3 RISK ANALYSIS AND CONTROL IN PRODUCTION
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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).

風險管理是一個"挑戰"，而當有重重的風險時，公司必須能處理各種風險，並且決定哪些風險可以接受，而哪些不可以接受！

\(^1\) 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.³ 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. & Hirsch, L., 2007).

For authorities

It will be up to the "authorities" to define acceptable risk levels. This implies characterising 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 organisation of monitoring (verification).

² The two components of product hygiene. See Chapter 2 of PIP Manual 1.
³ See PIP Manual 1.
1.1.2. The concepts of "hazard" and "risk"\textsuperscript{4}

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,\textsuperscript{5} European Regulation 178/2002\textsuperscript{6} calls for the use of the "Precautionary principle".

\textsuperscript{4} See PIP Manual 1.

\textsuperscript{5} This is the case when, for example, there is no scientific proof of harmful effects, of demonstrated links between a contaminant and the effects observed, as is often the case for chemical substances (such as endocrine disruptors) which act at extremely low concentration levels, and the potential causes of an overall effect seen in a population group have many sources. Entire groups must be worked with for this type of contaminant (residues of certain pesticides, Bisphenol A, etc.) which makes studies far more complex.

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**: 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) 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:

<table>
<thead>
<tr>
<th>FSMS</th>
<th>Food Safety Management System</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS</td>
<td>Auto-Control System (self assessment)</td>
</tr>
<tr>
<td>CCP</td>
<td>Critical control point for risk management (HACCP)</td>
</tr>
<tr>
<td>POA</td>
<td>Point of Attention in the risk management process (HACCP)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Hazard analysis</th>
<th>Risk analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implemented at the company level and specific to the given company (a link in the ) supply chain</td>
<td>Implemented at the sector or food chain level and involves all operators (the entire <em>food chain</em>)</td>
</tr>
<tr>
<td>Tied to the company’s production process</td>
<td>Related to the health policy of a country or sector and to the management methods implemented</td>
</tr>
<tr>
<td>Calls on internal expertise (the company’s quality control manager)</td>
<td>Calls on internal and external expertise (scientific and independent)</td>
</tr>
</tbody>
</table>

**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

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

ACS: *(Self Assessment) Auto-control system (see Chapter 3 of the Manual)*
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.**

It is tied to the processes implemented in a particular company. 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. & Berkvens, D., 2005).

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
   - The conditions leading to the above-mentioned items.

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8 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.

9 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.

10 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.
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" (see Chapter 2) or in a self assessment guide (see Chapter 3).

### 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 visualisation of the limits of risk management (and therefore of FSMS):

<table>
<thead>
<tr>
<th>Risk management (Companies)</th>
<th>Crisis management (Authorities)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal operations</td>
<td>Crisis management procedure</td>
</tr>
<tr>
<td>Incident</td>
<td>Crisis plan</td>
</tr>
<tr>
<td>FSMS operating procedures</td>
<td>Seizures/recalls</td>
</tr>
<tr>
<td>Management plan and monitoring (internal checks)</td>
<td>Emergency plan (corrective actions)</td>
</tr>
<tr>
<td>Traceability</td>
<td>Withdrawals</td>
</tr>
<tr>
<td></td>
<td>Information</td>
</tr>
</tbody>
</table>

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 characterise 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. & 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 specialised external resources which will also act at the company level if required (in-depth reorganisation 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". 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 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.

SPS measures cannot, however, include any unfounded, arbitrary or disguised restrictions that hinder trade. The existence of a risk must be scientifically proven, 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 (harmonisation of requirements).

2. Otherwise, use of a scientific risk assessment 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. & 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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13 That is, completely transparent and free of any pressure, and using a scientifically recognised methodology.

14 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.

15 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 characterisation
3. Exposure assessment
4. Risk characterisation

“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:

16 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 **organising and analysing available data**. The process consists of **four steps** as follows: (i) hazard identification; (ii) hazard characterisation (iii) exposure assessment and (iv) risk characterisation. It can be shown as follows:
Note that to be complete, the analysis must not end with a "figure" characterising 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\(^{17}\) 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\(^{18}\)).

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?

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\(^{17}\) The nature and cause of the various hazards are described in Manual 1 (Chapter 2) of the PIP. The goal is to describe them as thoroughly as possible by consulting a maximum number of reliable scientific sources.

\(^{18}\) 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).
How serious is the disease?
- How many cases or outbreaks have been reported?
- What foods are affected?
- 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:
- Is 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 organisations**
  - OMS: www.who.int
  - FAO: www.fao.org
  - OIE: www.oie.int

- **Specialised databases**
  - 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)
  - AFSCA: www.afsca.fgov.be (Belgian agency)
  - ANSES: www.afsaa.fr (French agency)
  - VWA: www2.vwa.nl (Dutch agency)
  - FSA: www.foodstandards.gov.uk (British agency)
Step no. 2: Hazard characterisation

Hazard characterisation 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 characterisation of (micro) biological hazards:

- What dose leads to infection, illness, hospitalisation 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 characterisation 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 characterisation of the contaminants will take **ingestion levels** into account:
Safe ingestion amount (Acceptable Daily Intake - ADI). 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 (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).

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19 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 PIP Manual 1 and the appendices of this chapter).

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

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 semi-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). Biological and chemical hazards can be differentiated:

a) 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

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21 And, in particular, groups at risk (YOPI’s: young, old, pregnant and immuno-suppressed).

22 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.
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 (see PIP Manual 1).

The level of bacterial contamination in a food can vary significantly depending on environmental conditions.\(^\text{23}\) 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 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?](image)

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).

b) 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.

\(^\text{23}\) See the "5 M" method (see PIP Manual 1).
Risk characterisation 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 characterisation 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 characterisation 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 characterisation 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.

<table>
<thead>
<tr>
<th>Severity of the effects</th>
<th>Types of effects on health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant</td>
<td>Irreversible damages (fatal)</td>
</tr>
<tr>
<td>Moderate</td>
<td>Effect is more or less serious but reversible</td>
</tr>
<tr>
<td>Low</td>
<td>Limited effect (short term)</td>
</tr>
<tr>
<td>Minimal</td>
<td>No known effect</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability</th>
<th>Minimal</th>
<th>Low</th>
<th>Moderate</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical and not likely</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has already occurred in the past - this risk can recur</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The risk occurs regularly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The risk occurs regularly to always</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This method enables the risk manager to easily prioritise 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 characterisation.
- Development of the management actions must also be done in participative mode to optimise 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 organisations. 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 behaviour. 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).

a) 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 and (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). 24

b) 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 authorised 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 recognised as acceptable in or on a food of animal origin (Regulation (EEC) 2377/90).

24 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**

- **Scheduling (What? In which product?):** Based on risks and self assessment in the sector.
- **Planning (Where? When? Frequency?):** Controls (in the sector, based on the programme).
- **Implementation of controls:** Controls, sampling, inspections, audits
- **Reporting of results:** Analysis results Controls, inspections and audit reports.

**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 - see Chapter 3) 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 organised by the authorities in a "Control Programme".** 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). 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).

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25 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.

26 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 summarised 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 organisations 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, organisations (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 emphasises 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.27

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 procedures28 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. **Organise “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.

27 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.

28 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.

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.

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

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.

Hazard characterisation
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.

Risk characterisation
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 characterisation 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.

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).
Risk estimate
The results of risk characterisation.

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.

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

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 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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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 analysed on arrival on European soil. The ethephon residue value provided by the analysis laboratory was 3.3 mg/kg, above the MRL for pineapples\(^{29}\) 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 characterisation**

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:

Data required for the PSTI calculation

<table>
<thead>
<tr>
<th>Data</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumption data at the 97.5 percentile for an adult (UK-PSD, LP adult)</td>
<td>0.3456 kg</td>
</tr>
<tr>
<td>Consumption data at P97.5 for a child (UK-PSDLP child)</td>
<td>0.4149 kg</td>
</tr>
<tr>
<td>Adult body weight (UK-PSD, bw adult)</td>
<td>76 kg</td>
</tr>
<tr>
<td>Child body weight (UK-PSD, bw child)</td>
<td>20.5 kg</td>
</tr>
<tr>
<td>Concentration of residue observed (OR)</td>
<td>3.3 mg/kg</td>
</tr>
<tr>
<td>Food unit weight (U)</td>
<td>1.6 kg</td>
</tr>
<tr>
<td>Variability factor (v)</td>
<td>5</td>
</tr>
<tr>
<td>Transformation factor (t) proposed by EFSA, removal of the pineapple skin</td>
<td>0.25</td>
</tr>
</tbody>
</table>

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):

\[ PSTI = \frac{(U \cdot OR \cdot v) + (LP-U) \cdot OR \cdot p}{bw} \]

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

<table>
<thead>
<tr>
<th>Adults</th>
<th>Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSTI :</td>
<td>0.0750</td>
</tr>
</tbody>
</table>

**Value of the ethephon residue observed in the pineapples:**

- 3.3 mg/kg

**PSTI using a processing factor of 0.25:**

- Adults: 0.0187
- Children: 0.0835

**% ARfD:**

- Adults: 37.4%
- Children: 167.0%
Step no. 4: risk characterisation

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

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

Children’s group: \((0.0835 / 0.050) \times 100 = 167.0\%\)

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 characterisation

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

**a) 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/litre) than in conventional (10.2 µg/litre) and artisanal (10.5 µg/litre) apple juices.

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

**b) 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.

**c) 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:

\[
\text{Patulin ingestion (µg/kg bw/day) = patulin concentration in apple juice (µg/kg) x apple juice consumption (g/kg bw/day) x 0.001 (g/kg)}
\]

<table>
<thead>
<tr>
<th>Exposure to patulin (µg/kg bw/day) for different apple juices (AJ) (median [90% confidence interval]):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organic AJ</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>P83*</td>
</tr>
<tr>
<td>P90</td>
</tr>
<tr>
<td>P95</td>
</tr>
<tr>
<td>P97.5</td>
</tr>
<tr>
<td>P99</td>
</tr>
<tr>
<td>P99.9</td>
</tr>
</tbody>
</table>

*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 characterisation**

  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 characterisation 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:

  a) Apple juice consumption be limited
  b) 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 measures in companies

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2.1. 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), the health quality and traceability manager of the company must:

1. Take into account internationally recognised 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 and decide on appropriate measures based on this.

2.1.1. 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. See PIP Manual 1.
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.

---

2.1.2. 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 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?

- **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, fertiliser, 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 minimise risks. Note that hand washing and *staff behaviour* 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 jewellery 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 an "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).

2.1.3. 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 organisation 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):

- **Manpower**
  - Suitable clothing
  - Medical check-up at hiring
  - Training
  - Inputs

- **Material**
  - Water
  - Packing
  - FIFO
  - Procedures
  - Auto-controls
  - Traceability
  - Ensuring hygiene rules are followed

- **Method**
  - Forward progress
  - Design

- **Milieu (Environment)**
  - Location
  - Design
  - Waste management
  - Visitor access
  - Lighting
  - Fight against pests
  - Air/Rain/Dust
  - Cleaning and disinfection

- **Machine**
  - Cold chain
  - Calibration
  - Cleaning plan
  - Disinfection
  - Maintenance

Maintain a hygienic environment throughout the production process.
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-authorised 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 fertilisers) | Excessive fertiliser (especially nitrogen which produces high nitrate concentrations in plants)  
|                                         | Poor calibration of the equipment used to apply fertilisers  
|                                         | 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 neighbouring 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  

Chapter 2  
Risk management measures in companies
2.1.4. 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, pasteurisation, ionising 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. 5

Production managers must set three goals for biological hazards:
1. Eliminate or reduce hazards to acceptable levels
2. Prevent or minimise 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, pasteurisation 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\(^6\)
- 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.

\(^6\) 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 thanks to reduced pH. Generally speaking, the acidification of products or the addition of salt inhibits the growth of micro-organisms.
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

**2.1.5. 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.

Risk management for these substances consists of two broad categories:

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.).

7 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.
The main management measures include:

- Management of "raw materials" supplies: setting specifications for raw materials and for all inputs likely to be used (fertilisers, 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).

2.1.6. 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.

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 organise staff training sessions that cover shipping, receiving, storage and handling as well as the maintenance and calibration of equipment.
2.2. 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 fertilisation 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!

### 2.2.1. Site set-up and characteristics

<table>
<thead>
<tr>
<th>Product contamination by:</th>
<th>Management measure</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residual pesticides in the soil</td>
<td>Do not grow in soil known to contain pesticide residues</td>
<td>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.</td>
</tr>
<tr>
<td>Heavy metals</td>
<td>Do not use soil known to contain heavy metal residues.</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

2.2.2. Fertiliser use

Product contamination by:

Management measure:

Proof of control:

Chemical fertilisers

Apply the quantities needed to comply with harvest requirements.

Recommendations for fertilisers provided by an expert adviser.

Calibrate fertiliser spreaders

Recommendations for fertilisers

Fertiliser sheets

Training record

Calibration sheets
## 2.2.3. Pesticide use

Two factors must be taken into consideration for pesticide management:

1. **Only authorised 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).  

2. **GAP (Good Agricultural Practices) must imperatively be complied with to ensure that pesticide residues on food are below the Maximum Residue Level** (MRL). When there is no national or EU MRL, the MLR of the *Codex Alimentarius* should be used.

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8 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.

9 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.

<table>
<thead>
<tr>
<th>Source of the hazard</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No records of the source of crop products (this is important when withdrawing a product and for pesticide use sheets).</td>
<td>The identity of each lot must be traceable from harvest, production and propagation back to the seeds.</td>
<td>Keep suitable files from planting through harvest.</td>
</tr>
<tr>
<td>No complete file on pesticides.</td>
<td>All details about the application on harvest must be kept current and filed for three years.</td>
<td>Ensure that the files actually exist.</td>
</tr>
<tr>
<td>Risk of crop contamination by pesticides due to poor dosage and poor application practices.</td>
<td>Only qualified employees should be allowed to apply pesticides. Provide training.</td>
<td>File employee training records. Warehouse inspection. Application file.</td>
</tr>
<tr>
<td>Risk of applying the wrong pesticide to the crop.</td>
<td>Ensure that there is an up-to-date list approved at the national level and by the client at the commercial level.</td>
<td>List of authorised 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.</td>
</tr>
<tr>
<td>Risk of crop contamination by pesticides due to a poorly calibrated sprayer.</td>
<td>Apply the sprayer maintenance and calibration plan.</td>
<td>Calibration sheet</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Crop contamination by dirty water in the spraying solution.</td>
<td>Examine water sources in neighbouring fields. Carry out a regular verification of the potential sources of microbial hazards.</td>
<td>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.</td>
</tr>
<tr>
<td>Crop contamination resulting from a poor location or to the safety of pesticide storage.</td>
<td>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.</td>
<td>Carry out a regular audit of the buildings and their content.</td>
</tr>
</tbody>
</table>

### 2.2.4. 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 they 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)*
<table>
<thead>
<tr>
<th>Source of the hazard</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contamination by jewellery, clothing and foreign bodies (animal excrement from manure, dead insects, stones, etc.)</td>
<td>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.</td>
<td>Provide employees with hygiene training. Raise worker awareness</td>
</tr>
<tr>
<td>Microbial contamination of products by field workers</td>
<td>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.</td>
<td>Keep employee files. Employee files Medical screening and employee responsibility Employee hygiene and behavioural training</td>
</tr>
</tbody>
</table>
Employees must report all illnesses that could be transmitted by food, including jaundice, fever and diarrhoea, and infected injuries, skin problems, runny eyes, ears or nose. Personal behaviour such as spitting, sneezing and coughing on products.

Cover all infected injuries, abrasions and wounds. Blue plaster with a magnetic strip. Raise employee awareness

### 2.2.5. 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.**

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contamination by metal fragments or lubricants</td>
<td>Ensure that all equipment used for harvesting is in good operating order thanks to a maintenance programme.</td>
<td>Regular checks, a maintenance programme and service files.</td>
</tr>
<tr>
<td>Contamination by soil, glass, plastic, wood or stones.</td>
<td>Adjust harvesting methods to avoid contamination. Ensure that containers are intact and undamaged.</td>
<td>Inspect and keep a record of all containers.</td>
</tr>
<tr>
<td>Contamination due to a dirty harvest or handling machine or to transport.</td>
<td>Do not use harvest trailers and containers to transport manure. The trailers used to transport product to the packing station must be covered.</td>
<td>Ensure that a cleaning programme is in place. Check the cleaning programme.</td>
</tr>
</tbody>
</table>
Product contamination due to poorly set or maintained refrigeration equipment.

Ensure that there is a regular maintenance programme.

Maintainence files

### 2.2.6. Product storage before transport or shipping

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.

![Temporary refrigerated storage room (Photo B. Schifffers)](image)

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product contamination due to poor maintenance of storage areas and rooms.</td>
<td>Servicing and maintenance plan Cleaning procedure</td>
<td>Maintenance files</td>
</tr>
<tr>
<td>Poorly set or maintained refrigeration equipment</td>
<td>Servicing and maintenance plan Temperature control</td>
<td>Maintenance files Regular recording of temperatures</td>
</tr>
</tbody>
</table>
2.3. 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.

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product deterioration due to poor temperature control.</td>
<td>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.</td>
<td>Monitor and track the temperature. Set a maximum load amount.</td>
</tr>
<tr>
<td>Contamination by previous loads.</td>
<td>Inspect the vehicle before loading. Clean thoroughly, if possible.</td>
<td>Refuse the vehicle. Proof of cleaning.</td>
</tr>
<tr>
<td>Contamination by other substances due to shared loads.</td>
<td>Check before loading if the products can be transported with another substance.</td>
<td>State of the items used to separate the various types of merchandise transported.</td>
</tr>
<tr>
<td>Contamination due to the presence of pests.</td>
<td>Guarantee from the transporter that there are no pests. Adequate cleaning.</td>
<td>Proof of cleaning.</td>
</tr>
<tr>
<td>Contamination by dust and various vehicle parts.</td>
<td>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.</td>
<td>Cleaning schedule.</td>
</tr>
</tbody>
</table>
2.4. Post-harvest: General facility requirements

2.4.1. General requirements for the set-up and overall organisation of a packhouse

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 colour).

- **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.

---

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.

2.4.2. Buildings and structures

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 metres or a physical separation).

Toilets and hand washing stations

- 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 (jewellery, 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 “forward 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.

Fertiliser and pesticide storage rooms

- It is forbidden to store fertilisers 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 fertiliser 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 fertilisers 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.

\[11\] For more information, see Manual no. 4 of the PIP.
2.4.3. 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 (authorised) detergents, 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.

<table>
<thead>
<tr>
<th>What should be cleaned?</th>
<th>Frequent examples</th>
<th>What pH?</th>
</tr>
</thead>
<tbody>
<tr>
<td>From organic sources (animal, plant or human: oil, grease, wine, blood, urine, etc.)</td>
<td>Fresh protein and fat deposits</td>
<td>A good degreaser, pH between 6 and 8</td>
</tr>
<tr>
<td></td>
<td>Cooked fats</td>
<td>Alkaline degreaser, pH between 9 and 12.5</td>
</tr>
<tr>
<td></td>
<td>Grease, mechanical oils, burnt grease, etc.</td>
<td>Very alkaline degreaser pH between 13.5 and 14</td>
</tr>
<tr>
<td></td>
<td>Very sugary residues</td>
<td>Acidic detergent pH &lt; 6</td>
</tr>
<tr>
<td>Mineral sources (tartar, cement, plaster, rust, etc.) They leave a film on surfaces.</td>
<td>Tartar (calcium)</td>
<td>Acidic detergent pH &lt; 6</td>
</tr>
</tbody>
</table>

---

12 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.
Chlorine + Acid $\rightarrow$ Release of toxic gas! 
(e.g.: Bleach + Acidic detergent)

Alkaline + Acid $\rightarrow$ Loss of effectiveness! (neutralisation)

Water quality, and notably its “hardness”\(^\text{13}\) 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 sterilisation which is intended to create a bacteria-free environment).

\(^\text{13}\) 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.
This operation uses disinfectants (biocides) authorised for this purpose and selected based on the types of micro-organisms to be eliminated and the surfaces to be cleaned.

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 viricide.

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!

---

**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 authorised 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 twice 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.

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14 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

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product contamination by cleaning solvents,</td>
<td>All chemical cleaning products must be compatible with food use.</td>
<td>Check product labels.</td>
</tr>
<tr>
<td>detergents and biocides</td>
<td>List the authorised products</td>
<td>File all safety data sheets</td>
</tr>
<tr>
<td></td>
<td>Train employees</td>
<td>List of products authorised for use at the company</td>
</tr>
<tr>
<td>Odours and infection by other food products,</td>
<td>All chemical cleaning products must be compatible with food use and may not contain</td>
<td>Check product labels.</td>
</tr>
<tr>
<td>disinfectants and fumes</td>
<td>fragrances.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Some food products will give off a smell.</td>
<td>Keep all chemical products separate from food products.</td>
</tr>
<tr>
<td></td>
<td>Chemical products must be stored far from food products.</td>
<td></td>
</tr>
</tbody>
</table>

2.4.4. 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 harbour 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.

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pest contamination</td>
<td>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.</td>
<td>Professional rat extermination log.</td>
</tr>
<tr>
<td>Contamination by faecal matter or dead organisms</td>
<td>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.</td>
<td>Service contracts</td>
</tr>
</tbody>
</table>
2.5. Post-harvest: Manpower requirements

2.5.1. 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 diarrhoea, or open wounds are a source of pathogenic agents.

- Employee cleanliness and clothing

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.

Clothing should be adapted to the product: apron closed to the neck, a hair net, boots, gloves, etc. (Photo B. Schiffers)
The importance of hand washing

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 be 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.
- Return equipment to its storage place after use and washing.
□ 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.

2.5.2. Personal behaviour

Agricultural workers must avoid behaviour that could lead to food contamination. This includes smoking, spitting, chewing gum, eating, sneezing or coughing near unprotected food.

Personal effects such as jewellery, 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 behaviour 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 jewellery, 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.

2.5.3. 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 diarrhoea 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

<table>
<thead>
<tr>
<th>Illness</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A virus</td>
<td>Fever, jaundice</td>
</tr>
<tr>
<td>Typhi salmonella</td>
<td>Fever</td>
</tr>
<tr>
<td>Shigella strains</td>
<td>Diarrhoea, fever, vomiting</td>
</tr>
<tr>
<td>Norwalk virus and related</td>
<td>Diarrhoea, fever, vomiting</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Diarrhoea, vomiting</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>Fever, angina with fever</td>
</tr>
</tbody>
</table>

#### 2.5.4. 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.
### 2.5.5. Summary of staff-related control measures

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contamination by jewellery, clothing and foreign bodies</td>
<td>Do not carry around jewellery 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.</td>
<td>Keep a record of hygiene training. Ensure that staff knows the policy. Implement signage.</td>
</tr>
<tr>
<td>Microbial contamination via dirty clothes or hands, unhygienic habits and infectious diseases.</td>
<td>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 diarrhoea, and infected injuries, skin problems, runny eyes, ears or nose. Personal behaviour such as spitting, sneezing and coughing on products. Wear clean clothing in the packing areas.</td>
<td>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 behaviour Cover all cuts, abrasions and wounds with waterproof plasters with a metal band. Raise employee awareness</td>
</tr>
<tr>
<td>Toilets</td>
<td>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.</td>
<td>Cleaning programme.</td>
</tr>
</tbody>
</table>
2.6. Post-harvest: Equipment requirements

2.6.1. 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.

2.6.2. 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**
  - 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 sanitised 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 colour coding to differentiate containers.

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product contamination by cleaning solvents, detergents and biocides</td>
<td>All chemical cleaning products must be compatible with food use. List the authorised products Train employees</td>
<td>Check product labels File all safety data sheets List of products authorised for use at the company</td>
</tr>
<tr>
<td>Contamination of packaging and packing materials</td>
<td>All materials must be stored in clean and dust-free areas. All packing materials must be made of food grade materials.</td>
<td>Building cleaning programme</td>
</tr>
<tr>
<td>Containers dirtied by inappropriate use or because there is no cleaning programme in place</td>
<td>Ensure that containers are used only for a given product. Container cleaning programme</td>
<td>Container logs Cleaning record</td>
</tr>
<tr>
<td>Contamination of pallet and crate wood</td>
<td>Try not to use unpolished wood where products are handled. Wood surfaces must be covered with paint to enable easy cleaning.</td>
<td>Routine inspections</td>
</tr>
</tbody>
</table>
2.6.3. Cold chain management requirements

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.

Maintenance of cold storage areas is essential (Photo B. Schiffers)

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.
2.7. Post-harvest: Material requirements

2.7.1. Water quality

Water is used for many purposes in the agricultural sector: irrigation, dilution of pesticides, fertiliser 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).
<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flood water and roof leaks</td>
<td>The building must prevent the entry of rainwater. Site drainage must be sufficient to ensure proper hygiene.</td>
<td>Site inspection.</td>
</tr>
<tr>
<td>Recycled water</td>
<td>Should not come into contact with the finished product. Only use drinkable water.</td>
<td>Take a sample to check the microbial level if using recycled or filtered water.</td>
</tr>
<tr>
<td>Contaminated cooling water</td>
<td>Check if water is contaminated by dirty products or at its source.</td>
<td>Take a water sample. Assess the risks. Equipment maintenance and cleaning programme.</td>
</tr>
</tbody>
</table>

**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)**

<table>
<thead>
<tr>
<th>Micro-biological standards</th>
<th>Expression of results in:</th>
<th>Maximum allowable concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total coliform (*)</td>
<td>100 ml</td>
<td>0</td>
</tr>
<tr>
<td>Thermo-tolerant coliform</td>
<td>100 ml</td>
<td>0</td>
</tr>
<tr>
<td>Faecal streptococcus</td>
<td>100 ml</td>
<td>0</td>
</tr>
<tr>
<td>Sulphite-reducing clostridia</td>
<td>20 ml</td>
<td>1</td>
</tr>
<tr>
<td>Salmonella</td>
<td>5 l</td>
<td>0</td>
</tr>
<tr>
<td>Pathogenic staphylococcus</td>
<td>100 ml</td>
<td>0</td>
</tr>
<tr>
<td>Enterovirus</td>
<td>10 l</td>
<td>0</td>
</tr>
</tbody>
</table>

(*) At least 95% of samples taken should not contain total coliform in 100 ml of water.
### Water drinkability: physico-chemical properties

<table>
<thead>
<tr>
<th>Physico-chemical criteria</th>
<th>Results expressed in:</th>
<th>Maximum allowable concentration (drinking water in France)</th>
<th>European directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>°C</td>
<td>25</td>
<td>12</td>
</tr>
<tr>
<td>Hydrogenic potential</td>
<td>pH units</td>
<td>6.5 &lt; pH &lt; 9</td>
<td>6.5 &lt; pH &lt; 8.5</td>
</tr>
<tr>
<td>Chlorides</td>
<td>mg/l Cl</td>
<td>250</td>
<td>25</td>
</tr>
<tr>
<td>Sulphates</td>
<td>mg/l SO₄</td>
<td>250</td>
<td>25</td>
</tr>
<tr>
<td>Magnesium</td>
<td>mg/l Mg</td>
<td>50</td>
<td>30</td>
</tr>
<tr>
<td>Sodium</td>
<td>mg/l Na</td>
<td>150</td>
<td>20</td>
</tr>
<tr>
<td>Potassium</td>
<td>mg/l K</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Total aluminium</td>
<td>mg/l Al</td>
<td>0.2</td>
<td>0.05</td>
</tr>
<tr>
<td>Nitrates</td>
<td>mg/l</td>
<td>50</td>
<td>25</td>
</tr>
<tr>
<td>Hardness</td>
<td>French degrees</td>
<td>50</td>
<td>-</td>
</tr>
<tr>
<td>Dry residues</td>
<td>mg/l (dry at 180°C)</td>
<td>1500</td>
<td>-</td>
</tr>
</tbody>
</table>

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 standardisation around the world.

[http://www.who.int/water_sanitation_health/dwq/](http://www.who.int/water_sanitation_health/dwq/)
2.7.2. 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. Schifers)*

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** can not 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.
2.8. Post-harvest: Operational requirements

2.8.1. 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.

2.8.2. Product cleaning and washing operations

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, neutralised 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 "sanitise" 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.

### 2.8.3. 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 harbour 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.15

### 2.8.4. 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.).

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15 See PIP Manual no. 2 on traceability.
All machines must be on a maintenance 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.

2.8.5. 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. 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.

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-approved materials (waxes, polymers, etc.)</td>
<td>Only use authorised waxing agents.</td>
<td>Check product labels.</td>
</tr>
<tr>
<td>No file on the source of the products (this is important when withdrawing a product and for recording pesticide use).</td>
<td>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.</td>
<td>Keep files from planting through harvest.</td>
</tr>
<tr>
<td>No complete file on pesticides.</td>
<td>All details about applications on crops must be kept current and filed for three years.</td>
<td>Ensure that files actually exist.</td>
</tr>
</tbody>
</table>

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.
| Risk of crop contamination by pesticides due to poor dosage and poor application practices. | Only qualified personnel is allowed to apply pesticides. Provide training. | Check staff certificates and 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 authorised 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. |
### 2.8.6. 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.

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-compliant products due to soiling, damage, excessive splintering or non-compliance with specifications.</td>
<td>Processing of discarded products should be done in a special area to avoid cross-contamination. Facilitate waste removal.</td>
<td>Waste management plan (inventory, classification, collection, storage, elimination, treatment and recycling measures). Personnel management</td>
</tr>
</tbody>
</table>

### 2.8.7. 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.)

<table>
<thead>
<tr>
<th>Source of the hazard:</th>
<th>Management measure:</th>
<th>Proof of control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvests contaminated by pesticides before shipping from the farm.</td>
<td>Keep harvested products away from pesticide storage and protect the spraying equipment.</td>
<td>Suitable storage after harvest.</td>
</tr>
<tr>
<td>Contamination by pests before shipping.</td>
<td>Ensure that there are no pests in the storage areas.</td>
<td>Rat extermination and control.</td>
</tr>
<tr>
<td>Contamination by waste before shipping.</td>
<td>Remove waste often from the trimming lines and avoid accumulation.</td>
<td>Waste removal schedule.</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Contamination by contaminated storage containers.</td>
<td>Ensure that a cleaning programme is in place. Do not use storage containers to transport manure, oil, fertilisers, etc.</td>
<td>Cleaning records.</td>
</tr>
<tr>
<td>Increase in waste.</td>
<td>Comply with the inventory policy and ensure that all products are sent fresh and at the correct temperature.</td>
<td>Inventory management policy and records.</td>
</tr>
</tbody>
</table>
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 litres 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

<table>
<thead>
<tr>
<th>Area or equipment</th>
<th>Tasks to be completed</th>
<th>Detergent or disinfectant concentration</th>
<th>Frequency of cleaning and disinfection</th>
</tr>
</thead>
</table>
| 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 detergent (caustic soda, 30 min contact)
- Water rinse
- Disinfection with bleach
- Water rinse after 30 min

- 1%
- 200 mg/l

Once a day
Sometimes twice a day at lunch time 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. Sterilised water and boxes of PCA should be easily available from a laboratory (medical centre, university, analysis laboratory).

 Principle

After cleaning and disinfection, the microbial load is estimated by sweeping the surface to be analysed 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 cm² 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:

<table>
<thead>
<tr>
<th>Bacterial load (in cfu/ 50 cm²)</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 300</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>100 - 300</td>
<td>Acceptable</td>
</tr>
<tr>
<td>10 - 100</td>
<td>Satisfactory</td>
</tr>
</tbody>
</table>

*cfu: colony-forming units

Note that only a certain proportion (about 40%) of the micro-flora present on the surface analysed 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 3

The self assessment system and self assessment guides

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3.1. General principles of a self assessment system

3.1.1. Origin of the self assessment concept

The difficulties encountered managing food crises in past years has demonstrated the need to require that the operators 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 organise 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).\(^4\) This regulatory system is intended to:

1. Set the hygiene rules applicable to all "operators" in the food sector including **importers**.
2. To 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. To 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.


\(^4\) See PIP Manual 1 (Chapter 1).
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. 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.

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5 See PIP Manual 1, Chapter 7, 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).
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-organised 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.

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.
3.1.2. 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 compromise 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, 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 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), HACCP, traceability, control plans and notification of the authorities of non-conformities found.

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6 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.

7 This is still a voluntary approach and they may choose not to use the guides to develop their self assessment system.

8 Note that these are Pre-Requisite Programs which precede the implementation of an HACCP system (see PIP Manual no. 1). PRP's refer to management measures which are not specific to a production process step but are generally applicable, for example: cleaning of premises and disinfection of tools, pest control (rodents, insects, birds), employee hygiene, etc.
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).

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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9 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).
 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 mobilisation 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 organise 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 analysed.
- Take an inventory and analyse 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.
- Analyse 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 categorised 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 organisations 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.

3.1.3. 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.10

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 check11 (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...

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10 (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.

11 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.
as 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.
3.2. Self assessment guides

3.2.1. 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", 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.

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12 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".
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 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.

3.2.2. 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 commercialisation 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 characterisation (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: Checklist 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 organisations (ICO)
- Certification procedures
- Auditor/controller and producer obligations
- Sanctions

3.2.3. 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, commercialisation 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 commercialisation 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 authorised 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 organisation)
- 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 organisation, their name and contact information must be provided. In addition to the data for the coordinating organisation, data must also be provided for associated professional organisations (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 organisation) 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 centres 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\(^{13}\)) requirements must be described and detailed in the guide. All key hygiene requirements must be developed in detail in the guide’s 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.

\(^{13}\) GAP: Good Agricultural Practices, BPP: Good Phytosanitary Practices
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 be 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 a 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 organised.

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.
3.3. Verification within the context of the self assessment system

3.3.1. 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:

1. Does the FSMS meet the objectives set by the company in its quality policy and food safety policy?
2. Does the FSMS meet customer requirements?
3. 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.

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The controls, analyses and internal audits, their content and their frequency should be defined in a specific procedure for the verification of the FSMS.

3.3.2. 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 organisational 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 fertilisers).
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.

Organisation 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.
Personal notes
Personal notes
Most used abbreviations and acronyms
# Most used abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ACP</td>
<td>African, Caribbean and Pacific (Group of ACP States that have signed a series of agreements with the EU, called the ‘Cotonou Agreements’)</td>
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<tr>
<td>ADI</td>
<td>Acceptable daily intake (in mg/kg bw/day)</td>
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<tr>
<td>AOEL</td>
<td>Acceptable operator exposure level: Acceptable level for operator exposure when pesticides are applied</td>
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<tr>
<td>ARfD</td>
<td>Acute reference dose</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service. Registration number for chemical substances</td>
</tr>
<tr>
<td>CCP</td>
<td>Critical control point (under the HACCP method)</td>
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<tr>
<td>CLP</td>
<td>The CLP Regulation is the name given to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures</td>
</tr>
<tr>
<td>CMR</td>
<td>Carcinogenic, mutagenic and reprotoxic substances</td>
</tr>
<tr>
<td>CSR</td>
<td>Corporate social responsibility</td>
</tr>
<tr>
<td>DT&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Half-life of a substance in a given soil (in days)</td>
</tr>
<tr>
<td>EC</td>
<td>Emulsifiable concentrate, liquid formulation of a solvent-based pesticide</td>
</tr>
<tr>
<td>ECR</td>
<td>Emerging chemical risk</td>
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<tr>
<td>EMS</td>
<td>Environmental management system</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>EPA</td>
<td>Environmental Protection Agency (USA)</td>
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<tr>
<td>EPPO</td>
<td>European and Mediterranean Plant Protection Organisation</td>
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<tr>
<td>ETI</td>
<td>Ethical trading initiative</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>EVPP</td>
<td>Empty pesticide product containers</td>
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<tr>
<td>EvRP</td>
<td>&quot;Evaluation des Risques professionnels&quot; (equivalent to HIRA - Hazard identification &amp; risk assessment)</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organisation: UN organisation that addresses food security problems in the world</td>
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<td>FBI</td>
<td>Foodborne illness outbreak</td>
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<tr>
<td>FLO</td>
<td>Fairtrade Labelling Organizations International (FLO) is an association of various fairtrade labelling initiatives</td>
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<tr>
<td>FSMS</td>
<td>Food safety management system (see also QMS)</td>
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<tr>
<td>GAP</td>
<td>Good agricultural practices (set of application conditions that must be defined: dosage, volume, formulation, technique, PHI)</td>
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<tr>
<td>GHS</td>
<td>General harmonised system (product classification and labelling)</td>
</tr>
<tr>
<td>GLP</td>
<td>Good laboratory practices</td>
</tr>
<tr>
<td>GMO</td>
<td>Genetically modified organism</td>
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<tr>
<td>GPP</td>
<td>Good phytosanitary practices (set of rules to follow to avoid contaminating the operator or the environment and to avoid residues)</td>
</tr>
<tr>
<td>HACCP</td>
<td>Hazard analysis critical control point: system that defines, assesses and prevents food safety problems</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
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<tr>
<td>ICB</td>
<td>Independent (third-party) certification body (see TPC)</td>
</tr>
<tr>
<td>ICM</td>
<td>Integrated crop management or integrated production</td>
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<tr>
<td>ILO</td>
<td>International Labour Organisation</td>
</tr>
<tr>
<td>INERIS</td>
<td>Institut National de l'Environnement industriel et des risques, the French national institute for industrial environment and hazards</td>
</tr>
<tr>
<td>INRS</td>
<td>Institut National de Recherche et de Sécurité, the national research and safety institute for the prevention of occupational accidents and diseases in France</td>
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<tr>
<td>IOBC</td>
<td>International Organization for Biological and Integrated Control of Noxious Animals and Plants</td>
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<tr>
<td>IPM</td>
<td>Integrated pest management</td>
</tr>
<tr>
<td>IPPC</td>
<td>International Plant Protection Convention</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization. ISO is the international standards body whose members are the national standards institutes of 149 countries</td>
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<tr>
<td>IUPAC</td>
<td>International Union of Pure and Applied Chemistry</td>
</tr>
<tr>
<td>JECFA</td>
<td>Joint FAO/WHO Expert Committee on Food Additives</td>
</tr>
<tr>
<td>JHA</td>
<td>Job hazard analysis</td>
</tr>
<tr>
<td>Kd</td>
<td>Adsorption coefficient (measures how tightly the pesticide binds or sticks to soil particles)</td>
</tr>
<tr>
<td>LCA</td>
<td>Life cycle assessment (or analysis)</td>
</tr>
<tr>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Lethal dose 50 (mg/kg bw)</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>LOAEL</td>
<td>Lowest observed adverse effect level. Lowest concentration causing an adverse effect. See also NOAEL - no observable adverse effect level.</td>
</tr>
<tr>
<td>LOD</td>
<td>Detection limit</td>
</tr>
<tr>
<td>LOQ</td>
<td>Limit of quantification (also called limit of determination)</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum residue level</td>
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<tr>
<td>MSDS</td>
<td>Material safety data sheet</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental Organisation</td>
</tr>
<tr>
<td>NOAEL</td>
<td>No observable adverse effect level</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>OEL</td>
<td>Occupational exposure limits</td>
</tr>
<tr>
<td>OHSAS</td>
<td>Occupational Health and Safety Assessment Series</td>
</tr>
<tr>
<td>OSHA-EU</td>
<td>European Agency for Safety and Health at Work</td>
</tr>
<tr>
<td>PCB</td>
<td>Polychlorinated biphenyls, chlorinated aromatic compounds (209 congeners)</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction, a technique to amplify gene sequences</td>
</tr>
<tr>
<td>PHI</td>
<td>Pre-harvest interval (number of days to wait before harvesting)</td>
</tr>
<tr>
<td>PNEC</td>
<td>Predicted no-effect concentration, for aquatic species.</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal protective equipment</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>PPNU</td>
<td>Non-usable pesticide products (outdated or obsolete)</td>
</tr>
<tr>
<td>PS</td>
<td>Private, or voluntary, standard</td>
</tr>
<tr>
<td>PTMI</td>
<td>Provisional tolerable monthly intake</td>
</tr>
<tr>
<td>PTWI</td>
<td>Provisional tolerable weekly intake</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System (see also FSMS)</td>
</tr>
<tr>
<td>REACH</td>
<td>Regulation (EC) No 1907/2006 on chemicals (1 June 2007)</td>
</tr>
<tr>
<td>SA 8000</td>
<td>A standard considered as the first private international reference standard concerning the rights and respect of the individual on the job</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety data sheet: technical note detailing all the dangers of a product, means of prevention and emergency measures, also see MSDS</td>
</tr>
<tr>
<td>TDI</td>
<td>Tolerable daily intake</td>
</tr>
<tr>
<td>TEQ</td>
<td>Toxic equivalent</td>
</tr>
<tr>
<td>TNC</td>
<td>Tesco Nature's Choice: a TESCO private standard</td>
</tr>
<tr>
<td>TPC</td>
<td>Third-party certifier (see ICB)</td>
</tr>
<tr>
<td>TRV</td>
<td>Toxicological reference value</td>
</tr>
<tr>
<td>TWI</td>
<td>Tolerable weekly intake</td>
</tr>
<tr>
<td>UL</td>
<td>Oil-based concentrated solution, liquid pesticide formulation</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations Organisation</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>UNCED</td>
<td>United Nations Conference on Environment and Development</td>
</tr>
<tr>
<td>UNECE</td>
<td>The United Nations Economic Commission for Europe</td>
</tr>
<tr>
<td>WG</td>
<td>Water-dispersible granules, solid pesticide formulation</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>WP</td>
<td>Wettable powders, solid pesticide formulation</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organisation</td>
</tr>
</tbody>
</table>
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Bibliographical references

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Useful Websites
Useful Websites

AFSCA-FAVV (Federal Agency for the Safety of the Food Chain):

ANSES (French Agency for Food Environmental and Occupational Health & Safety):
http://www.anses.fr/

ACIA (Canadian Food Inspection Agency):

BRITISH RETAIL CONSORTIUM (BRC):
http://www.brcdirectory.com/

EUROPEAN COMMISSION:

EUROPEAN COMMISSION: Pesticides database (MLR and TLV)
http://ec.europa.eu/sanco_pesticides/public/index.cfm

FOOD SAFETY MANAGEMENT:
http://www.foodsafetymanagement.info

FSS (Food Surveillance System):
http://www.food.gov.uk/enforcement/monitoring/fss/

GLOBALG.A.P:
http://www.globalgap.org

INTERNATIONAL FOOD SAFETY:
http://www.ifs-online.eu/index.php?SID=2d800b70a2d2ec72ed49e53ee64fcb60&page=home&content=public_content&desc=home&language=english

NORME-ISO22000.INFO:
http://www.norme-iso22000.info/home.htm

ISO Management Systems:
http://www.iso.org/iso/22000_implementation_ims_06_03.pdf

PSD (Pesticide Safety Directorate):
http://www.pesticides.gov.uk/

RASFF(CE):
http://ec.europa.eu/food/food/rapidalert/index_en.htm
COLEACP PIP Training manuals

1. PRINCIPLES OF HYGIENE AND OF FOOD SAFETY MANAGEMENT
2. TRACEABILITY
3. RISK ANALYSIS AND CONTROL IN PRODUCTION
4. OPERATOR SAFETY AND GOOD CROP PROTECTION PRACTICES
5. REGULATIONS, NORMS AND PRIVATE STANDARDS
6. TECHNIQUES IN COMMUNICATION
7. FOUNDATIONS OF CROP PROTECTION
8. TECHNIQUES OF TRAINING
9. SUSTAINABLE AND RESPONSIBLE PRODUCTION
10. BIOLOGICAL CONTROL AND INTEGRATED CROP PROTECTION
11. ETHICAL PRODUCTION
12. ORGANIC FRUIT AND VEGETABLE PRODUCTION IN ACP COUNTRIES