• Public hearings • Public meetings • Briefings • Question and answer sessions • Town hall meetings • Panel discussions • Focus groups • Workshops	• Interviews • Hotlines and toll-free numbers • Web sites • Advertising and flyers • Television and radio • Reports, brochures and newsletters • Booths, exhibits and displays • Contests and events

While there will probably always be a need for detailed written documents, scientific reports and official government analyses of food safety issues and decisions, effective communication often requires additional approaches. Some of the familiar mechanisms, such as meetings, briefings and workshops, can be tailored so as to attract participation by different stakeholders whose involvement is desired. For instance, a workshop on scientific and economic aspects of the food safety controls relevant to the issue under consideration would be likely to attract robust food industry participation, while a panel discussion on the latest advances in risk analysis methodologies should appeal to many academic experts, as well as to other stakeholders.

Some of the 'non-meeting' approaches can be quite creative. For example, a number of years ago government officials and consumer organizations in Trinidad and Tobago organized a calypso contest to engage community members in promoting awareness of food safety and a variety of other consumer issues. Especially when the goal is to inform and engage the public, messages intended for specific audiences need to be presented in media the audiences pay attention to, and efforts to gather information need to be carried out in a place and in a manner that will encourage those with the desired information to take part in the process.

Which of these approaches, or perhaps others, may be most appropriate will depend on the issue, the type and nature of stakeholder groups, and the context. In general, large public meetings are not especially effective for eliciting the transparent dialogue that risk communication seeks to achieve. When involving members of the general public is one of the objectives, internet discussion boards and chat rooms and call-in television and radio programmes enable members of the general public to share views and concerns and to obtain information from experts and decision-makers.



Chapter 5

Risk management measures in companies

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5.1. Which management measures?

Each company must decide which management measures to implement. Every manager must first assess the risks their company is facing and set the goals to be attained.

The present chapter presents a catalogue of **generic risk management measures** that are generally appropriate for the fresh fruit and vegetables growing and packing sector. Most of them are based on the recommendations of the *Codex Alimentarius*, the requirements of international rules and the guidelines of recognised standards or Good Practices Guides.

It is, however, necessary to **adapt the measures and the requirements level** depending on the product, the process and local circumstances!

In order to decide on the management measures to include in their ***Management and Monitoring of Sanitary Risks Plan*** (MMSRP),[1] the health quality and traceability manager of the company must:

1. Take into account internationally recognized recommendations and regulations requirements (in this case 'management measures' become 'requirements').
2. Undertake a systematic assessment of the risks and sources of contamination in their operation using, for example, the '5M' method[2] and decide on appropriate measures based on this.

5.1.1. Approach based on international references

To choose appropriate management measures (effective and economically viable), the head of the company can look to:

1. The **requirements defined by the *Codex Alimentarius Commission*** in the *Recommended International Code of Practice - General Principles of Food Hygiene*– CAC/RCP 1-1969, REV, 4 (2003). These requirements are applicable to all WTO countries that have signed the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

   This is the base document to be consulted first because this **Code also covers the elements of primary production** (Section III).

[1] Note that we prefer to speak of a *Management and Monitoring of Sanitary Risks Plan* (MMSRP) rather than, as some authors do, of a food safety management plan (FSMP) to refer to verification operations (self-assessment) which are inseparable from rational risk management.

[2] Or the Ishikawa diagram.

It contains general advice applicable to all operators even though hygiene practices vary considerably from one food to the next and that, if need be, specific 'Codes' must be used.

It will also be necessary to refer to the *Code of Hygienic Practice for Fresh Fruit and Vegetables* CAC/RCP 53 – 2003 of the *Codex Alimentarius*.

2. The **requirements of Regulation (EC) 852/2004** (Appendix I, Part A)[3] on the hygiene of foodstuffs and the keeping of logs. This regulation covers general hygiene provisions applicable to primary production and to related operations such as transport, warehousing and handling.

3. The **standards** entitled *Requirements for food safety management applied to IAA* (BTSF, DG SANCO, January 2010).

   These are technical standards written for use by the competent authorities of the Member States of the African Union for the certification of agri-foods companies.

   The standards include the Good Hygiene Practices requirements applicable to processing companies and, to the extent that they complete them, they also include certain aspects of Good Manufacturing Practice.

   They are based on the general principles of food hygiene (CAC/RCP 1-1969, Rev. 4-2003) of the *Codex Alimentarius* and, therefore, cover the safety of foodstuffs but not their quality. The standards can be combined with audit grids to enable an evaluation of their implementation.

   They can also be consulted by the companies of ACP countries and the present chapter will refer to many items mentioned in them. However, **these standards do not cover primary production** requirements which limits their interest for fruit and vegetable production.

4. The general hygiene principles of all **Codes of Good Practice** (Good Agricultural Practices, Good Transport Practices, Good Hygiene Practices, Good Manufacturing Practice, Good Distribution Practice).

5. **International standards** (notably the ISO 22000 standard based on HACCP), national and industrial standards.

5.1.2. Approach based on a hazard analysis

The Codex acknowledges that: *"There will inevitably be situations where some of the specific requirements contained in the Code will not be applicable*." Therefore, "*The*

[3] Regulation (EC) 852/2004 on the hygiene of foodstuffs. *OJEU*, L139/1 of 30 April 2004.

fundamental question in every case is 'what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"

In practice, this means that, although a requirement found in these reference documents is generally appropriate and reasonable, **there will nevertheless be some situations where it is neither necessary nor appropriate** from the standpoint of food safety and their acceptability.

In deciding whether a requirement is necessary or appropriate, it is therefore necessary to **identify the risks** (e.g. using the HACCP approach) and to **evaluate the level of acceptable risk**.

The choice of '**acceptable hazard levels**' must be justifiable!

With respect to biological and chemical hazards, the company manager can turn to:

1) regulatory and legal requirements (first) ;
2) food safety objectives (FSO) defined for their product.

For physical hazards, he will preferably look to contractual requirements (specifications for the finished product).

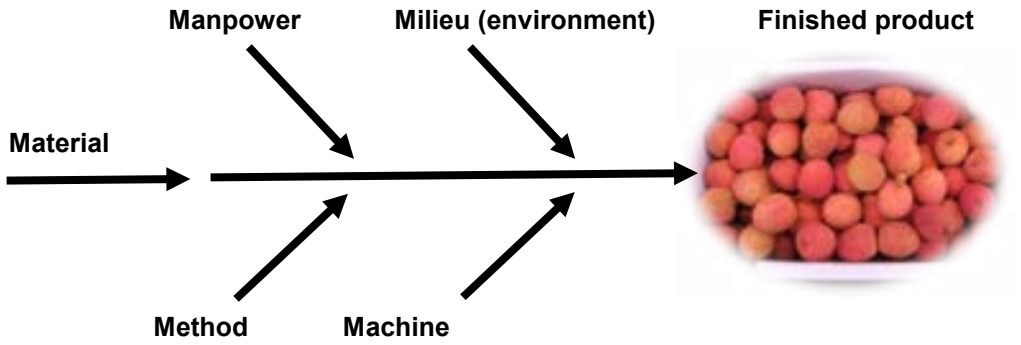
This approach, based on hazard analysis, enables application of the requirements of the Codes of practice and standards **with flexibility and common sense** knowing that the overall objective is to produce safe foods that are suitable for consumption (*Codex Alimentarius*, 2004).

Operators must (adapted from BTSF, 2010):

1. Identify all steps in their processes and activities which are decisive for food safety (**hazard analysis**)
2. Implement verification procedures (**self-assessments**) that are effective at every step
3. Ensure that self-assessments are followed up on to ensure their efficiency and ongoing effectiveness (**inspections and internal audits**)
4. Review control procedures periodically (to ensure that they are effective and efficient) and every time operations or manufactured products change (**continuous improvement**)
5. Create documentation for their FSMP which should include recording the controls and measures carried out (**traceability**).

Company managers can use the **'5 M**' method to identify all hazards and their source.

What are the potential sources of process contamination?



The '5 M' method consists in identifying the possible sources of contamination in the process by examining:

- ***Material (raw materials)***
  Several aspects must be considered such as the origin, cleanliness, conformity, labelling and characteristics (e.g. temperature, water content) of the products. For our purposes, we are interested in both **harvested products** (raw material to be packed) and the **inputs used** (seed, water, fertilizer, enrichment, packaging, phytosanitary products, etc.)

- ***Manpower***
  Every person handling the products is a potential carrier of pathogenic micro-organisms transmittable by foods. Several precautions must be taken in order to minimize risks. Note that hand washing and **staff behavior** are a key first step. **Clothing** is another key issue. Most employee hygiene rules have become routine, including **medical check-ups**, aprons, hair nets and the removal of all jewelry when handling food.

- ***Method***
  This includes all **processes** used in production (**technical itinerary**, from seed to harvest), harvesting, transport and packing to product shipping. 'GMP' (**Good Manufacturing Practice**) must be complied with.

- ***Machine***
  All equipment (**machines, tools and packing materials**) can contaminate food if it is not suited to the purpose or properly maintained. Correct cleaning is not sufficient to accomplish this. Companies must also train employees to think about the maintenance of machines, of spreading equipment, of transport vehicles and of cold storage (defrosting, cleaning and disinfection).

- ***Milieu (environment)***
  Working areas, whether in the fields or packing stations must be **clean and protected** from entry by pests at all times. It is of utmost importance to ensure, for example, that doors and windows are adjusted and closed, that the hygiene of premises and work surfaces is checked and that wastewater evacuation pipes, waste bins, ventilation and lighting are taken care of.

The availability, in a sector, of a reference document such as a ***Self-Assessment Guide*** containing the basics of an HACCP plan for the production of products identical to its own will greatly facilitate the task of the head of the company.

The latter can also find useful information in the "Application Guide Good Manufacturing Practice, Good Hygiene Practices and HAACP" (2010) prepared by BTSF (Better Training for Safer Food, DG SANCO).

5.1.3. Implementation of the PRP based on the 5 M

❑ **A reminder about pre-requisite programmes (PRP)**

Pre-Requisite Programmes (PRP) are defined as "*the **basic conditions and activities** necessary to maintain a hygienic environment throughout the food supply chain which is suitable for production, handling and provision of safe end products and safe food for human consumption"* (according to the ISO 22000 standard which identifies at least 10 site wide measures).

Pre-Requisite Programmes (PRP):

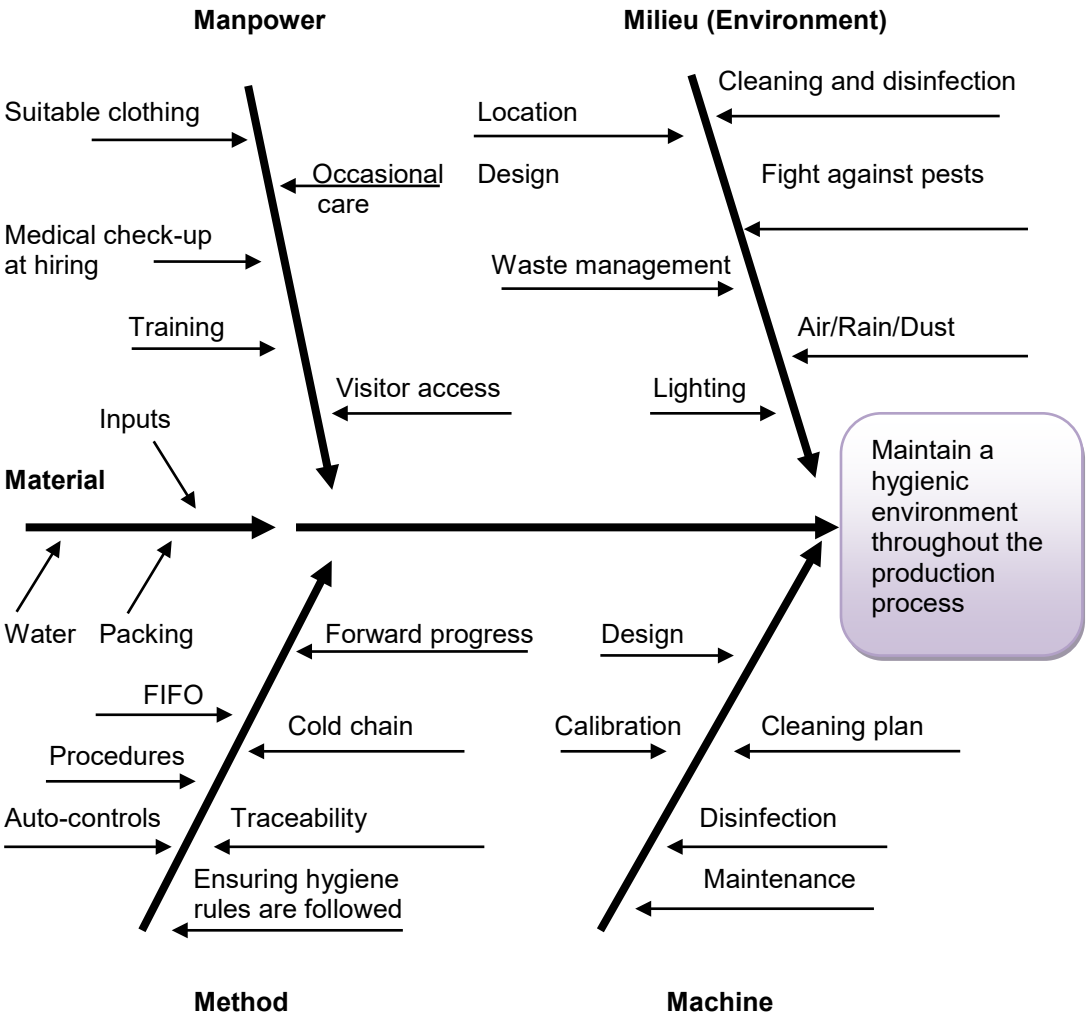
1. depend on the sector (and the type of product), the operator and the segment of the food chain involved;
2. relate to management measures that are **not specific to a production process step;**
3. relate to elements that cannot be measured continuously and for which it would be very difficult to define a critical limit such as: the quality of installations, the cleanliness of operator work clothes, their level of knowledge of basic food hygiene rules, the effectiveness of a cleaning and disinfection plan etc.

In line with the BTSF (2010) standards and the ISO 22000 standard, the site wide measures below will be presented in detail:

- requirements for the set-up and overall organization of an operation or station, for the premises, equipment and their maintenance and for the supply of air, water energy etc.;
- requirements for the implementation and follow-up of a plan to control pests;
- requirements for setting up supply controls and recording the information necessary for the operation of a traceability system;
- requirements for the implementation of an employee health policy;
- requirements for managing employee hygiene covering hand hygiene and clothing;
- requirements for the implementation, follow-up and verification of a pre-established cleaning plan.

❑ **Finding sources of contamination using the 5 M method**

The Ishikawa diagram can be used to identify **sources** of contamination (according to Boutou, 2008):



In order to be able to bring to market foods that meet required health and plant health criteria, all companies must implement a certain number of measures (or PRP) enabling compliance with the general hygiene principles of the *Codex Alimentarius*.

The **first category** of measures to be implemented in a company is intended to manage contamination (biological, chemical and physical) caused by installations, raw materials and operators.

A **second category** of measures is intended to ensure the cleanliness of the premises, of the surroundings and of the materials used in production, as well as employee hygiene.

❑ Main problem sources in primary production

Production site selection (field, orchard)	Presence of heavy metals in the soil Soil contaminated by pesticide residue Glass and metal debris in the soil
Seedling production	Non-authorized chemical treatment on seeds
Irrigation (water quality)	Rivers and water reservoirs are more susceptible to contamination than wells Contamination by human or animal faecal matter is the main problem for irrigation water Contamination of water by chemicals
Crop nutrition (use of fertilizers)	Excessive fertilizers (especially nitrogen which produces high nitrate concentrations in plants) Poor calibration of the equipment used to apply fertilizers Risk of crop contamination by animal manure (pathogenic agents). The use of animal and poultry manure is risky because they contain pathogenic organisms that are dangerous for humans. Manure pathogens can be transmitted by splashing rain, during crop operations, during weeding and harvesting, etc. and by absorption by plant roots.
Pesticide management	Inappropriate choice of pesticides Incorrect application of pesticides Poor sprayer calibration Drift from/on neighboring crops Contamination of water by chemicals Inadequate training of spraying personnel
Harvest (employee hygiene)	Dirty harvest containers Poorly maintained harvest/cutting equipment Poor personal hygiene in workers responsible for harvesting, presence of children, no toilets Inappropriate/dirty clothing worn by employees responsible for harvesting
Use of machines and equipment	Poor maintenance leading to leaks (hydrocarbons, lubricants, refrigerants)
Storage area before transport to the station	Contamination by contact with vermin Dirty or broken containers

❑ **Main problem sources in the packhouse**

Set-up of the premises and construction quality	Biological contamination (lack of hygiene) No forward progress, cross-contamination Moulds and mycotoxins (poor cleaning, no disinfection, absorbent materials) Foreign bodies (poorly maintained site) Pest infestation (no screens on doors and windows)
Product reception	Lack of personal hygiene and inappropriate employee clothing Dirty or poorly maintained containers
Washing	Faecal or chemical water contamination Inappropriate frequency of water renewal in the wash basin Poorly maintained washing equipment Lack of personal hygiene and inappropriate employee clothing
Sorting & trimming	Lack of personal hygiene and inappropriate employee clothing Poorly maintained equipment
Processing after harvest	Incorrect choice of pesticides Incorrect application of pesticides Poorly maintained equipment
Waxing	Non-approved waxes (or non-approved emulsifier) Poor wax application Poorly maintained application equipment
Drying	Poorly maintained drying equipment
Calibration	Lack of personal hygiene and inappropriate employee clothing Poorly maintained calibration equipment
Packing	Lack of personal hygiene and inappropriate employee clothing Poorly maintained packing equipment Dirty or broken containers
Palletization	Broken or split wood
Pre-refrigeration	Faecal or chemical water contamination Poorly maintained cooling equipment
Storage	Poorly maintained storage equipment (poor temperature control) Buildings not protected from vermin (pests) Waste not removed, foreign bodies Dirty or broken containers Loss of traceability Chemical contamination (fertilizers, biocides or

	pesticides)
Transport Shipping	Dirty vehicle unsuited to food transport

5.1.4. General comments on managing biological hazards

Biological hazards (bacteria, viruses, worms, etc.) can be **controlled by limiting their numbers** in the product. This can be done by **eliminating them** (e.g.: by cooking, pasteurization, ionizing radiation, etc.) or **by acting on the growth factors** they need to survive and proliferate (or produce toxins).

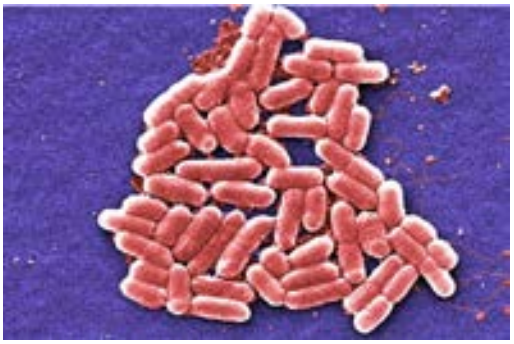
These growth factors are primarily **temperature** (pathogenic agents can be destroyed, eliminated or controlled by heating or freezing), and **water activity (*aw*)** (inhibition by drying), pH, redox potential, the use of additives, etc.

Production managers must set **three goals** for biological hazards:

1. eliminate or reduce hazards to acceptable levels;
2. prevent or minimize the growth or micro-organisms and the production of toxins;
3. manage product contamination.

Note that for biological hazards, the 'acceptable level' of risk corresponds to the level of a specific danger in a finished product leaving the company **required to guarantee the safety of food products at the next step in the food chain** (either for consumption or later processing. For example, fruits can be eaten fresh or pressed for juice.).

❑ **Controlling bacteria**



Most bacteria can develop quickly in a product at normal working temperatures.

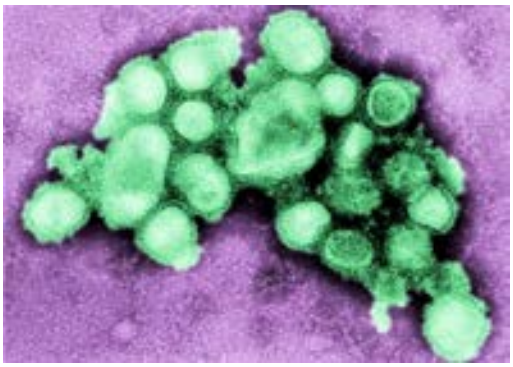
As a result, in addition to the **Good Hygiene Practices which are decisive in ensuring the prevention of contamination by bacteria**, production management measures must be implemented to stop their development in the product, notably by (AFNOR 2008):

- use of the 'temperature/time' pair:
  - appropriate management of refrigeration time or a thermal treatment applied for a given period at the correct temperature (cooking, pasteurization or canning);
  - compliance with the cold chain;
- drying (the action of which is intended to reduce aw in foods and inhibit bacteria growth), the use of pH or vacuum packing;[4]

[4] Two phenomena are at work in this case: (1) inhibition of aerobic bacteria by removal of oxygen; (2) followed by the selection of lactic bacteria which can develop through anaerobiosis, and whose metabolites acidify the environment and inhibit the growth of other micro-organisms

- management of supplies, that is, being certain that raw materials/foods have low contamination levels (obtaining proof from suppliers and shippers that they effectively manage contamination by micro-organisms);
- cleaning and disinfection which enable the elimination or reduction of microbial contamination levels;
- the design and management of installations that prevent cross-contamination between raw materials ('dirty') and finished products ('clean').

❑ **Controlling viruses**



Note that food viruses can come from water or from foods contaminated by humans, animals or the environment.

Contrary to bacteria, viruses are not able to reproduce outside of a living cell. **They cannot, therefore, proliferate in food** as it is an inanimate vector.

Control measures therefore consist essentially of:

- thermal treatment: heating and cooking methods such as steaming, frying or oven cooking can destroy most but not all viruses (the type of virus will determine the control method to be used);
- employee hygiene practices, and in particular, the exclusion of workers suffering from viral illness such as hepatitis.

❑ **Controlling other parasites**

In addition to managing supplies, other management measures include:

- heating, smoking, drying and freezing;
- salting and pickling.

5.1.5. General comments on managing chemical hazards

Some chemical substances from natural sources (e.g.: mycotoxins, alkaloids, allergens) or from synthesis (e.g.: pesticides) can be hazardous if they are present in unacceptable concentrations in the product (above the maximum levels set).

If the authorities have set **maximum levels (ML or MRL)** for a food, the hazard in question **automatically** becomes **relevant for that product**.

---

thanks to reduced pH. Generally speaking, the acidification of products or the addition of salt inhibits the growth of micro-organisms.

Risk management for these substances consists of two broad categories:[5]

1. Harvested products brought to the packhouse **are either contaminated** in the field, at harvest time, or during transport. Contamination can come from the soil, the environment (pollution) or from crop operations and crop protection practices. This is the case of pesticide product residues.
2. Either the product to be packed is **contaminated during the operations that follow** harvesting (greases/lubricants from machines and conveyor belts, disinfectants, detergents, fungicides applied after harvest, fruit sulphuring etc.).

Application of chemical fertilizers. Doses are random without a measuring device!
(Photo AFD)

The main management measures include:

- management of 'raw materials' supplies: setting specifications for raw materials and for **all inputs** likely to be used (fertilizers, pesticides, soil enrichment, disinfectants and other biocides, detergents etc.), traceability and the keeping of logs on the use of inputs and staff training;
- the requirement for a supplier and transporter certification system that guarantees that the delivered products do not contain any dangerous chemical contaminants;
- management of packing processes: management of post-harvest operations (washing, processing), appropriate additive concentration and use;
- the use of transport and packing materials acceptable for the handling of foodstuffs (to avoid migration);
- removal of non-food grade products (including by-products and waste) during storage and processing;
- monitoring of accidental contamination risks (detergents, greases, lubricants, inks, commonly used water treatment and heating products, paints etc.);
- management of labelling (ensuring that the product is correctly labelled indicating the ingredients and allergens).

5.1.6. General comments on physical hazards

The presence of foreign bodies (stones, pieces of glass or metal, splinters, etc.) in food can be a result of accidental contamination and/or poor practices.

[5] In practice, it isn't always so cut and dried. Certain mycotoxins can appear before harvesting with the growth of fungi in the fields whereas others only appear during storage. Pesticide products are used before and after harvesting.

Appropriate management measures can be easily designed when the main sources of physical risk in food are identified:

- glass: The main sources in food processing plants are light bulbs and glass containers for food or other products;
- metal: the main sources of metal are fragments from equipment (splinters, blades, broken needles, pieces of worn tools, staples etc.);
- plastics: the most common sources are packing materials, gloves worn by employees, tools used to clean equipment and tools used to remove processed product from machines;
- stones: large crop plants such as, for example, peas and beans can contain small stones picked up during harvesting. Stones can also come from the company's concrete buildings and floors;
- wood: splinters from wood structures and pallets used for storage and transporting ingredients or products.

The following are examples of management measures for physical hazards (Canadian Food Inspection Agency – CFIA):

- inspect ingredients and unprocessed foods to ensure that they do not contain contaminants from fields (for example, small stones) that were not detected during the initial inspection;
- describe the expected characteristics of all ingredients and components used, including unprocessed foods and packing materials (e.g.: recycled cardboard used for packing sometimes contains traces of metal) and indicate established control measures;
- install metal detectors or magnets to find metal fragments in the production chain and filters or sieves to remove foreign bodies at reception time. Metal detectors must be adjusted and well-maintained to ensure that they are precise and don't return false positives;
- manage the environment: ensure that good manufacturing practices are followed and that no physical contamination comes from buildings, installations, work rooms or equipment. Adopt good warehousing practices, evaluate the potential risks present in storage areas (sources of broken glass, such as light bulbs or staples on cardboard boxes etc.) and use protective acrylic bulb and lamp covers;
- ensure correct and regular maintenance of all equipment to avoid sources of physical hazards such as worn machines;
- periodically organize staff training sessions that cover shipping, receiving, storage and handling as well as the maintenance and calibration of equipment.

Example of a metal detector used by industry

5.2. Primary production requirements and controls

The main hazards for the safety of fresh fruits and vegetables in primary production are tied to the **use of pesticides**, to **employee hygiene**, to harvesting equipment and to transport equipment used to bring the products to the packing station. Other factors such as the presence of heavy metals in the soil, irrigation, pollution and fertilization can also be a source of hazards.

Generally speaking, **polluted areas must be avoided** as should industrial areas which may be a serious contamination threat to food (atmospheric pollution and the risk of air-borne pollution), areas prone to flooding (contamination by wastewater), areas that are potentially infested with pests (e.g.: home to many rodents, which transmit diseases, or flies) and areas from which solid and liquid wastes cannot be efficiently removed.

Market gardening near urban areas does not always meet these requirements!

5.2.1. Site set-up and characteristics

Product contamination by:	**Management measure**	**Proof of control:**
Residual pesticides in the soil	Do not grow in soil known to contain pesticide residues	Evaluate the history of previous crops and site use. Carry out a soil analysis before planting if the previous uses of the site or previous crops are not known.
Heavy metals	Do not use soil known to contain heavy metal residues.	Evaluate the history of previous crops and site use. Evaluate the history of previous crops and site use. Carry out a soil analysis before planting if the previous uses of the site or previous crops are not known.

Animals, birds, insects and vermin	Check if it would be effective to enclose the growing area and to use repellents.	Potentially refuse the site if the problem cannot be eliminated.
Dirty irrigation water	Do not use soil where non-treated wastewater has been used. Review water sources in light of use in adjoining areas. Potentially use more sophisticated irrigation methods. Take into consideration factors such as the height of crops compared to the ground, crops that are ready to eat or for cooking, peeled or not, and the time between irrigation and harvest. Verify potential sources of micro-biological hazards on a regular basis.	Evaluate the history of previous crops and site use. Carry out a soil analysis before planting if the previous uses of the site or previous crops are not known. Carry out a risk assessment for the water source and possible contamination by human and animal faecal matter. Change water sources if necessary. Take a water sample and record the results of the analysis. *(according to the WHO, the minimum standard is: <1000 cfu/100ml for faecal coliform)*
Flood waters	Prevent contaminated flood water from reaching crops, for example with ditches.	Assess the site's risks.

5.2.2. Fertilizer use

Product contamination by:	**Management measure:**	**Proof of control:**
Chemical fertilizers	Apply the quantities needed to comply with harvest requirements. Recommendations for fertilizers provided by an expert adviser. Calibrate fertilizer spreaders	Recommendations for fertilizers Fertilizer sheets Training record Calibration sheets

Organic fertilizers	Do not apply directly on crops. Maximize the timer period between application on the ground and the harvest. Compost to reduce the microbial load (composting manure before spreading can considerably limit the development of pathogens). The presence of domestic animals on production sites must be controlled or forbidden (requirements found in certain standards). Reduce run-off, filtering and wind-borne contamination. Ensure compliance with the client's code of practices for times between application and harvest.	Application sheets. Keep the code of practices on file Plot sheets Carefully clean all equipment after contact with manure and before contact with products.

5.2.3. Pesticide use

Two factors must be taken into consideration for pesticide management:

1. **Only authorized pesticides can be used on crops** (these are normally the only ones with an MRL). Producers should only use phytosanitary products certified for the intended use. Their effectiveness for use on the target has been verified via multiple tests that set the dose, the method of use and the time to harvest (TTH).[6]
2. **GAP (Good Agricultural Practices) must imperatively be complied with to ensure that pesticide residues on food are below the Maximum Residue Level** (MRL).[7] When there is no national or EU MRL, the MLR of the *Codex Alimentarius* should be used.

[6] Private standards require producers to use only locally certified products but they also usually require that (e.g.: GLOBALG.A.P.) only active substances certified in the European Union be used.

[7] In order to prevent the risk of non-compliance with MRLs, certain European importers and distributors carry out analyses in the country of production prior to the export and reception of the lots. If MRLs are exceeded, the importer and their supplier can have lots from future shipments refused (for example, they may be added to a blacklist in the United Kingdom).

A reminder about GAPs and MRLs

A **MRL** (in mg of an active substance per kg of food) is the maximum level of pesticide residue that can be expected to be found at harvest time in the edible part if Good Agricultural Practice has been complied with. MRLs provide a quantifiable way of ensuring that there is no abuse of the use of pesticide products

Good Agricultural Practice (GAP) is primarily tied to:

- the use of recommended active substances;
- the application dose/ha or (dose/ha);
- the Time to Harvest (TTH, expressed in days);
- the (maximum) number of applications.

Source of the hazard:	**Management measure:**	**Proof of control:**
No records of the source of crop products (this is important when withdrawing a product and for pesticide use sheets).	The identity of each lot must be traceable from harvest, production and propagation back to the seeds.	Keep suitable files from planting through harvest.
No complete file on pesticides.	All details about the application on harvest must be kept current and filed for three years.	Ensure that the files actually exist.
Risk of crop contamination by pesticides due to poor dosage and poor application practices.	Only qualified employees should be allowed to apply pesticides. Provide training.	File employee training records. Warehouse inspection. Application file.
Risk of applying the wrong pesticide to the crop.	Ensure that there is an up-to-date list approved at the national level and by the client at the commercial level.	List of authorized pesticides, approved, up-to-date and available (note the dose/ha and the time to harvest). Provide the exporter with a list of pesticides proposed for use before the beginning of the season.

Risk of crop contamination by pesticides due to a poorly calibrated sprayer.	Apply the sprayer maintenance and calibration plan.	Calibration sheet
Crop contamination by dirty water in the spraying solution.	Examine water sources in neighboring fields. Carry out a regular verification of the potential sources of microbial hazards.	Carry out a risk assessment on the water source to check for the possibility of contamination by faecal or animal matter. Take a water sample and record the results of the analysis.
Crop contamination resulting from a poor location or to the safety of pesticide storage.	The storage area must be at a given distance from waterways. Ensure that the exterior of the building is sound, safe and protected by a low wall. Permanent shelf with adequate lighting and ventilation. Good inventory control.	Carry out a regular audit of the buildings and their content.

5.2.4. Hygiene at harvest time

Employee hygiene is particularly important to prevent the contamination of products **at harvest time**, notably for products that are not washed prior to export or that are ready to be eaten unpeeled.

Employees must be made aware of, and trained in, good personal hygiene practices and t**hey must be provided with all means** required to comply with these good practices. Proof of application of these good practices may be required by certain European importers and distributors.

Example of a water source for hand washing (Photo B. Schiffers)

Source of the hazard:	Management measure:	Proof of control:
Contamination by jewelry, clothing and foreign bodies (animal excrement from manure, dead insects, stones, etc.)	The collection and storage of fruits and vegetables on pallets. Remove earth and debris from vegetables that can stick to the sides of the crates, boxes and cases used and, as a result, dirty the products. Regularly inspect the containers used for fruit and vegetable handling. Physical hazards can come from bits of packing material or from handling equipment which can fall into the packaging. Pallets and certain types of packing (wooden boxes) contain metal: nails, staples, bindings, etc. that can come off under abnormal use conditions. Choose containers and materials that reduce to a minimum the potential for physical damage to the products. Supervise workers in the field during harvesting. Ensure that appropriate clothing is worn. Implement a policy for the use of tobacco, food and drinks.	Provide employees with hygiene training. Raise worker awareness
Microbial contamination of products by field workers	Provide suitable training in basic personal and food hygiene. Provide toilets and sinks close to the workers. Check workers' state of health (infectious diseases). Provide smoking areas away from products.	Keep employee files. Employee files Medical screening and employee responsibility Employee hygiene and behavioral training

	Employees must report all illnesses that could be transmitted by food, including jaundice, fever and diarrhea, and infected injuries, skin problems, runny eyes, ears or nose. Personal behavior such as spitting, sneezing and coughing on products.	Cover all infected injuries, abrasions and wounds. Blue plaster with a magnetic strip. Raise employee awareness

5.2.5. Machine and equipment use

Machines and equipment can become a source of contamination of soils and products (metals, oils and greases, various debris, etc.) due to poor **maintenance or cleaning** or an accident.

Appropriate maintenance, cleaning and servicing of machines are the best prevention methods.

Source of the hazard:	**Management measure:**	**Proof of control:**
Contamination by metal fragments or lubricants	Ensure that all equipment used for harvesting is in good operating order thanks to a maintenance programme.	Regular checks, a maintenance programme and service files.
Contamination by soil, glass, plastic, wood or stones.	Adjust harvesting methods to avoid contamination. Ensure that containers are intact and undamaged.	Inspect and keep a record of all containers.
Contamination due to a dirty harvest or handling machine or to transport.	Do not use harvest trailers and containers to transport manure. The trailers used to transport product to the packing station must be covered.	Ensure that a cleaning programme is in place. Check the cleaning programme.
Product contamination due to poorly set or maintained refrigeration equipment.	Ensure that there is a regular maintenance programme.	Maintenance files

5.2.6. Product storage before transport or shipping

Temporary refrigerated storage room (Photo B. Schiffers)

In the event that products need to be stored on site, storage must be done in the right conditions. In particular, products must be kept out of the **sun and excessive heat**, or they could deteriorate physically and micro-biologically.

If storage is required, suitable storage areas must be available (ideally refrigerated rooms) and an inventory management procedure must be set up. Cleaning and maintenance of storage areas and rooms is essential to ensuring product integrity.

Source of the hazard:	**Management measure:**	**Proof of control:**
Product contamination due to poor maintenance of storage areas and rooms.	Servicing and maintenance plan Cleaning procedure	Maintenance files
Poorly set or maintained refrigeration equipment	Servicing and maintenance plan Temperature control	Maintenance files Regular recording of temperatures

5.3. Transport requirements

Product safety hazards must be avoided during transport between the field and orchard and the packing station as well as between the packing site and the shipping port or airport through arrival in the importing country.

Hazards can appear when products are **left in the sun** on the road, airport runways or in ports before shipment. This can lead to respiratory stress and product deterioration.

Contamination can also occur during transport, because of the container or mixing with other merchandise transported at the same time or previously.

If the company sub-contracts transport, there must be a written contract covering: the state of hygiene of the vehicle, the ability to protect the products, a guarantee that the products will not be contaminated by other products transported at the same time or previously and, if possible, a guarantee that the temperature in the vehicles will be properly regulated during transport.

If the products are in good condition when they are loaded in the sealed container, the temperature is controlled and the equipment is in good operating condition, and access is restricted, there is very little likelihood of external contamination or product deterioration.

Source of the hazard:	**Management measure:**	**Proof of control:**
Product deterioration due to poor temperature control.	Ensure that the temperature control devices have been properly calibrated and serviced regularly. Ensure that the products are properly loaded to ensure the circulation of fresh air around the load to prevent the creation of hot spots.	Monitor and track the temperature. Set a maximum load amount.
Contamination by previous loads.	Inspect the vehicle before loading. Clean thoroughly, if possible.	Refuse the vehicle. Proof of cleaning.

Contamination by other substances due to shared loads.	Check before loading if the products can be transported with another substance.	State of the items used to separate the various types of merchandise transported.
Contamination due to the presence of pests.	Guarantee from the transporter that there are no pests. Adequate cleaning.	Proof of cleaning.
Contamination by dust and various vehicle parts.	Reduce the number of openings. Equipment must be maintained in good operating condition to ensure that paint does not peel off and to avoid mud, oil, grease, rust and product debris. All surfaces must be easy to clean.	Cleaning schedule.

5.4. Post-harvest: General facility requirements

5.4.1. General requirements for the set-up and overall organization of a packhouse[8]

The requirements for locations to be avoided are globally the same as for fields and orchards. In addition, water and energy supplies must be available under all circumstances via supply networks and, potentially, substitution systems belonging to the companies (water reservoirs, electrical generators, etc.) and activated when required.

The general principles to be implemented are:

- ***Product flow***: successive work operations must ensure the product's forward progress on the production line, without any backward movement, from less processed to more processed, from less healthy to more healthy, and from less fragile to more fragile. In order to avoid breaking this rule, operators may not move about and are required to remain at the work station to which they are assigned.

- ***Segregation***: the different production chains cannot intersect. They can merge (assembly of composite products, be put in a previously washed container) or be separated (processing chains for by-products obtained from the preparation of a main product).

- ***Separation of hot and cold chains***: the areas in which hot foods are processed must be clearly differentiated from areas in which cold foods are processed in order to avoid any breakdown of the cold chain by thermal pollution of cold foods.

- ***Separation of clean and waste areas***: the waste products of each production step must be evacuated immediately, and as directly as possible, toward rooms dedicated to their treatment (sinks) or for disposal (waste room). The alternative method of separating incompatible activities in time rather than physically can also be considered in some companies.

- ***Drinking water supply***: drinking and non-drinking water supplies (fire network, steam production, cooling circuits, etc.) must be completely separate and identified (pipe color).

- ***Building rules*** are applicable to all premises including those dedicated to the storage of foodstuffs: this includes materials used, the premises, the layout of the premises, their set-up and their cleaning and maintenance. These requirements are further described below.

The layout and set-up of the premises are important factors.

[8] BTSF (2010) recommendations for company organisation.

The following areas must be available, at a minimum:

1. Toilets and hand washing stations
2. Changing rooms
3. A product reception area
4. A product processing area (sorting, quality control, washing, calibration, packing, etc.)
5. A packing materials storage area
6. A storage or warehousing area (refrigerated)
7. An area for waste
8. Rooms to store inputs
9. Separate offices, laboratories, etc.

5.4.2. Buildings and structures

*Premises must be designed, built and laid out, and of dimensions suitable to enable the implementation of **good hygiene practices** and notably to **prevent any contamination** of foodstuffs.*

(Photo B. Schiffers)

- ***Surfaces*** (floors, walls and ceilings) must be well-maintained and in good repair and easy to clean and/or disinfect. They must be made of hard, non-absorbent, washable and non-toxic materials.

- ***The premises***, including the toilets, must be adequately ventilated. Air flows must be avoided between dirty areas and clean areas.

- ***Ceilings*** must be designed, built and maintained to prevent dirt build-up, condensation, moulds and the accumulation of particulates.

- ***Safety lighting*** must be used (with protective plastic covers or sheathing to ensure that any broken glass stays in the protective system). However, they are only compulsory when there is a real danger of product contamination, that is, when lighting is installed directly above the harvested plant products.

- ***Replace*** all broken (broken, cracked) windows, lamps, mirrors etc.

- ***All openings*** (doors, windows, etc.) must remain closed and must be equipped with a system to prevent entry by pests (insects, rodents, birds, animals etc.).

- ***Storage and packing buildings*** must be at a sufficient distance from waste, debris and rubbish areas (e.g.: sorting rejects).

- ***When fuel tanks are located in the production***, processing and/or storage area, there must be a safe distance between the tank and the primary products (at least four meters or a physical separation).

❑ **Toilets and hand washing stations**

Hand washing stations (Photos B. Schiffers)

- It is essential to have clean and well-maintained toilets and hand washing stations to promote employee hygiene and cleanliness to reduce contamination risks for fruits and vegetables, particularly those due to faecal matter.
- The premises must have a sufficient number of toilets. They must be equipped with a flush system and be connected to an effective wastewater evacuation system. The toilets must be kept clean at all times.
- Toilets and urinals cannot be directly accessible from the working areas. They must be located far enough away from the product handling areas but laid out in such a way to ensure that employees can consistently wash their hands before starting their shift, every time they leave the packing chain and after using the toilets.
- There must be a sink in or near the facilities. It must be supplied with hot and cold water and with products to wash and dry hands hygienically (paper towels). The toilets and hand washing stations must be cleaned regularly.
- The use of air dryers is forbidden on premises where there is unwrapped or unprotected food.

❑ Changing rooms

- Employees must be prohibited from drinking, eating or smoking in work areas.
- In addition, employees should not bring personal effects (jewelry, watches, coins, etc.) into the packing area.
- In order to facilitate compliance with these measures, there should be changing rooms in the station and steps should be taken to ensure that workers can securely keep their personal belongs in lockers, closets or cupboards with locks.
- Workers should share lockers if there aren't enough of them.

❑ Product reception area

- It's essential that packing buildings, equipment and areas be **clean and well-maintained.**
- It is important that packing areas not be contaminated by materials from the fields when the harvest crates are received.
- It is **recommended that part of the reception area be set aside for cleaning pallets** and the containers used to transport fresh products. Animal and plant waste must be removed from the surface of pallets, crates, etc.
- The harvest reception area can also be used for **lot identification** depending on the source of deliveries, within the framework of traceability follow-up.
- **Fresh fruit reception areas must be clearly separate from processed product storage areas (cardboard boxes).**
- Reception areas should be large enough to cover all products and protect them from rain and sun.
- They should be sufficiently well lit with natural or artificial light to facilitate visual examination of stocks and detection of infestations.
- No containers or bins for fruit, vegetable or food waste should be in storage areas to prevent cross-contamination.
- Adequate measures should be taken in storage areas to repel or eliminate pests (traps). Bait for pest traps should be covered to avoid all product contamination.

❑ **Sorting and product preparation area**

- Following reception and identification of the lots, the products must be moved to the processing area for sorting, quality control, weighing, washing, calibration... and packing **in line with the principle of 'fo**rward progress'.
- In order to reduce the risk of contamination, it is important not to mix **received product flows** (unprocessed products) with packaged product flows (processed products).
- Clear markings on the ground and/or signage panels can be used to indicate zones and raise employee awareness.
- It must be far from the waste, debris and scrap areas.
- It should be sufficiently well lit with natural or artificial light to facilitate visual examination and the detection of infestations.
- **Covered bait** and all other means of fighting against pests (traps) must be located in the processing and/or packing areas.

❑ Storage or warehousing area for sorted products

- In order to comply with the principle of forward progress, the storage or warehousing area must be located just beyond the packing line.
- It must be set up according to temperature and humidity guidelines defined to maintain the stability and good conservation of fresh products.
- Storage and warehousing is generally located in **coolers**. The person responsible for the coolers must comply with two principles:
  1. Group products by category of fruit and vegetable and by lot. To ensure product traceability by lot, it is essential that they not be mixed up when they are stored.
  2. Put the first products lots received in front and the last ones behind and, if possible, take the shipping schedule into account. **Since fresh products are perishable, they must be stored for as short a time as possible**. There must be passageways to be able to access the products for removal.

❑ Fertilizer and pesticide storage rooms

- It is forbidden to store fertilizers or pesticide products near food products. They must be kept in a separate location, in locked rooms which are not accessible to untrained persons or children.
- There should be no direct access between the fertilizer and pesticide storage rooms and other areas.
- The storage rooms must have a threshold and be designed to prevent any product run-off or leakage outside of the room.
- Otherwise, chests or cupboards with locks should be used. They should be located away from the product processing, packing and storage rooms.
- Solid fertilizers can be stored in bulk in a clean and dry area. This area should have a hard floor (there should never be any risk of groundwater contamination).
- Premises should be dry and protected from rain.
- Good ventilation: there should be a screened opening for ventilation.
- They should be sufficiently well lit with natural or artificial light to facilitate visual examination of stocks and the detection of leaks.
- There should be no desk in the storage rooms.

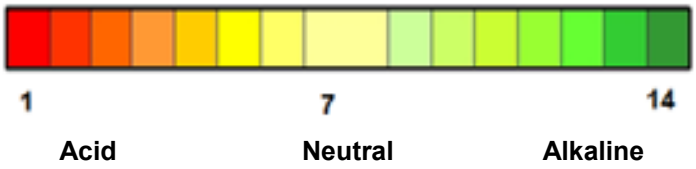
5.4.3. Cleaning and disinfection of the premises

❑ **Cleaning**

Cleaning consists in **eliminating dirt etc.** using mechanical and/or chemical methods (to make surfaces clean to the eye) to ensure cleanliness, hygiene, aesthetic appeal and preventive maintenance of surfaces and buildings.

Four factors are required for effective cleaning: temperature (water), action time (time of contact), mechanical action (depending on intensity) and chemical action (concentration).

Cleaning is carried out with (authorized) detergents,[9] selected based on the type of dirt and residues and the surfaces to be cleaned. **Detergents can be differentiated by their pH.** There are acid, neutral and alkaline detergents.



What should be cleaned?	Frequent examples	What pH?
From organic sources (animal, plant or human: oil, grease, wine, blood, urine, etc.)	Fresh protein and fat deposits	A good degreaser, pH between 6 and 8
	Cooked fats	Alkaline degreaser, pH between 9 and 12.5
	Grease, mechanical oils, burnt grease, etc.	Very alkaline degreaser pH between 13.5 and 14
	Very sugary residues	Acidic detergent pH < 6
Mineral sources (tartar, cement, plaster, rust etc.) They leave a film on surfaces.	Tartar (calcium)	Acidic detergent pH < 6

[9] The European 'biocides' directive (98/8/EC) requires that disinfecting products and insecticides sold for use in the agri-foods industry be certified. The approval of disinfectants for use on harvest, transport and storage rooms and equipment for products from animal and/or plant sources (PAO/PVO) is normally compulsory in the agri-foods industry.

General cleaning safety rules

- Train employees in cleaning and disinfection tasks.
- Wear tighter fitting clothing suitable for the products being used (caustic, aggressive on skin and eyes) to avoid accidents.
- **Never mix cleaning products**!
- Do not transfer products into unlabelled containers.
- Do not enter refrigerated areas when they are being disinfected.

Chlorine + Acid → Release of toxic gas!

(e.g.: Bleach + Acidic detergent)

Alkaline + Acid → Loss of effectiveness! (neutralization)

Water quality, and notably its '**hardness**',[10] also plays a part in the effectiveness of cleaning:

- water that is too hard (over 35 degrees of hardness) can alter the effectiveness of the products used (requiring the installation of water softeners);
- when water is too soft, **rinsing becomes difficult.**

❑ **Disinfection**

This operation is intended to **temporarily reduce the total number of living bacteria** and destroy pathogenic germs (this is different from sterilization which is intended to create a bacteria-free environment).

This operation uses disinfectants (**biocides**) authorized for this purpose and selected based on the types of micro-organisms to be eliminated and the surfaces to be cleaned.

[10] Note that hardness indicates the water's mineral content. It is primarily due to calcium and magnesium ions. Water hardness is expressed in mg/L of $CaCO_3$ or in French degrees.

Five different product types come under the term disinfection:

- *bactericides*: Products that kill bacteria
- *yeasticides*: Products that kill yeasts
- *fungicides*: Products that kill fungi (yeasts and moulds)
- *sporicides*: Products that kill bacterial spores
- *virucides*: Products that deactivate viruses

A given disinfectant may be a bactericide only, whereas another may combine a bactericide, a fungicide and a virucide.

The effects of disinfection are limited to the micro-organisms present at the time it is done. **Disinfection does not prevent later contamination.** This is why it is important to repeat on a regular basis!

*To be authorized for use with food, the disinfectant products used must comply with **European standard NF EN 1276 March 2010**.*[11]

*This is an 'application' standard which defines the **conditions of effectiveness of the disinfectant** (application dose, etc.) for a given use.*

❑ Premises cleaning schedule

A cleaning and disinfection plan suitable for the premises and identified risks must be designed and implemented.

Frequency, maintenance and the products authorized for cleaning (packing rooms) are all listed on the cleaning plan for the premises:

- ***daily floor cleaning*** with emphasis on the dirtiest areas;
- ***weekly cleaning and disinfection*** at a minimum, conveyor belts and areas in contact with the fruit;
- ***regular cleaning of walls***, partitions and doors, **at least *tw*ice a year.**

The premises must be clean and well maintained. Storage areas must be kept clear of any unused items and of all debris and other visible dirt at all times. **Sorting scraps, waste, damaged and rotten products must be removed from the premises on a regular basis**. Animal excrement cannot be present on the premises.

Exhaust fumes must be avoided on the premises insofar as possible. Ensure that the least amount of exhaust fumes possible enters when products are received.

[11] Standard NF EN 1276 March 2010 (Chemical antiseptics and disinfectants – Quantitative suspension test for the evaluation of bactericidal activity of chemical antiseptics and disinfectants used in food, industrial, domestic and institutional areas).

❑ **Cold storage cleaning and disinfection**

Cold storage (floors, walls) must be cleaned and disinfected on a suitable and regular schedule (e.g.: **twice a year**).

Several processes can be used to disinfect storage areas.

Fumigation, fogging and thermal fogging enable the disinfectant to get to areas that are difficult to reach and simultaneously ensure disinfection of walls, evaporators and the air.

Ventilation will help good dispersion. Some products are approved for use around packing materials.

❑ **Cleaning and disinfection risks**

Source of the hazard:	**Management measure:**	**Proof of control:**
Product contamination by cleaning solvents, detergents and biocides	All chemical cleaning products must be compatible with food use. List the authorized products Train employees	Check product labels File all safety data sheets List of products authorized for use at the company
Odors and infection by other food products, disinfectants and fumes	All chemical cleaning products must be compatible with food use and may not contain fragrances. Some food products will give off a smell. Chemical products must be stored far from food products.	Check product labels. Keep all chemical products separate from food products.

5.4.4. Pest Control

All pests, birds, rodents and insects are potential vectors of microbial contamination of fresh fruits and vegetables. Problems caused by pests can be countered by taking the following precautions:

1. Implement a pest control plan

A pest control plan must be implemented at all installations. This is key to reducing the risk of contamination by animals such as rodents. To ensure effectiveness, the plan must include regular and frequent inspections of areas that may harbor an infestation.

Inspection dates, reports and measures taken to correct each problem should be recorded in a log book. A pest control programme should also include frequent visits to areas infested and treated to evaluate the effectiveness of the protection or eradication method used.

2. Keep the premises well-maintained

There should be no garbage or residues in the immediate vicinity of packing areas. All grass-covered areas where certain types of pests such as rodents and reptiles may reproduce, nest or feed should be cut or mowed.

The premises should be cleared of any unused, obsolete or broken accessories and equipment to prevent rodents, reptiles or insects from living in them. Discarded fruit and vegetables from the harvest can attract pests and should be removed daily from processing and storage areas as well as from their vicinity.

Good drainage will help control pest reproduction and proliferation.

The seven golden rules of rodent control

1. Use specific products for the rodents found.
2. Put out traps every 5 to 10 metres along walls and in corners. Do not put traps near droppings (leave a space of one metre at least). Put the traps at ground level to ensure that they won't fall on food.
3. Use enclosed traps: rodents are fearful by nature and bait should preferably be set in boxes where they will eat more.
4. Put traps out in all areas that may be home to rodents as well as around the building.
5. Lay out traps in all rooms except processing rooms.
6. Clean the premises.
7. Bait until eating stops.

Pest control must be done by professionals.

Source of the hazard:	**Management measure:**	**Proof of control:**
Pest contamination	Buildings must be designed to prevent entry by pests. Doors must remain closed at all times when not moving about. It is preferable to have both outside and inside doors. Use screens treated against insects when windows must stay open. Check that there are no pests in wastewater evacuation areas. There should be no waste, grass or garbage in the area around the packhouse.	Professional rat extermination log.
Contamination by faecal matter or dead organisms	Products must not be placed under bird perches. Always use the services of a known pest control professional unless there is sufficient expertise in-house.	Service contracts

5.5. Post-harvest: Manpower requirements

5.5.1. General employee hygiene measures

The bodily hygiene and cleanliness of employees is essential to fighting the risk of microbial contamination. Employees can involuntarily contaminate fresh fruits and vegetables (direct contamination), water resources, the equipment used or other workers and spread pathogenic micro-organisms if they don't follow essential hygiene rules.

Recent cases of food poisoning linked to the consumption of fresh fruits and vegetables have often been caused by **contamination by faecal matter.** Priority must therefore be given to elementary hygiene practices such as **wearing suitable clothing and regular hand washing**!

In addition, employees suffering from infectious diseases, health issues with diarrhea, or open wounds are a source of pathogenic agents.

❑ Employee cleanliness and clothing

Clothing should be adapted to the product: apron closed to the neck, a hair net, boots, gloves, etc. (Photo B. Schiffers)

Employees working in the stations must have good bodily hygiene habits and wear clean clothing.

Proper hygiene protects workers from illnesses while reducing the risk of transmission to fresh fruits and vegetables of pathogenic agents that could infect a large number of consumers.

❑ The importance of hand washing

Hand washing before entering the station (Photo B. Schiffers)

Employees must wash their hands when handling fresh fruits and vegetables or any other equipment that comes into contact with them.

Before handling fruits and vegetables, **employees must wash their hands every time they return to the handling areas after a break, immediately after using the toilets,** and after handling contaminated products.

It is imperative that employees carefully wash their hands before starting work and after using the toilets.

Many pathogenic agents responsible for food poisoning can be found living in the intestinal tract and in faecal matter. Workers generally do not know **how to wash their hands correctly**. They must be taught the following rules:

- hands must be washed with water;
- soap must be used;
- brushing (notably under nails and between nails), rinsing and drying must be done carefully;
- sharing towels is not recommended.

Main station hygiene rules

- Smoking is forbidden in the packhouse.
- An overall must be worn. Hair must tied up and nails must be trimmed and clean.
- Hands must be washed every time the toilets are used.
- Hands must be washed after handling dirty materials.
- Wear appropriate and clean clothing.
- Avoid coughing or sneezing on food products.
- In the event of an injury to hands, disinfect and wear a waterproof plaster.
- Remove all rings, bracelets and watches.

❑ **Measures related to access to the premises**

The operator and their employees must know all hygiene measures (clothing and hand washing) and comply with the company's general hygiene rules.

Visitors and employees must be informed of hygiene measures within the company and the industry.

5.5.2. Personal behavior

Agricultural workers must avoid behavior that could lead to food contamination. This includes smoking, spitting, chewing gum, eating, sneezing or coughing near unprotected food.

Personal effects such as jewelry, watches and other items must not be worn or brought into the fresh fruit and vegetable production areas if they are a risk for the health and acceptability of the food.

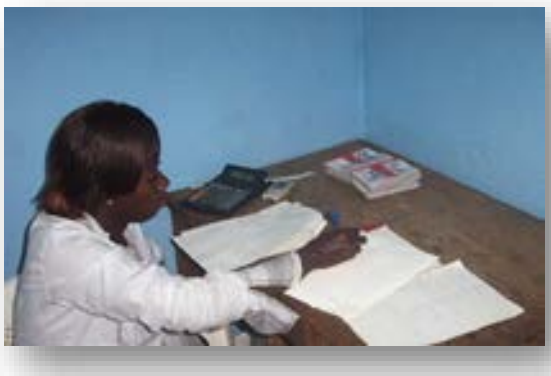
Under some circumstances, disposable gloves can be very useful to supplement hand washing. **If gloves are used, care should be taken to ensure that they do not become a vector for spreading pathogenic agents.** The use of gloves should in no way be a substitute for other indispensable hygiene measures such as hand washing.

Agricultural workers must avoid behavior that can lead to contamination of fruits and vegetables, for example, **smoking, spitting, eating or sneezing** directly on or near uncovered products. Personal effects such as jewelry, watches and other items must not be worn in the production areas, particularly in the packhouses.

Health measures applicable to all people working in the food sector are also applicable to those in the primary sector.

All visitors to the fields and, especially, to the packhouse must be required to follow the hygiene practices in effect when they handle fresh fruits and vegetables.

5.5.3. Employee health



Anyone suffering or believed to be suffering from an illness or health complaint should be refused entry to the product handling areas. Anyone in this case must immediately inform management of the illness or the symptoms.

Maintaining employee records.

Employees suffering from health issues with diarrhea or open lesions (skin lesions or infected wounds) are a risk vector. Persons with cuts or wounds must cover them to avoid all direct contact with products. A purulent lesion or infected wound can contaminate fresh fruits and vegetables or equipment used for harvesting, sorting and packing on contact. A training plan must be implemented to teach management personnel about the typical symptoms of infectious diseases.

Some typical symptoms of infectious diseases

Illness	Symptoms
Hepatitis A virus	Fever, jaundice
Typhi salmonella	Fever
Shigella strains	Diarrhea, fever, vomiting
Norwalk virus and related	Diarrhea, fever, vomiting
Staphylococcus aureus	Diarrhea, vomiting
Streptococcus pyogenes	Fever, angina with fever

5.5.4. Employee training

All employees (team leaders, full-time and part-time employees and seasonal workers) must have practical knowledge of basic health rules for the position they work in.

A training programme must be defined based on the risks identified.

All personnel must be trained in good health practices. **Every employee must understand the food contamination risks** for their position caused by unhealthy practices and poor personal hygiene.

It's important to teach workers how to correctly wash their hands, how to avoid contaminating water resources and how to prevent spreading of micro-organisms that can cause food poisoning.

5.5.5. Summary of staff-related control measures

Source of the hazard:	Management measure:	Proof of control:
Contamination by jewelry, clothing and foreign bodies	Do not carry around jewelry that is not being worn in packing areas. Implement a policy for tobacco, food and drinks. Provide separate smoking areas. The metal detection system must be operational.	Keep a record of hygiene training. Ensure that staff knows the policy. Implement signage.
Microbial contamination via dirty clothes or hands, unhygienic habits and infectious diseases.	All staff (and visitors) must wash their hands before entering the packing areas and after using the toilets, eating or drinking. Toilets and washing areas must be provided. Employees must report all illnesses that could be transmitted by food, including jaundice, fever and diarrhea, and infected injuries, skin problems, runny eyes, ears or nose. Personal behavior such as spitting, sneezing and coughing on products. Wear clean clothing in the packing areas.	Staff must be able to demonstrate that they have been trained. Management must provide proof that training records exist. Medical screening and employee reports Personal hygiene and training in appropriate behavior Cover all cuts, abrasions and wounds with waterproof plasters with a metal band. Raise employee awareness
Toilets	Install an appropriate number of toilets for workers and ensure that they are kept clean. Separate the women's toilets from the men's toilets. Provide soap, clean water and paper towels. Install hands-free, foot- or piston-operated taps to reduce the risk of re-contamination.	Cleaning programme.

5.6. Post-harvest: Equipment requirements

5.6.1. Facilities and equipment maintenance

All sorting, calibration and packing equipment can spread pathogenic germs to the products with which they come into contact. **All earth and debris must be removed from the equipment daily.** Packing, washing, sorting, calibrating and packaging lines must be cleaned and disinfected. Accessories such as knives, saws, blades, boots, gloves, overalls and aprons must be cleaned and inspected on a regular basis. They must be replaced if their condition precludes cleaning.

All equipment must be designed to facilitate cleaning. These factors, and the way the equipment is used can contribute to reducing the risk of contamination.

5.6.2. Container hygiene requirements

❑ **Container and packing materials hygiene**

Containers and packing materials that come into contact with fresh fruits and vegetables must be made of non-toxic materials. They must be designed and made in such a way as to facilitate washing, disinfection and maintenance. Specific hygiene requirements for each piece of equipment used must be set based on the type of fruit or vegetable.

❑ **Some general rules for containers**

Cleaning containers in the field (Photo B. Schiffers)

- Design a cleaning programme for containers and packing materials. Create a log to record all cleaning and maintenance operations carried out on containers and packing materials.
- After unloading, always clean the containers, tubs, etc. used to avoid cross-contamination of fresh fruits and vegetables.
- Before loading, inspect the containers and packing materials to check their smell and ensure they are clean.
- Take into account the previous loads for which the containers were used before using them for another load. For example, containers used to transport non-food products can contaminate fresh fruits and vegetables if they are not cleaned between loads.
- Regularly inspect containers and packing materials (cases, crates, trays, etc.) to check for any damage that could become a source of pathogenic bacteria and damage the surface of fruits and vegetables.

- Repair or throw out all damaged cases and crates. Any packing materials that do not meet hygiene criteria must be thrown away.
- Protect cleaned containers and new packing materials from contamination during storage. All packing materials must be protected from contamination by pests (such as rodents), dirt, etc.
- Containers must be cleaned and sanitized before use if they are stored away from the packing area.
- Containers intended for waste, by-products, and non-edible or dangerous substances must be specially marked.
- Use pallets to avoid putting packing materials in contact with the ground.
- If possible, avoid using the same crates for different types of products in order to reduce the risk of cross-contamination. If need be, use color coding to differentiate containers.

Source of the hazard:	**Management measure:**	**Proof of control:**
Product contamination by cleaning solvents, detergents and biocides	All chemical cleaning products must be compatible with food use. List the authorized products Train employees	Check product labels File all safety data sheets List of products authorized for use at the company
Contamination of packaging and packing materials	All materials must be stored in clean and dust-free areas. All packing materials must be made of food grade materials.	Building cleaning programme
Containers dirtied by inappropriate use or because there is no cleaning programme in place	Ensure that containers are used only for a given product. Container cleaning programme	Container logs Cleaning record
Contamination of pallet and crate wood	Try not to use unpolished wood where products are handled. Wood surfaces must be covered with paint to enable easy cleaning.	Routine inspections

5.6.3. Cold chain management requirements

Maintenance of cold storage areas is essential (Photo B. Schiffers)

Cold storage equipment must be maintained in good operating order. Cooling equipment must be inspected daily. All debris must be removed and the equipment must be cleaned if necessary. The facilities must be inspected on a regular basis to detect pest infestations and possible animal-based contamination. All food and water sources that can be used by pests must be removed.

All animals (e.g. birds, mice) and insects that have died or been locked in the facilities must be removed immediately to ensure that the premises remain healthy and to avoid attracting other pests that eat these species. Eliminate all areas in which pests can hide or reproduce insofar as possible.

5.7. Post-harvest: Material requirements

5.7.1. Water quality

Water is used for many purposes in the agricultural sector: irrigation, dilution of pesticides, fertilizer spraying, washing, facilities cleaning, etc.

It can be a major source of direct or indirect contamination and spread micro-organisms in crops, on farm installations and throughout the transport chains. All water coming into contact with fruits and vegetables is **a potential source of pathogenic agents** which can live on products and threaten consumer health. Several factors impact the spread of pathogenic agents and, therefore, the risk of food poisoning:

- the type of crop;
- the time between the exposure to contaminated water and harvesting;
- the methods used to handle the harvested products...

All sources of farm water contamination must be researched and controlled. This exercise may seem difficult in ACP countries because water sources are inconsistent (distribution networks, bore holes, running water, ponds, irrigation channels, and open canals, lakes, rivers, wells, etc.).

The level of contamination of fresh fruits and vegetables by dirty water depends on the source of the water and on the way and time of its use as well as on the characteristics of the crop.

Large surface vegetables (leafy vegetables) and textured vegetables (for example, rough leaf) that can catch and hold micro-organisms are more prone to contamination, especially if contact with water occurs a short time before harvest or during the steps that follow harvesting.

To better assess the quality of water used on their farms and select the management measures to control food contamination risks, operators should use the practices best-suited to their particular case to reach the food health objective sought.

❑ **Water contamination on the farm**

Surface water can be contaminated intermittently by leachate from upstream breeding farms, cattle entering the water, the flushing of toilets into the water reservoir, etc. **Ground water** is more vulnerable to contamination (cracked sceptic tank, etc.) Whenever possible, all sources of potential water contamination on the operation should be researched and controlled using appropriate methods. Several measures can be used: building suitable septic tanks, the installation of bio-treatment systems for faecal matter, **the use of irrigation methods that limit or avoid contact between water and fruits and vegetables** (e.g. avoid overhead spray irrigation and use drip irrigation).

Source of the hazard:	Management measure:	Proof of control:
Flood water and roof leaks	The building must prevent the entry of rainwater. Site drainage must be sufficient to ensure proper hygiene.	Site inspection.
Recycled water	Should not come into contact with the finished product. Only use drinkable water.	Take a sample to check the microbial level if using recycled or filtered water.
Contaminated cooling water	Check if water is contaminated by dirty products or at its source.	Take a water sample. Assess the risks. Equipment maintenance and cleaning programme.

❑ Drinking water quality

Water coming into contact with food (including rinse water after cleaning) must be drinkable. To be considered 'drinkable', the water must meet certain micro-biological and physico-chemical criteria.

Water drinkability: micro-biological criteria (French regulations)

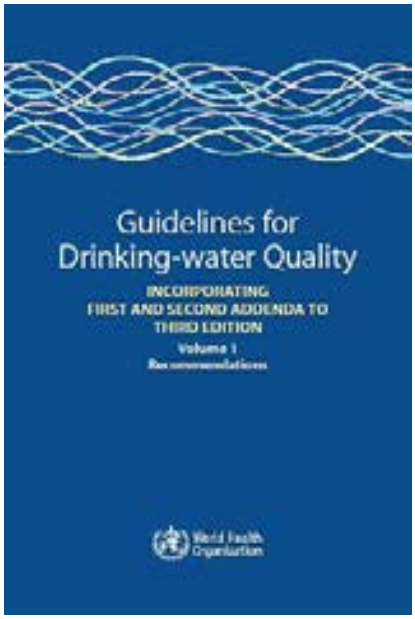
Micro-biological standards	Expression of results in:	Maximum allowable concentration
Total coliform (*)	100 ml	0
Thermo-tolerant coliform	100 ml	0
Faecal streptococcus	100 ml	0
Sulphite-reducing clostridia	20 ml	1
Salmonella	5 l	0
Pathogenic staphylococcus	100 ml	0
Enterovirus	10 l	0

(*) At least 95% of samples taken should not contain total coliform in 100 ml of water.

Water drinkability: physico-chemical properties

Physico-chemical criteria	***Results expressed in:***	***Maximum allowable concentration (drinking water in France)***	***European directive***
Temperature	°C	25	12
Hydrogenic potential	pH units	6.5 < pH < 9	6.5 < pH < 8.5
Chlorides	mg/l Cl	250	25
Sulphates	mg/l SO_4	250	25
Magnesium	mg/l Mg	50	30
Sodium	mg/l Na	150	20
Potassium	mg/l K	12	10
Total aluminum	mg/l Al	0.2	0.05
Nitrates	mg/l	50	25
Hardness	French degrees	50	-
Dry residues	mg/l (dry at 180 °C)	1500	-

If the company does not have a drinking water supply, it must treat its water with sodium hypochlorite (bleach) to obtain 1 to 2 mg/l of active chlorine in the water to make it drinkable. The concentration of active chlorine in the treated water must be checked every day.



WHO publishes international guidelines for water quality standards and human health. These are used as the basis for regulations and standardization around the world.

http://www.who.int/water_sanitation_health/dwq/

5.7.2. Packing materials: type of materials and hygiene

Packing materials (e.g. cardboard boxes) must be stored in **hygienic conditions** to ensure that they are not damaged and do not become sources of food product contamination.

When cardboard boxes are kept in bulk as shown in this photo, it's impossible to be sure that there will be no contamination.

Well-stacked boxes, kept off the floor by a clean pallet.
(Photo B. Schiffers)

The design of the packing materials must provide maximum protection for food products to effectively reduce contamination, prevent damage to **foods and enable adequate labelling:**

- **packing materials** cannot be **toxic** (solvents in plastics, marking inks, label glue, gas injected into the package, etc.)
- Reusable packing materials (used for exchanges between companies) **must be easy to thoroughly clean and disinfect** (glass, plastics). Reuse of the packing materials must be forbidden when these conditions are not met.

5.8. Post-harvest: Operational requirements

5.8.1. Unloading fruits and vegetables at the packhouse

Foreign bodies can find their way into containers during unloading if handling is not done carefully: containers on the ground, improper stacking of containers of different sizes or types, etc.

Physical risks are primarily the result of pieces of packing material or handling equipment falling into fruit or vegetables at harvest time, during transport or during packing. A foreign body that finds its way into products during packing is difficult to find once packing is finished.

Special care is required during this step! A monitoring and control plan for foreign bodies must be set up to detect them. The use of a check-list is often very effective.

5.8.2. Product cleaning and washing operations

Basin for washing mangoes by immersion (Photo B. Samb)

Washing fresh fruit and vegetables when they are brought in from the fields can reduce the risk of microbial contamination.

This step is key because most pathogenic agents are found on surface areas. If these agents are not eliminated, neutralized or controlled, they can propagate and contaminate a large portion of the harvest.

It's most effective to clean fruits and vegetables with brushes but these need to be cleaned on a regular basis.

Vigorous washing that doesn't damage the fruit or vegetable can help to eliminate pathogenic agents from the surface of harvested products. Washing with water, which may be treated with an anti-microbial agent (bleach, etc.), reduces the load of pathogenic agents on the product surface **but does not eliminate them entirely**. When a disinfectant is used, the microbial load can be reduced 10 to 100 times!

In some cases, it's preferable **to wash the products** several times. Treatment can begin with a first wash **to remove soil.** This is followed by several other washes and/or soaking in a 'disinfecting' solution (the term 'sanitize' rather than 'disinfect' is used!) and lastly by a **rinse in cool drinkable** water.

Depending on the product, the wash can be done by immersion, spraying or by a combination of the two. Normally, **washing with sprayed water is less likely than immersion to spread pathogenic bacteria found in harvested products**.

In addition, **wash water can contribute to spreading if** it is re-used. Regardless of the wash method selected, operators should use adequate measures to ensure the ongoing quality of the water used.

5.8.3. Grading and packing operations

Grading and packing installations vary tremendously between companies in terms of the complexity of their systems and facilities. Grading and packing areas can potentially harbor significant levels of contamination if hygiene measures are not well implemented. **Calibration and packing buildings must be designed to enable adequate maintenance and cleaning**. The buildings must be well ventilated to avoid condensation. Dust control systems must be installed, that is, exhaust fans and sufficient lighting.

Products coming from multiple sources are handled and shipped from the calibration and packing lines. If the cleaning schedule is not adhered to**, a lot can contaminate several other product lots** intended for different markets.

Products are not solely responsible for packhouse contamination. Since there are many workers on the lines, employees are a potential and significant source of product contamination if high priority is not given to health rules and personal hygiene.

All products coming into the packing area must be clearly identifiable. Lots from multiple sites must be identifiable.

Packed products (cardboard boxes, pallets) **leaving the packing site must all be identified and labelled**.

5.8.4. Machine and equipment monitoring

Manufacturer instructions must be followed carefully and filed in order to reduce risks linked to the use of machines and equipment in the field (tractors, generators, pumps, etc.) and the packhouse (calibrators, sorters, packers, forklifts, etc.).

All machines must be on a m**aintenance and servicing plan**:

- Set up a maintenance and servicing plan for machines based on manufacturer instructions: greasing, oil change, parts replacement.
- Check for leaks and immediately fix them (fuel or oil) on machines that can soil fruits and vegetables directly or indirectly.
- If oil changes are done in the field or station, all measures must be taken to ensure that they are done far enough away from crop growing and storage areas.
- Sorting, calibrating and packing lines must carefully follow the servicing and maintenance programmes implemented to avoid contamination of foodstuffs and to prevent technical failures.
- A cleaning and maintenance programme must be set up for cold storage. The various components of the cold storage systems, electrical outlets and light covers must be checked on a regular basis.

5.8.5. Post-harvest treatments

Treatments carried out after harvest include:

1. The application of **pesticides, waxes and preservatives** after the harvest. The use of pesticides after harvest is **a real threat** to the safety of food products because **MRL's can be exceeded** since application takes place close to consumption time.[12] The application method must be complied with and the interval between pesticide application after harvest and consumption must be known. All restrictions on the use of products required by regulations and clients must also be complied with.
2. The application of **chemical cleaning products.** The use of chemical cleaning products in calibration and packing areas can also lead to contamination just before consumption.

Source of the hazard:	**Management measure:**	**Proof of control:**
Non-approved materials (waxes, polymers, etc.)	Only use authorized waxing agents.	Check product labels.
No file on the source of the products (this is important when withdrawing a product and for recording pesticide use).	It must be possible to trace the identity of each lot at each step of the harvest and production and back to the seed source.	Keep files from planting through harvest.
No complete file on pesticides.	All details about applications on crops must be kept current and filed for three years.	Ensure that files actually exist.
Risk of crop	Only qualified personnel is allowed	Check staff certificates and

[12] The results of monitoring programmes in Europe have shown that MRL's are exceeded in many instances by treatment occurring after the harvest of bananas, citrus fruits, etc.

contamination by pesticides due to poor dosage and poor application practices.	to apply pesticides. Provide training.	files. Inspect the storage areas. Application file
Risk of applying the wrong pesticide on products.	Ensure that there is an updated and approved list at the national level and by the client at the commercial level.	Updated list of approved and authorized pesticides. Provide the exporter with a list of proposed pesticides before the beginning of the season.
Risk of crop contamination by pesticides due to poorly calibrated spraying equipment.	Carry out the scheduled maintenance and equipment calibration.	Record the calibrations done.
Crop contamination due to the use of dirty water in the sprayed solution.	Carry out a risk assessment of the water source taking into consideration the likelihood of human and animal contamination. Regularly check potential sources of microbial risk (maximum 1000 CFU per 100 ml for faecal coliform). The water used for the last rinse must be drinkable.	Ensure that the risk assessment is available for inspection if requested. Take water samples and file the results.
Crop contamination due to the inappropriate location or insufficient security of the storage area.	Storage located away from waterways. Ensure that the exteriors of buildings are sound, safe and protected by a low wall. Permanent shelves with adequate lighting and ventilation. Inventory control.	Carry out a regular audit of the buildings and their content.

5.8.6. Management of non-compliant products – Waste management

Non-compliant products must be placed in a **clearly identified area.**

It's important to remove waste quickly and effectively to decrease the probability of contamination. Waste must be removed **daily at least**. Waste storage must be located far from packing areas and must be outside of the buildings.

Source of the hazard:	**Management measure:**	**Proof of control:**
Non-compliant products due to soiling, damage,	Processing of discarded products should be done in a special area to avoid cross-contamination.	Waste management plan (inventory, classification, collection, storage,

excessive splintering or non-compliance with specifications.	Facilitate waste removal.	elimination, treatment and recycling measures). Personnel management

5.8.7. Storage and inventory management

Storage areas must be located away from areas at risk of flooding and industrial pollution. They must include a wastewater evacuation system, be kept at the right temperature, be easy to clean and maintain in good hygienic conditions.

Poor inventory management can lead to product deterioration and the risk of microbial contamination. Raw materials, work in progress, packing materials and finished products must be properly labelled **to enable effective inventory rotation based on the FIFO method** (First In, First Out).

Microbiological analyses of products at every step can be requested or carried out by certain demanding clients (total flora, moulds, yeasts, *E coli*, salmonella, *staphylococcus*, etc.)

Source of the hazard:	**Management measure:**	**Proof of control:**
Harvests contaminated by pesticides before shipping from the farm.	Keep harvested products away from pesticide storage and protect the spraying equipment.	Suitable storage after harvest.
Contamination by pests before shipping.	Ensure that there are no pests in the storage areas.	Rat extermination and control.
Contamination by waste before shipping.	Remove waste often from the trimming lines and avoid accumulation.	Waste removal schedule.
Contamination by contaminated storage containers.	Ensure that a cleaning programme is in place. Do not use storage containers to transport manure, oil, fertilizers etc.	Cleaning records.
Increase in waste.	Comply with the inventory policy and ensure that all products are sent fresh and at the correct temperature.	Inventory management policy and records.

Appendices: Cleaning and disinfection

A.1. Routine cleaning and disinfection

Cleaning and disinfection should be carried out as follows:

- All cases, baskets, cans, knives and all work tools should be picked up at the end of each day.
- All waste should be scraped away and put in waste bins.
- Walls, floors and all work surfaces should be sprayed with water for a first rinse.
- A 0.5% to 1% caustic soda solution is applied manually to all surfaces to be cleaned using a sponge.
- Rinse a second time with water after 30 minutes.
- Disinfection of surfaces is done by manual application of sodium hypochlorite (bleach) with 200 mg/l of active chlorine. The basic disinfectant is '12° chlorimetric bleach' with 3.6% active chlorine. A disinfectant solution at 200 ppm is made by mixing 56 ml of base solution, which is about five large soup spoons in 10 liters of water.
- Rinse with water after about 30 minutes to remove the disinfectant.
- All work tools should be rinsed in water then placed in a 1% caustic soda solution for 30 minutes before being rinsed again and put in a 200 ppm active chlorine disinfecting solution for 30 minutes. After rinsing in water, the tools should be dried and stored until the next use.
- If need be, particularly when it's hot and the work load is heavy, cleaning and disinfecting should be done twice: once at lunch time and the second time at the end of the day. What's more, surfaces should be scraped and rinsed regularly during the work day.

A.2. Sample cleaning and disinfection programme

Area or equipment	Tasks to be completed	Detergent or disinfectant concentration	Frequency of cleaning and disinfection
Packing room (floors, walls, drains, etc.)	- Surface scraping - Water rinse - Cleaning with detergent (30 min contact) - Water rinse - Disinfection (30 min contact)	- 1% - 200 mg/l	Once a day Sometimes twice a day at lunch time and at the end of the work day.
Work tables and benches	- Surface scraping - Water rinse - Cleaning with	- 1% - 200 mg/l	Once a day Sometimes twice a day at lunch time

	detergent (caustic soda, 30 min contact) - Water rinse - Disinfection with bleach - Water rinse after 30 min		and at the end of the work day.
Toilets and premises Annexes	- Surface scraping - Water rinse - Cleaning with detergent (30 min contact) - Water rinse - Disinfection with bleach	- 1% - 200 mg/l	Once a day, generally at the end of the work day. Sometimes twice a day and as needed.
Containers, work tools etc.	- Water rinse - Cleaning with detergent (caustic soda: 30 min contact) - Water rinse - Disinfection with bleach - Water rinse after 30 min	- 0.5% to 1% - 200 mg/l	After use, the tools should be picked up and washed then disinfected and left to drip dry.
Transport vehicles	- Surface scraping - Water rinse - Cleaning with detergent (30 min contact) - Water rinse - Disinfection with bleach - Water rinse after 30 min	- 0.5% to 1% - 200 mg/l	After every delivery.
Hand washing and disinfection	- Water rinse - Cleaning with a detergent - Water rinse - Disinfection with bleach	- soap - 50 mg/l	When returning to work after using the toilets and as required.

A.3. Control of cleaning and disinfection effectiveness

The method presented below uses basic techniques that can be used in companies with basic training and equipment. Sterilized water and boxes of PCA should be easily available from a laboratory (medical center, university, analysis laboratory).

❑ Principle

After cleaning and disinfection, the microbial load is estimated by sweeping the surface to be analyzed with a sterile swab which is then transferred to sterile distilled water for dilution. The bacteria are dispersed by agitation in water and a count is made in an agar culture environment.

❑ Method

The critical areas of the company are identified. These are areas where preparation tasks requiring careful cleaning and disinfection are concentrated. Mark off an area of 100 to 400 cm^2 area. Brush with a sterile swab and transfer it to 250 ml of sterile peptone water (0.1% weight/volume). Disperse the bacteria (e.g. using a Vortex mixer) before preparing successive decimal dilutions in peptone water (0.1% w/v). Counts are made using the dilutions to seed the agar 'Plate Count Agar – PCA' for total flora. Seed the PCA Petri dishes and incubate them at 35 °C for 72 hours.

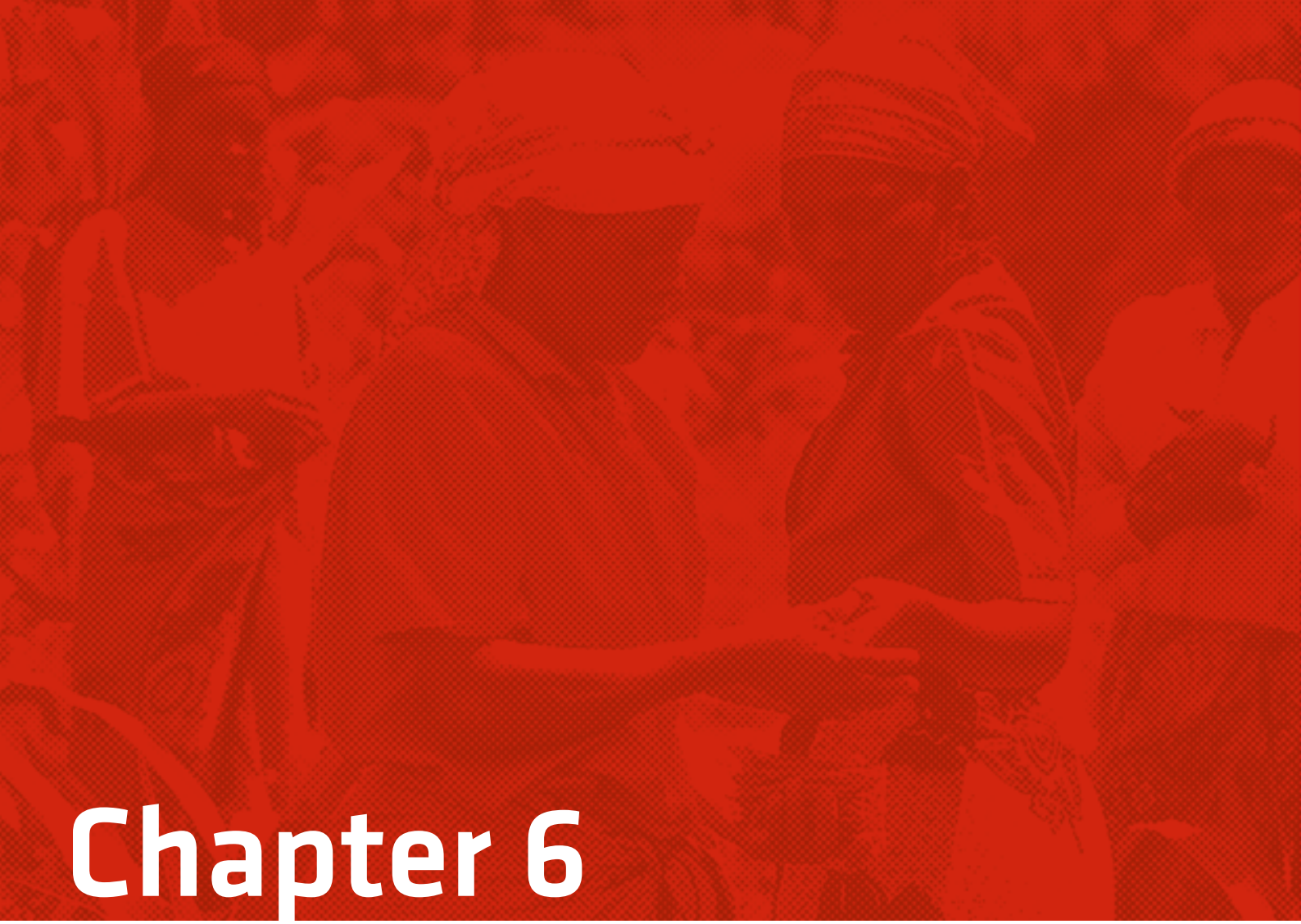
❑ Results interpretation

The effectiveness of cleaning and disinfection is evaluated based on the following table:

Bacterial load (in cfu/ 50 cm^2)	Classification
> 300	Unacceptable
100 - 300	Acceptable
10 - 100	Satisfactory

**cfu: colony-forming units*

Note that only a certain proportion (about 40%) of the micro-flora present on the surface analyzed is sampled. Results are used primarily to compare two different surfaces and study the changes in results over time to detect the build-up of 'environmental bacteria'. In which case the disinfectant and the cleaning and disinfecting programme must be changed, at least temporarily until the bacteria* are eliminated.



Chapter 6

The self-assessment system and self-assessment guides

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6.1. General principles of a self-assessment system

6.1.1. Origin of the self-assessment concept

The difficulties encountered managing food crises in past years has demonstrated the need to require that the operators[1] involved:

- implement **reliable self-assessment systems** in their companies;
- demonstrate a high level of **transparency toward official control services** and, notably, **notify** without delay all information about events that could endanger the safety of the food chain;
- implement **product traceability** to quickly organize a recall if required and, if need be, to find the contamination source.

These requirements are covered in **Regulation (EC) 178/2002**[2] which is the basis for food-related hygiene, the founder of the European Food Safety Authority (EFSA) and of the European Rapid Alert System for Food and Feed (RASFF). The regulation sets the main principles for precaution, transparency and traceability and defines the specific obligations of food chain professionals (results requirement) who must now prove that they have implemented suitable control measures to meet the objectives of the regulation.

The effect of the provisions of the 'Hygiene Package'[3] of the European regulation was to **transfer the burden of proof** for plant product compliance onto operators (it is no longer on official services when they detect non-complying products). This regulatory system is intended to:

1. set the hygiene rules applicable to all 'operators' in the food sector including **importers**;
2. make **operators liable** by making them responsible for results while allowing them the **choice of means** to achieve the results. However, regulation (EC) 852/2004 set some means which **operators must use** in order to meet the required results and to provide proof that the safety of foods from plant sources has been achieved (e.g.: use of the HACCP system to determine the safety management measures that must be applied and kept up to date within companies). A distinction must also be made between requirements tied to primary production and those for processing (such as drying, for example);
3. promote the creation and application of **Good Hygiene Practices Guides** (and self-assessment guides).

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1 By 'operator' we mean all those who are directly involved in the channel and may have an impact on the quality and safety of the product: producers, harvesters, transporters, processors, exporters etc.

2 In effect since 1 January 2005.

3 Notably, Regulations (EC) 882/2004, 852/2004, 853/2004 and 183/2005.

Operators responsible for primary production, processing, distribution and export activities for food products must implement and manage these activities in such a way as to prevent or eliminate hazards that might compromise the safety of food products or reduce to acceptable levels. Operators must be able to provide all materials (e.g., records, control and analysis results), both to the operator at the next step (e.g., the importer) and supervising authorities, to **document the compliance of their products** at **each step of their process**.

For this reason, the **company must decide on a strategy and implement 'a quality approach'** and ensure that they **always** meet all requirements for food product quality. These have increased as a result of the growing complexity of supply chains and markets.

Achieving this goal **means, first of all,** that the company must set up a '**Food Safety Management System**' (FSMS), whose extent and **complexity** will depend on:

- the target markets (e.g.: the regulatory requirements of the destination markets and the nature of the customer's in-house standards);
- the size and complexity of the supply chain (including the type of links the company has with small producers);
- the nature and type of product exported;
- the number and types of risks identified for the product.

This **implies** that a 'continuous improvement system' (P, D, C, A) be implemented by the company.[4]

Therefore, to make progress, the company must equip itself with **effective methods and tools to assess performance** and identify any dysfunctions in its management system 'Check').

Corrective measures must then be taken to improve the workings and effectiveness of the system ('Act'). The effectiveness of these measures must in turn be verified.

[4] The principle of continuous improvement is illustrated by the *'Deming* wheel'. It is characterised by a continuous loop of four repeating phases (PDCA): (1) *Plan*: the objectives to be achieved are defined (compliance with standards and requirements) and the list of control actions is planned out. (2) *Do*: the planned actions are implemented (in the procedures). (3) *Check*: verification, measurement and evaluation of the effectiveness of the actions implemented and of achievement of the objectives (e.g., MRL compliance). (4) *Act*: lastly, based on performance analysis and system results, a decision is taken to act or not, and on what (e.g., employee training).

All FSMS's must have an **internal and external 'verification system'**: this is the implementation of **self-assessment** (the word 'autocontrol' is also used).

Checks are made to ensure that the FSMS system is working well at the operator level and guarantees that the products sold comply with food safety requirements.

Self-assessment is the set of measures which the '**operator**' must implement to ensure that at every production, harvesting, transport, packaging, processing and distribution step, his products:

- Meet regulatory food safety requirements
- Meet regulatory requirements for product quality
- Meet traceability and monitoring requirements to ensure that the specifications are being complied with

Depending on their activities, the nature of their products and processes and on the potential related risks, the operators must implement control measures and procedures to guarantee the safety of their production (**hazard identification** and **risk level analysis** are therefore indispensable).

Operators must also be able to provide complete and precise **traceability** for their operations and products at all times ('traceability file').

Self-assessment implies that requirements must be complied with at every production, processing and distribution step and that compliance with the requirements **is monitored**.

Implementing self-assessment therefore provides a **guarantee** that producers are following 'Good Practices'. Self-assessment will also provide a relevant component for building their traceability system.

The implementation of well-organized and consistent 'self-assessment' is highly recommended (as is HACCP) within the context of **primary production**, but it isn't **compulsory**. Producers must, however, be able to demonstrate at all times that they are complying with good agricultural practices and good hygiene practices and record the products applied to their crops.

Note, also that **self-assessment does not necessarily have to be limited to areas related to the food and crop safety of products**. It can also include many other areas (e.g., protection of the environment, social protection, organic farming, etc.) and other requirements...as long as they are not in conflict with the regulatory requirements of product safety.

6.1.2. Building a self-assessment system

❑ **Objectives to be considered**

- Consumers must have trust. Their health cannot be toyed with, regardless of whether they are locals or foreigners. In addition to the moral dimension of putting another person's life in danger, the economic impact can be severe in terms of loss of customers and market access, social consequences on revenues, employment and poverty.

- Buyers must be given a guarantee of compliance. Products must be checked and proof must be provided that the product is safe at every step of the chain, up to the time of consumption (results requirement stated in the introduction). Note also that EU importers are held legally responsible should they bring contaminated products onto European soil.

- The control system **should not co**mpromise company profitability (effectiveness and efficiency). It would be too expensive and ineffectual to check each and every vegetable and fruit, every producer, every activity. It would also be too expensive and of questionable sustainability to certify producers on an individual, private and voluntary basis.

- The **sector's collective approach must be transparent**, credible, predictable and flexible. Thanks to the sector guide, every operator knows which good practice must be applied at every step and how to verify that they have been (self-assessment). This is possible **as long as everyone knows their individual and collective responsibilities well,** and plays their part (or runs the risk of incurring the sanctions in place). Regulatory changes can be made to the sector guide over time and good practices can be adjusted in turn to ensure that they are followed by the entire sector (**more effective communication**).

- The responsibility of countries, at both the national and international levels, can be brought to bear through **more effective and efficient official controls**. The means available are put to better use thanks to surveys at every step of the chain and for every type of operator then by targeting identified weaknesses (and no longer at local consumption points or export exit points when all of the value added to the product has made it more expensive). Capacity building needs can be better targeted and justified and therefore more likely to be met.

- The **public-private dialogue** implemented at each step of the collective self-assessment system must promote the move from an official system of control via sanctions (and of its slide into 'not seen-not done')… to a more pedagogical, proactive, cost-effective and responsible operator system.

Self-assessment must enable '**evolution without revolution**' in any given sector.

Operators who insist on **endangering the sector's collective image** will receive more effective notification of the need to react... or take their business elsewhere.

❑ A self-assessment system is built at the 'sector' level

Self-assessment should not consist in the mere application of requirements found in a generic 'checklist' (e.g., GLOBALG.A.P.). In this respect, a self-assessment system is **very different from quality standards** that issue a set of requirements that must be closely followed regardless of process specificities, the environment and operator means. On the contrary, the idea is to implement a risk analysis and practices monitoring system in the companies of a given sector. It should be **based on an in-depth exchange between all of the operators of the sector**,[5] who can then share:

- their detailed knowledge of production processes (in a broad sense);
- their knowledge of the potential hazards for this type of production;
- the ability to assess risk levels within the context of their normal work environment;
- their experience with the effectiveness of control measures for the risks involved compared to available resources;
- their interest in effective monitoring of all of the sector's products coming to market.

All of the operators of a sector must cooperate to define suitable management and verification measures and voluntarily take part in the 'Self-assessment system'. The system must be based on HACCP to ensure food safety.

Since risk analysis is reviewed periodically, sector requirements (recommended management measures and controls to be carried out) must also be updated on a regular basis. They must include the results of controls, inspections and audits carried out in the sector.

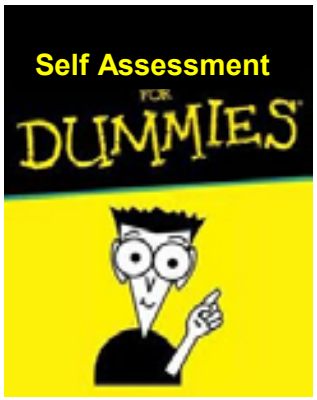
❑ Writing self-assessment guides

Each sector can write a self-assessment guide to assist operators in implementing self-assessment in their company.

They must be **approved by the supervising authority** before implementation. They will be managed and distributed by the sector's professional associations.

Companies that wish to[6] can use the guides to implement their self-assessment system and write their internal procedures. Otherwise, they must at least **keep records**.

*The guides must be based on an analysis of **the relevant hazards in the sector**, and cover topics such as Good Hygiene Practices (PRP's[7]), HACCP, traceability, control plans and notification of the authorities of non-conformities found.*



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5 The greater the number of operators of a given sector involved in the self-assessment system, the better the results will be. For it to be credible, it is estimated that 70% to 80% of operators must support the system.

6 This is still a voluntary approach and they may choose not to use the guides to develop their self-assessment system.

7 Note that these are *Pre-Requisite Programs* which precede the implementation of an HACCP system. *PRP's* refer to management measures which are not specific to a production process

Self-assessment guides must be easy for companies to use.

They must meet a certain number of criteria which are described further on.

It is valuable to write and use a guide for the following reasons:

- first, the guides provide **valuable help** for the implementation of self-assessment systems in companies, notably thanks to a description of the hazards identified, the management measures to be taken and the list of controls to be carried out (where, when and how);
- next, the guides provide the authorities with an assurance that food safety precautions will be taken and that professionals are committed to doing all of the basic controls themselves;
- and lastly, the guides enable companies to call on certifying bodies (ICO) (notably to reassure their customers) to **carry out combined audits** "validation of the self-assessment system/compliance with private specifications" and, if the results of the audits are positive, to obtain certificates.

❑ How is a self-assessment system implemented?

A **self-assessment system** consists of **two** inseparable and complementary items:

1. **Management and verification measures** (control plan) that the operator, active in a sector, implements voluntarily (self-assessment *per se*).
2. External **verification** of their quality management system (with or without certification[8]).

It necessarily implies **consultation** amongst private operators (professionals active in the same production sector) and the public sector.

The implementation of a 'self-assessment system' will provide a **guarantee of transparency and credibility** for the sector adopting the approach. It will strengthen **the confidence** of customers and the supervisory authorities in the health quality management systems implemented in the sector's companies.

The implementation of a self-assessment system in a sector includes **several steps** that must be managed as a 'project' by all of the operators involved.

This can be diagrammed as follows:

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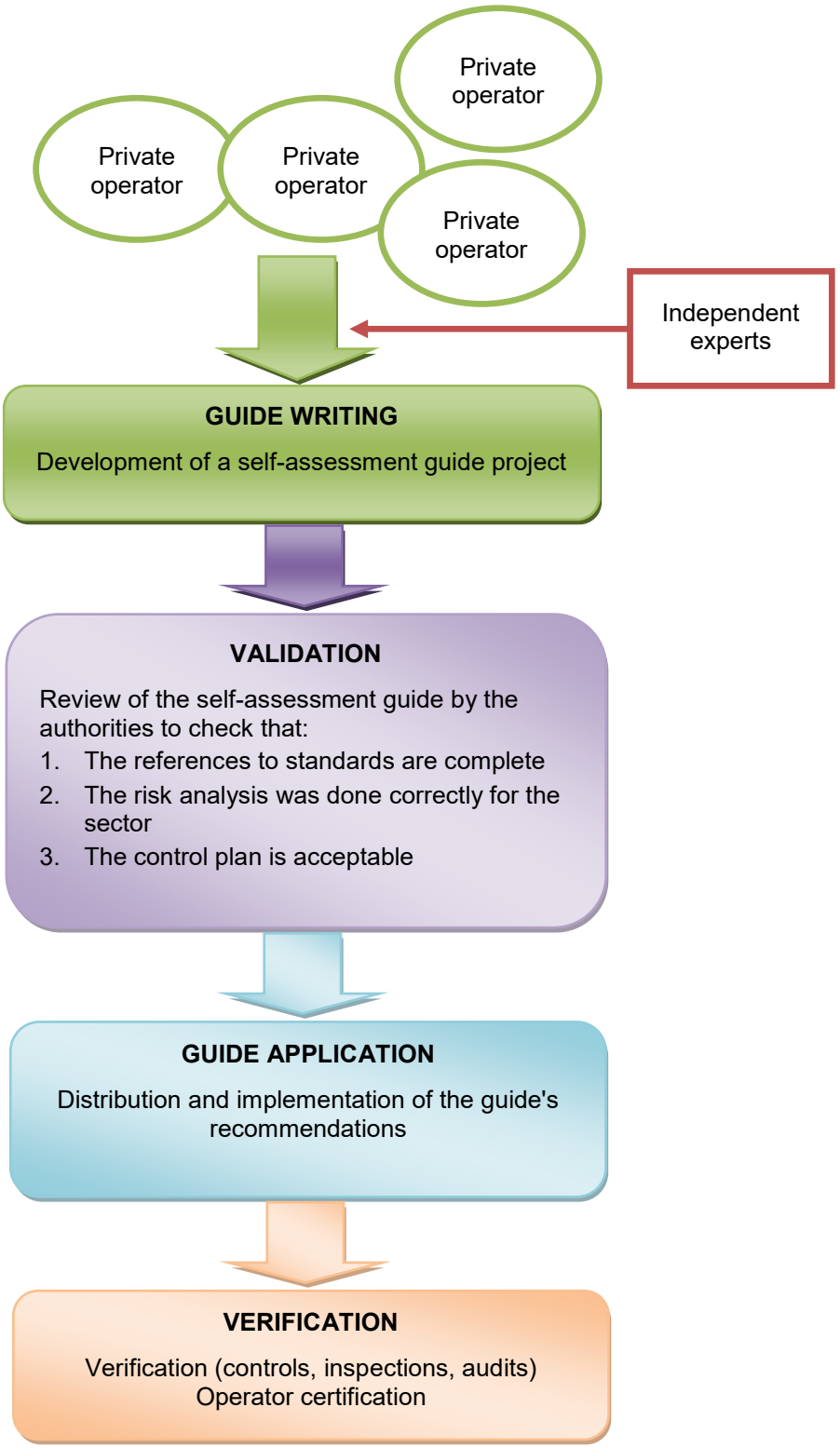
step but are generally applicable, for example: cleaning of premises and disinfection of tools, pest control (rodents, insects, birds), employee hygiene etc.

[8] Since certification is only feasible based on standards, in this case, on the existence of a 'self-assessment guide' adopted by a majority of operators active in a sector (the term usually used is 'Sector Self-assessment Guide' – ACS).


Private operator
Private operator
Private operator
Private operator
Independent experts
GUIDE WRITING
Development of a self-assessment guide project
VALIDATION
Review of the self-assessment guide by the authorities to check that:
1. The references to standards are complete
2. The risk analysis was done correctly for the sector
3. The control plan is acceptable
GUIDE APPLICATION
Distribution and implementation of the guide's recommendations
VERIFICATION
Verification (controls, inspections, audits)
Operator certification

The method to be followed can be illustrated using the example of primary vegetable production (for example: lychee production):

❑ Step 1: Raising awareness in the channel and setting up a Steering Committee

The foundations of the sector approach to risk analysis and the methodology to follow to develop a self-assessment guide must be defined with local experts from the private and public sectors. These local contacts will act as 'relays' with all of the producers. A 'Steering Committee' consisting of, at least, representatives from the private sector (producers and exporters) and representatives from the public sector will be created to promote the mobilization and cooperation of stakeholders in the risk analysis exercise in the field and good communication with the public and private operators involved throughout the entire process. It will preferably be led by an expert from outside the channel.

The role of the 'Steering Committee' will be to organize the sharing and validation of results at each step of the programme, to facilitate the creation of private/public sector work groups, to facilitate the validation of results and of the documents used for the 'self-assessment guide' and to prepare an action plan for the implementation of the self-assessment system in the channel.

The following is required:

- identify sector operators and collect sector information;
- write a guide plan (text and visuals);
- raise the awareness of and train local relay-experts;
- launch a communication campaign for sector operators;
- create and lead the Steering Committee.

❑ Step 2: Inquiries in the main production basins, inventory of the regulations and standards relevant to the sector

During this step, the goal is to collect data and information that will ensure that the risk analysis, the management measures to be recommended and the control plan to be established are realistic and suitable to the sector context.

The following is required:

- define the main production schemes (processes) found in the lychee channel based on which existing and emerging SPS risks will be analyzed;
- take an inventory and analyze local and international regulations and standards applicable to the lychee sector;
- identify the control laboratories available and their level of competence based on the types of analysis needed (types of analyses possible, annual capacity, staff qualifications, cost of analysis and levels of performance, existing and upcoming certifications);
- collect all economic and technical information and data available on the channel (operators, OP, volumes produced, product types, supply chain, technical operators etc.); crop production schedules, harvesting, transport and packing; number of orchards, age of trees, varieties, production practices, use of inputs,

equipment and employees for input application and harvesting, packing employees (qualifications and experience), basic hygiene infrastructure, transport conditions, packing structure, packing facilities, waste management, recording and documentation systems in place, quality controls carried out, etc.; main production and post-harvest phytosanitary issues; chemical and non-chemical treatments (type, products used, application methods, time to harvest, alternatives, effectiveness of the methods used etc.).

- identify all unresolved critical points in the channel based on regulatory and standards requirements ('Gap Analysis') and the main product quality problems encountered.

❑ **Step 3: Risk analysis based on the process/Proposals for risk management measures/Operations and product traceability/Procedures to track non-compliance**

At this stage, it will be a matter of consolidating and using the data from inquiries, carrying out an in-depth risk analysis based on production processes and conditions and proposing appropriate management measures. It will also be useful to work with the sector on the recommended self-assessments to be implemented, on compulsory notification limits, to establish a reaction procedure in the event of non-conformities and on the basics of a sector control plan.

The following is required:

- proceed with the risk analysis itself and determine the critical points to be managed in the channel with respect to SPS using the field data and scientific literature available;
- propose realistic management measures to be implemented;
- propose self-assessments to be implemented in companies and at the sector level;
- set conditions for the information provided by companies to the authorities;
- analyze shortcomings/opportunities in local regulations in the context of international SPS requirements;
- verify that control laboratory capacities are in line with needs. Produce a self-assessment guide draft for the channel.

The self-assessment guide will become available once this step is completed. Food and crop safety risks must be inventoried and categorized based on their importance (frequency, severity of effects) (work carried out in close cooperation with the sector and local experts).

The type of self-assessments to be carried out in the channel (types of control, sampling frequency, action limits in the event of non-respect of standards, etc.) based on identified risk categories should be identified, and the self-assessment scheme validated by a majority in the profession. Critical limits should be set for each risk category.

Management procedures for non-conformities in companies and communication procedures with the authorities are created. Requirements for traceability and self-assessment documentation and results are defined.

❑ **Step 4: Design and write tools for mass distribution to facilitate the implementation of the self-assessment system/Training of OP representatives and of public services agents**

In this step, the guide is translated into illustrated and practical 'good practices guides' suited to the level of, and for use by, each category of operators. They will supervise application of the ACS in companies using these tools. Training for the representatives of professional organizations and the qualified agents of public services should be held.

❑ **Step 5: Assess company certification needs/Create an action plan for the channel**

The certification needs of the sector should be identified and, if need be, potential certification schemes defined. In certain instances, the needs of the channel must also be specified (e.g.: new standards) and an action plan created: strengthen the analysis capacities for controls, set up a schedule for upgrading structures, updating standards and/or regulations, strengthening sector capacities etc.

6.1.3. The benefits of a 'self-assessment system'

The implementation of a self-assessment system in a production sector provides benefits for both operators and the competent authorities.[9]

❑ **Producer benefits**

The implementation of a self-assessment system has several benefits for **producers**:

1) In terms of production controls and final product control:

- **better targeted controls**, notably to **reduce the number of most expensive analyses** (residue analyses, microbiological analyses) since, currently, the level of sampling required is not always required by importers (this is the case, for example, for analyses for each lot, even though there may be a series of small lots);
- reduction in the financial burden of final product control. When a process is entirely under self-assessment, the final control is often a **simple document check**[10] (for example, the reading of logs listing the products used, doses, application dates and harvest dates rather than consistent sampling and residue analyses);
- **reduction in the number of external verifications**. An operator who doesn't have a validated self-assessment system will be considered 'less safe' by the authorities (they are said to have a '**risk profile**') and will therefore be controlled more often and more in depth. If the person mandated to carry out the controls by the authorities notices shortcomings, they will carry out as many further inspections as

[9] (Competent) authorities: all state bodies (e.g., ministries, food agencies, etc.) recognised by the state as being 'competent' to carry out the controls required by regulations (and to validate the self-assessment system). It should be pointed out that the supervisory authority of a country can, under certain circumstances, delegate part of its competences to another 'body' which it certifies to carry out given control tasks on its behalf.

[10] Reliability is confirmed by regular internal audits which comply with self-assessment procedures without which control procedures could slip or become inadequate and lead to the production of non-compliant products.

necessary to ensure that the required corrective measures were taken by the operator and are complied with.

2) In terms of managing the production process:

- detection of non-conformities and failures as early as possible (notably **before entry into the packhouse and product shipping**). A positive financial impact is tied to cost-savings and to the fact that there is no useless added value in the defective products (e.g., at packing time);
- the search for and rapid detection of non-conformities thanks to consistent control of production operations by the persons who are carrying them out. Compliance with specifications is improved via **increased awareness** and changed practices.

3) In terms of operator involvement in their work:

- controlling one's own work is said to increase the sense of responsibility (when the extent and complexity of control are not beyond the skill set). Operators who supply non-compliant products feel more involved and feel an obligation to better master their procedures;
- self-assessment is one of the ways operators can prove and measure the quality of their work (or the qualities and defects of their process).

4) For small producers, it is a less expensive alternative to private certification and guarantees an equivalent level of food safety.

❑ Benefits for the authorities

For the authorities, the implementation of a self-assessment system will also provide several non-negligible benefits given the low level of resources available in most public services:

- identification of producers and of all operators (visibility, traceability, easier control);
- assistance with the implementation of an effective national health control system because it is based on risk analysis carried out in different sectors;
- strengthening of the control capacities of all actors involved thanks to more effective targeting;
- scheduling and planning of controls becomes easier and there is a reduction in finished product controls ;
- transparency of problems found in each sector (communication of results to the authorities);
- a guarantee of traceability and of effective withdrawal or recall measures in the event of a crisis (planned procedure);
- overall credibility for the origin and the national SPS system;
- potential knowledge transfers between the various sectors.

6.2. Self-assessment guides

6.2.1. Good practices guides and the self-assessment guide

To guide producers, manufacturers and distributors, and to enable them to meet their hygiene obligations, the professionals of a sector (e.g., fruits and vegetables, meat, milk, chocolate etc.) can work together to create a *Good Hygiene Practices Guide* specific to their activities and the risks of their sector.

Initially, this type of guide primarily brings together all of the hygiene rules applicable to the various steps of the food chain. Within the framework of European regulations on food security and food product hygiene (Regulations (EC) 178/2002 and 852/2004) and also including elements related to the systematic control of practices throughout the entire process, the concept of 'Good Practices' has been extended to 'self-assessment' in production.

The self-assessment guide is built on a '**sector risk analysis**',[11] based on the identification of hazards relevant **for a given type of product** (e.g., meat production, milk production, flour manufacturing, plant production etc.). In addition, it also includes: the bases of a production risk management system, the application of HACCP principles (recording of critical control points and their management), a proposal for a sampling plan made by the sector (type and number of samples to be taken each year and the analysis parameters deemed to be relevant: residues, heavy metals, micro-organisms etc.), compulsory records and the notification procedure for the authorities in the event of non-compliance with standards.

There should be a guide for each production 'sector' because:

- There are different hazards tied to activities, processes, equipment, employees, the environment and the products.
- 'Sensitivity' to contamination will depend to a large extent on the product but also on the local production and packing conditions.
- Operators active in the sector have **the best understanding** of the problems usually encountered.
- These operators are the best judges of which control measures will be **financially feasible for them**.

On one hand, the 'sector self-assessment guides' are developed by professionals and evaluated by a committee of experts appointed by the authorities to ensure that the

[11] Defining a 'sector' is not always as self-evident as it might seem. Work can involve one channel (e.g., lychees) or several channels at a time (e.g., 'fruits and vegetables' or even 'primary plant production'. The important thing is to always maintain consistency of requirements throughout the various sector guides. The authorities must remain attentive to this point. There can be 'overlapping' between the application fields of self-assessment guides: thus, there can be a 'lychee production guide' and also a 'fruit juice production guide'.

sector hazard analysis on which the guide is based is complete and that the measures are appropriate. On the other, once a guide has been validated, the authorities will verify its correct application at the sector level.

There are national guides available in Europe which can be found on the websites of national agencies (ANSES, AFSCA etc.). There are also community guides developed at the European food sector level and published in the *Official Journal of the European Union* (C series).

A **self-assessment guide must**:

- be valid for all companies in a channel (or 'sector');
- … and be transferable to each company;
- provide **a sampling plan** based on a sector risk analysis;
- be **easy to use** by the companies concerned: understandable (illustrations, diagrams, etc.), easily applicable (detailed HACCP examples), accessible (distributed or sold by the sector);
- be written and distributed by the different sectors or sub-sectors in **consultation with the representatives of the parties concerned**… whose interests can **really be affected**;
- be validated. The **reliability** of the guide comes from the **authorities**.

The ***general recommendations*** *for guide development are found in part B of Appendix 1 of* ***Regulation (EC) 852/2004***.

6.2.2. Contents of the self-assessment guides

A sector guide is developed to assist small and large companies in the sector to comply with hygiene rules and to apply HACCP rules. This type of guide **must be practical, understandable,** even for poorly qualified operators and **illustrated with examples and real cases** to facilitate understanding and use. It must be a **reference document based on a solid scientific foundation**.

Concrete examples, including a hazard analysis, presented based on the HACCP approach can facilitate comprehension and application of the guide. However, it is often preferable to **prepare** a number of **training leaflets along with** the guide. These should be illustrated and simplified and targeted at each category of operator working on the production chain. For example, a first leaflet for small farmers, another one for collectors and a third for exporters.

An example of a **typical summary** of a self-assessment guide for the plant sector is presented below (e.g., self-assessment guide for mangoes prepared for Mali and Burkina Faso in 2009 by PCDA and PAFASP in collaboration with COLEACP):

❑ **Part one: General provisions of the guide**

- Object and scope
  - Activities covered by the guide
  - Production and commercialization procedures
  - Mango growing
  - Quality criteria
- Use of the guide
  - Guide users
  - Guide user instructions
  - Goal and relationship to legislation
  - Producer user instructions
  - Company control instructions
- Work groups and guide writing
  - Expertise
  - Work group make-up
  - Sector representativity
  - Concept of sector self-assessment guide
- Standards reference
  - National and European legislation
  - Other standards
- Terms, definitions and abbreviations
- Distribution, guide updating and access to the guide

❑ **Part two: Risk analysis and general requirements for the sector**

- General requirements for sanitary and phytosanitary quality
- Production process risk analysis
  - Production scheme
  - Hazard identification
  - Risk characterization (scores)
- General hygiene requirements (self-assessment, GHP, HACCP)
  - Employees and third parties
  - Production site
  - Company and buildings
  - Machines, equipment and tools in contact with the product during pre- and post-harvest treatment
  - Boxes, containers, packing materials and box pallets
- Description of the growing techniques:
  - Crop management and GAP
  - Identification of harmful organisms
  - Pesticide treatments
  - Post-harvest treatments
  - Waste management

- Operations control: C*hecklist* of general guide requirements (major and minor requirements and recommendations)

➢ Traceability:
- Identifications required
- Records
- Documentation

❑ **Part three: Non-conformity control and follow-up plan**

➢ Sampling plan
➢ General conditions:
- Basis for a statistical approach for sampling
- Sampling and analysis done by an independent third party
- Creation of the sector sampling and analysis plan
- Collection and use of results

➢ Controls to be carried out pre-harvest
➢ Sampling and controls to be carried post-harvest
➢ Notification procedure for the authorities:
- Generalities
- Overview of action limits (notification)
- Blocking and recall procedures

Part four: Certification of the company self-assessment system

➢ Framework and objectives of the certification
➢ Object and scope of application
➢ Inspection and audit procedures
➢ Conditions for independent certification organizations (ICO)
➢ Certification procedures
➢ Auditor/controller and producer obligations
➢ Sanctions

6.2.3. Recommendations for writing self-assessment guides

❑ **Generalities**

The guide presented must have a clearly indicated **version number** because only the version presented will be validated later.

Likewise, communication about the guide will refer to this number.

❑ **Defining the field of application**

Definitions:
- Activities covered by the guide (based on the complete process)
- Production, transport, commercialization and other procedures

- Finished products (fresh fruit, dried fruit, vegetables, juices, preserves etc.)

A single guide per field of application. A guide must clearly specify the activities, manufacturing and commercialization processes and products it covers. This must be relevant to self-assessment.

A given field of application (same activities and/or same type of products) cannot be covered in separate guides.

However, based on social, economic or traditional factors, some cases can be considered as separate sub-sectors and separate guides will be authorized if the need can be justified.

❑ **Defining the expected use**

Specification of all potential users.

Directions for use, instructions etc.:

- goal;
- data included in the guide;
- how the specifications pertain to legal requirements;
- how to make practical use of the data.

All **potential users** must be identified and defined.

It must be clearly stated for which (what type) of users the guide is intended. Only the specified users will use the guide. Potential users must understand the relevance to food and crop safety.

The use of this guide must be explained. **Directions for use** must motivate potential users to use the guide for their operations (for example, by attracting attention to certain aspects that encourage ease of use/application of the guide). They must indicate **the goal of the guide** within the context of legally required self-assessment.

Users must be made aware of the reasons for using the guide. The importance of self-assessment and of the **assumption of responsibility** tied to it must be clearly explained. Users who have been made aware of the objectives will put more goodwill into implementing, applying and maintaining their self-assessment system.

In addition to the goal, the recommendations/data contained in the guide must also be pointed out (a clear table of contents with a brief commentary describing the data contained in the guide). Users must be able to find their way around the guide easily.

Given that the guide will be used to meet legal requirements, it will be necessary to clearly state how the guide's provisions **relate to regulatory requirements.**

It is very important to explain how the recommendations can be put to practice. Therefore, **a step-by-step explanation of how users can use the guide to build their own self-assessment system** adapted to their company should be provided.

❑ **Appointment of the work group and consultation**

➢ ***The sector:***
- sector data;
- indicate representativity.

➢ ***The work group (composition):***
- names of the work group members;
- their position (chairman, observer etc.);
- their origin (home organization);
- their expertise (local and external experts).

➢ ***The parties involved:***
- list of all the parties affected by the writing/application of the guide;
- the way in which all of the parties have been consulted.

Guides must clearly mention **all professional associations** (with their names and contact information).

If the validation request is presented by a **coordinating organization**, their name and contact information must be provided. In addition to the data for the coordinating organization, data must also be provided for associated professional organizations (name, contact information and the field they represent).

The **level of representation** of the association(s) in the sector(s) in question must also be provided. Various parameters are used to demonstrate their representation. These include the number of companies (e.g. % of sector companies who are members of the professional association), the number of people employed, tonnage, revenues, etc. or a combination of this information. A reason must be provided as to why a given parameter was used to demonstrate representativity in the sector.

The **work group** tasked with developing and writing the guide must be **clearly identified**. The names of all of the members of the work group must be listed for this purpose. In addition to the name, the position (chairman, observer etc.), origin (from which organization) and expertise of each member must be provided.

All parties taking part in writing a guide must be listed in the guide along with the way in which they were consulted for its development (via the work group or some other way, in writing or via meetings, etc.). Therefore, parties not included in the work group but involved must be listed, and the way and extent to which they were involved must be described. Parties involved include producers, 'facilitators', collectors, suppliers (seed, seedlings, inputs, etc.) and customers (including importers).

❑ **List the means used**

Description of the means and **expertise used**. The means (e.g., consultation in production areas) and expertise (local and external) called on to write the guide must be mentioned in the guide. For example: consultation with research and project centers and consulting companies, university studies, laboratory analyses (soil, water, residues etc.), bibliographical references and other. Relevant URL's (internet site addresses) can also be an added plus for users.

❑ Content recommendations

Starting points and inclusion of expected users:

- the guide should be **adapted** to the expected users;
- notices about potential examples;
- the starting point for writing must be, and take into account, the following:
  - a hazard analysis (based on HACCP);
  - use codes recommended at the international level;
  - relevant legislation;
  - all other relevant sources.

The provisions of a guide **must be suited** to the expected users. The latter must be able to read, understand and **easily put the guide into practice**.
The guide should be written taking as its starting point and taking into account:

- a hazard analysis of activities, processes, equipment, employees, the environment and the products in question;
- international codes recommended in the field of the products in question (e.g., those of the *Codex Alimentarius*);
- the various legislative and regulatory requirements (based on each market);
- all other relevant sources (e.g., scientific articles, the results of analyses to build a sampling plan).

Hazard analysis and local, regional and European legislation are key compulsory elements.

Concrete examples of the self-assessment system should be described in the guide. It must be clearly indicated that these are only examples and that a self-assessment system **must be created specifically for the company in question**.

For this purpose, the example should at least be preceded by the following warning - or a similar one: "*This example is provided for illustration purposes only. It can under no circumstances be used as is for a self-assessment system application in any given company"*.

This point is quite critical because taking the examples without modification can, in fact, be assumed to mean that there is no effective self-assessment system.

All essential requirements for the following must be included:

- GAP (Good Agricultural Practices);
- GHP (Good Hygiene Practices);
- HACCP (Hazard Analysis and Critical Control Points): take into account **all** types of contamination hazards: biological, chemical and physical.

The provisions of the guide cannot simply paraphrase basic regulatory requirements. All key GAP (and therefore GPP[12]) requirements must be described and detailed in the guide. All key hygiene requirements must be **developed in detail in the guide's**

[12] GAP: Good Agricultural Practices, BPP: Good Phytosanitary Practices

provisions. The provisions and their application method must be suited to the various companies of the sector.

The guide must draw the attention of companies to a series of significant hazards, all the more so because the guide must be based on a hazard analysis and contain clear directives explaining to companies how to carry out an effective analysis based on the seven HACCP principles. An HACCP example can be provided in the appendix.

The guide must take into account all types of product contamination hazards with respect to food safety (biological, chemical and physical hazards) even if they are theoretical only. Criticality (probability x severity) should be established on this basis.

Never simply paraphrase basic legal requirements.

Two particularly important points:

The following are found nowhere in local and international regulations:

- interpretations,
- derogations,
- contradictions.

The guidebook must contain all relevant information about:

- food safety and product quality,
- traceability,
- notification of the authorities and the management of non-conformities.

A guide is expected to explain to users how they can comply with legislation in matters of food safety. **The guide must contain a reference to relevant legislation for** each area of food safety covered. The way in which the company can meet the legal requirements must also the indicated.

In addition, a specific chapter containing an **inventory of relevant legislation** should be included. It must also be clear for the control body that all legal aspects (related to food safety) must be controlled (e.g., **provide a legislation checklist**). Insofar as aspects related to quality are covered in the guide, it is recommended (but not compulsory) that the legal reference be provided in this context (e.g., Codex standards etc.).

Items related to food safety and traceability are compulsory. The guide must indicate how the link between incoming and outgoing products is made and at what minimum level the link must be set. In addition to this internal traceability, it is also important to provide techniques that must/can be used to prevent recording errors in the logs. Likewise, **notification** is compulsory item.

Quality-related items do not necessarily have to be covered in the guide, but it is **recommended**. Private international **standards** (for example, GLOBALG.A.P, BRC, IFS, etc.) are not ‘self-assessment guides’ and can, therefore, not be validated as such by a national ‘food agency’. They are missing elements or contain elements that cannot be validated by this type of agency.

❑ Requirements for external control bodies

Description of the rules for certified control bodies:

- reference standards for accreditation;
- a certification system with certification rules (including the frequency and extent of audits);
- an inspection system with the frequency of inspections;
- documentation on quality, records, and technical aspects which must, at a minimum, be checked by the auditors/inspectors;
- the rules for product sampling and analysis;
- the minimum number of hours/workdays to be applied;
- the minimum contents of reports;
- qualifications required for inspectors and auditors.

Given that application of the guide and compliance with its requirements may be carried out by external bodies, the guide must also **mention the accreditation standard** the inspection or certification body potentially involved is associated with (reference standard EN 45004, EN 45011 or EN 45012 or the ISO 17000 series). The final decision must be documented.

The certification rules to be applied in a certification system must be defined (they will, notably, include the delivery of certificates, including monitoring of the certificates delivered, user obligations, etc.) and include the frequency and extent of audits.

The **frequency of inspections** must be defined in an inspection system. Documentation on quality, records and technical aspects which must, at a minimum, be controlled by auditors/inspectors must also specified. The minimum content of inspection reports must be defined, taking its recipients into account.

Rules for **sampling and product analysis** must be covered. This will range from methods and frequencies to the way in which operations are organized.

In order to be able to properly carry out the audit/inspection, directives on the minimum time auditors/inspectors (number of hours or days of work, depending on volume and activity) must spend in the company to review application of the guide must be written. These data must be written in a way that removes any possibility for interpretation.

The setting of requirements for **inspector/auditor** qualifications will be of particular importance!

Along with the content of the guide, the competence of the auditors will determine the value of the self-assessment system implemented.

Among the skills that can be required are basic qualifications, training (for example in HACCP), experience in the sector, number of years of work experience and in auditing (in this type of production sector).

❑ Directives for layout

The contents of the guide must be:

- accessible to producers;

- clear;
- coherent;
- logical.

All aspects of the guide must be presented in a clear, coherent and logical way. This will all impact the ease of use of the guide. A great deal of thought must therefore be given to the **layout of the guide** (illustrations, photos etc.) and to the language used.

❑ **Distribution**

The conditions under which the guide will be available. The guide must also list the conditions under which it is available. It must be available to any person whose interest in the guide is reasonable. Following validation, the guide should be made available on the Internet.

6.3. Verification within the context of the self-assessment system

6.3.1. Internal verification

Internal verification is carried out by the operator or by a third party acting on their own behalf. It covers evaluation of the company's FSMS. It can be a complete and systematic control (visual controls, measurements, internal audit) or a more targeted and limited control (residue analysis, microbiological analysis, soil and water analysis, etc.).

The goal of verification is to ensure that:

- **internal procedures** in place really **work** and are effective;
- records will attest to and **provide all necessary proof** of food safety management and of compliance with regulatory requirements (product safety) and with those of 'specifications' and 'quality standards' (product quality).

Evaluation of the FSMS must answer the following **three questions**:

- Does the FSMS meet the objectives set by the company in its quality policy and food safety policy?
- Does the FSMS meet customer requirements?
- Does the FSMS enable continuous improvement of the safety and quality processes and procedures implemented?

The internal verification or self-assessment system includes:

1. **Ongoing controls**. Visits and inspections carried out with a frequency pre-set in an 'internal control plan' and other unscheduled ones. They are carried out by the quality-traceability manager (and his team, in larger companies). They are rounded out with measurements, samplings and targeted analyses according to the risk analysis carried out based on the processes.

2. **Internal audits**. Are carried out by auditors trained in auditing food product safety to ensure that all aspects of the FSMS are operating effectively. It should be pointed out that even though these are 'internal' audits (that is, the results are not normally shared outside the company), the company can call on external auditors, which it remunerates, to supplement the lack of internal competences or to obtain the opinion of an outside expert. The internal audit is generally carried out **once or twice a year** or when **key processes change**!

The frequency of verification and of analyses must be sufficient to confirm that hazard identification, risk assessment, controls and corrective action are working correctly.

The controls, analyses and internal audits, their content and their frequency should be defined in a specific procedure for the verification of the FSMS.

6.3.2. External verification

❑ **Verification types and planning**

Note that all 'self-assessment systems' include a self-assessment guide (for application in the private sector) and a set of **control procedures** (for application by the public sector).

The scheduling of external verification (type and frequency of controls) should be based on the risk analysis carried out for the channel.

External verification primarily includes:

- **sampling** for analysis (pre-harvest, in the station on unprocessed or finished products, at shipping points and, sometimes, in markets). This sampling is part of the overall monitoring plan;
- **inspections** carried out on the basis of known check lists (the same ones as used by operators for internal verification). They are part of the control plan applied to the sector;
- **audits** done either by the authority's agents or by a third party designated and accredited by the authority to ensure, notably, that hygiene instructions are being followed and logs kept.

Inspection: verification at time '*t*' of the operating status of the FSMS and of its performance. This provides an instant picture of compliance with requirements without providing a guarantee of the time period over which proper operations will be maintained.

Audit: systematic and independent examination intended to determine if the activities and their results comply with the established plans and if these plans have been executed effectively and continue to be adequate to reach the goals set (*source*: Regulation (EC) 882/2004. This provides a feeling for the robustness of the system.

Within the framework of a self-assessment system, the most important controls are in-company audits which are carried out at a set interval (e.g., one audit every 3, 6, or 12 months) depending on the sector. Only the results of the risk analysis carried out in consultation with sector professionals and validated by independent scientific experts enable the objective pre-setting of the frequency of required external controls, by taking into consideration the following points:

- the '***risk profile of the sector***' based on the 'vulnerability' of the product (e.g., risks are normally higher for consumers with products from animal sources compared to fruits and vegetables);
- the '***normal profile of operators***' active in the sector based on their organizational level, the implementation of self-assessments, the certification for their FSMS or others, the characteristics of the overall environment of the sector (e.g., the technical itineraries adopted, with or without pesticides and chemical fertilizers).

The **frequency of verification at companies** will therefore depend on many factors which will be at the discretion of the authorities. The frequency can be lowered for operators who voluntarily apply the recommendations of their sector's self-assessment

guide.

❑ **Organization of external audits**

An audit cannot be improvised and it always consists of several steps. The company must be notified in advance of the date the auditor will come and of the extent of the audit. Ideally, there should be an audit checklist. That is, a document that lists the audit steps, the documents/areas to be inspected, the persons to be interviewed and the goals of the audit.

➢ ***Preliminary meeting:***

The auditor will check:

- Previous audit reports
- All documents that may contain important information.

The auditor is provided with all relevant data about the company to be audited. The required forms are prepared and filled in with known information.

➢ ***Opening meeting:***

The audit process communicated to the company in writing is confirmed during the opening meeting. The auditor will make sure that there are no obstacles with respect to scheduling and carrying out the audit and that all documents and people will be available.

➢ ***Examination and evaluation of results***

The auditor will verify if the hygiene requirements found in the self-assessment guide have been complied with, if the logs are available, if they contain all required information and if they are correctly filed.

The documents available are reviewed and evaluated for content by the auditor who will also pay careful attention to the practical implementation of requirements when carrying out interviews and visual inspections.

A certain 'tolerance' of 'accidental errors' is acceptable. However, the number of non-conformities, interpretation of the numbers and the level of confidence generated by the implementation of good hygiene practices and log keeping will be decisive for the final result.

In the event of shortcomings, the auditor will prepare a report to be presented to the operator during the closing meeting.

➢ ***Closing meeting***

The results of the audit will be communicated to the company by the auditor during the closing meeting. The main non-compliance issues observed are also communicated. Serious non-conformities will, however, be explained to the company's managers and sent in writing after the audit. The company's managers can propose corrective measures. The auditor will give his opinion on the corrective measures.

Following the audit, the auditor will write a report and send it to the company. If everything is in order, the auditor will sign the "*validation of the implementation of good hygiene practices and keeping of logs*". Otherwise, a decision can be taken by the authorities following the report (e.g., additional audit, shut-down of operations, etc.). Non-conformities must be corrected by the time of the next audit. Likewise, the audit regime may be modified as a result of the observations made.

Most used abbreviations and acronyms

Most used abbreviations and acronyms

ACMSF	Advisory Committee on the Microbiological Safety of Food
ACP	African, Caribbean and Pacific (Group of ACP States that have signed a series of agreements with the EU, called the 'Cotonou Agreements')
ACS	Auto-Control System (self-assessment)
ADI	Acceptable Daily Intake
AFI	Agro-Food Industries
AgHBs+	Hepatitis B virus
AJ	Apple juice
ALOP	Acceptable Level Of Protection
ANSES	*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* (French Agency for Food, Environmental and Occupational Health & Safety)
ARfD	Acute reference dose
A_w	Water activity
BSE	Bovine spongiform encephalopathy
BTSF	Better training for safer food
bw	Body weight
$CaCO_3$	Chemical symbol for calcium carbonate

CAC	*Codex Alimentarius* Commission
CCFAC	*Codex* Committee on Food Additives and Contaminants
CCFH	*Codex* Committee on Food Hygiene
CCP	Critical control point (under the HACCP method)
CFIA	Canadian Food Inspection Agency
cfu	Colony-forming units
COPAIA	Pan American Health Organization
Cr	Criticality of a risk
EFSA	European Food Safery Authority
EPA	Environmental Protection Agency (USA)
EU	European Union
FAO	Food and Agriculture Organisation: UN organisation that addresses food security problems in the world
FASFC	Federal Agency for the Safety of the Food Chain
FDA	Food and Drug Administration
FSANZ	Food Standards Australia New Zealand
FSIS	Food Safety and Inspection Service

FSMS	Food safety management system (see also QMS)
FSO	Food Safety Objective
GAP	Good Agricultural Practices (set of application conditions that must be defined: dosage, volume, formulation, technique, PHI)
GDP	Good Distribution Practices
GHP	Good Hygiene Practices
GLP	Good laboratory practices
GMO	Genetically modified organism
GMP	Good Manufacturing Practices
GPP	Good Phytosanitary Practices (set of rules to follow to avoid contaminating the operator or the environment and to avoid residues)
GTP	Good Transport Practices
GVP	Good Veterinary Practices
HACCP	Hazard analysis critical control point: system that defines, assesses and prevents food safety problems
HHS	US Department of Health and Human Services
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IPM	Integrated pest management

IPPC	International Plant Protection Convention
ISO	International Organization for Standardization. ISO is the international standards body whose members are the national standards institutes of 149 countries
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMRA	Joint FAO/WHO expert meetings on microbiological risk assessment
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	Lowest observed adverse effect level. Lowest concentration causing an adverse effect. See also NOAEL - no observable adverse effect level.
LOD	Detection limit
LOQ	Limit of quantification (also called limit of determination)
ML	Maximum Level
MMSRP	Management and Monitoring of Sanitary Risks Plan
MRL	Maximum residue level
NAS/NRC	National Academy of Sciences/National Research Council
NHANES	National Health and Nutrition Examination Survey
NOAEL	No observable adverse effect level
NRC	National Research Council
NVWA	*Nederlandse Voedsel- en Warenautoriteit* (Dutch Food Agency)

NZFSA	New Zealand Food Safety Authority
OIE	*Office international des épizooties* (Wordl Organization for Animal Health)
OJEC	*Official Journal of the European Community*
OJEU	*Official Journal of the European Union*
OR	Observed residue, in mg/kg
p	Processing factor
PAFASP	Program to support the agro-sylvo-pastoral sectors
PAH	Polycyclic Aromatic Hydrocarbons
PC	Performance Criteria
PCB	Polychlorinated biphenyls, chlorinated aromatic compounds (209 congeners)
PCDA	Agricultural Competitiveness and Diversification Program
PDCA	Plan-Do-Check-Act
pH	Potential of hydrogen
PO	Performance objective
POA	Point of Attention in the risk management process (HACCP)
Pr	Product of probability

PRP	Pre-requisit Programmes
PSD	Pesticides Safety Directorate
PSTI	Predictable Short Term Intake
PTMI	Provisional tolerable monthly intake
PTWI	Provisional tolerable weekly intake
QMS	Quality Management System (see also FSMS)
QTM	Quality and traceability manager
RD	Reference Dose
RMF	Risk Management Frame
Se	Severity of the effect
SPS	Sanitary and phytosanitary (measures)
STEC	Shiga toxin producing E. coli
t	Transformation factor
TDI	Tolerable daily intake
TRV/VTR	Toxicological reference value (*Valeur toxique de référence*)
TWI	Tolerable weekly intake

U	Unit
USDA	US Department of Agriculture
v	Variability factor
VDIC	Vesalius Documentation and Information Center
WHO	World Health Organisation
WTO	World Trade Organisation

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Useful Websites

Useful Websites

AFSCA-FAVV (Federal Agency for the Safety of the Food Chain): www.afsca.be/home-en

ANSES (Freanch Agency for Food Environmental and Occupational Health & Safety): www.anses.fr

ACIA (Canadian Food Inspection Agency): www.inspection.gc.ca/english

British Retail Consortium (BRC): www.brcdirectory.com

ChemIDplus: chem.sis.nlm.nih.gov/chemid

EFSA: www.efsa.europa.eu

European Commission: ec.europa.eu

FAO: www.fao.org/home/en

Fish Scam: www.fishscam.com

FSA: www.foodstandards.gov.uk

Food Safety Management: www.foodsafetymanagement.info

FSS (Food Surveillance System): www.food.gov.uk/enforcement/monitoring/fss

GLOBALG.A.P: www.globalgap.org

IARC: www.iarc.fr

International Food Safety: www.ifs-online.eu

International Organization for Standardization (ISO): www.iso.org/home.html

IPCS: www.who.int/pcs

ISO 22000: www.norme-iso22000.info/home.htm

JECFA: www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en

JEMRA: www.fao.org/food/food-safety-quality/scientific-advice/jemra/en

NZFSA: www.nzfsa.govt.nz/science/risk-profiles/index.htm

OIE: www.oie.int/en

PSD (Pesticide Safety Directorate): www.pesticides.gov.uk

PubMed: www.ncbi.nlm.nih.gov/pubmed/15604709

RASFF(CE): ec.europa.eu/food/food/rapidalert/index_en.htm

Science Direct: www.sciencedirect.com

Toxnet: toxnet.nlm.nih.gov

USDA Food Safety and Inspection Service: www.fsis.usda.gov

VDIC: www.vesalius.be

VWA : www.vwa.nl

WHO: www.who.int/en

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