



# TRAINING --- MANUAL

- FOOD SAFETY -

## PRINCIPLES OF HYGIENE AND FOOD SAFETY MANAGEMENT



**COLEACP**

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# **- FOOD SAFETY -**

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# Chapter 1

## Basic food safety concepts

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## 1.1. Food safety: facts and figures

### 1.1.1. A global problem

Every day in every country people fall ill from the food they have eaten. These **foodborne illnesses** are caused by dangerous micro-organisms and/or toxic chemicals.

Even though governments throughout the world do their utmost to improve the safety and quality of food, the high number of foodborne illnesses is a major public health issue for all countries. The WHO (World Health Organization) has estimated that **1,800,000 people die each year** from diarrheal diseases, and most cases can be attributed to contaminated food or drinking water (WHO, 2007). The cost in human suffering is thus far too high, in particular for the most vulnerable population groups (infants and young children, pregnant women, the elderly, the ill, etc.). Malnutrition, coupled with diarrhea caused by unsanitary food, can be devastating and this vicious combination is the primary cause of child mortality in hygiene-deficient countries.

The WHO has also recognized that foodborne illnesses:

- are a problem in developing and developed countries alike;
- place a burden on healthcare systems;
- seriously affect infants, young children, the elderly and those who are already ill;
- spawn a vicious circle of diarrhea and malnutrition;
- undermine the economy and national development efforts, as well as international trade.



Participants in the WHO/FAO International Conference on Nutrition (Rome, 1992) recognized that “Access to [...] safe food is a right of each individual”. In this context, the availability of suitable food should be seen as a top priority by governments, industry and consumers.

Yet cases of food poisoning are **constantly rising**. It is estimated that foodborne illnesses affect from 5 to 10% of the population in industrialized countries (WHO, 1999). Epidemics caused by bacteria such as *Campylobacter jejuni*, *Escherichia coli* O157, *Listeria monocytogenes*, *Salmonella* etc. or by viruses have struck thousands of victims in Europe, Japan and the USA. **New hazards** are discovered every year, associated with the presence of chemical contaminants or toxins that form when food is processed or prepared. Food allergies are also on the rise.

### 1.1.2. A steady increase in the number of cases registered

This increase in the number of cases (referred to as ‘prevalence’) is the result of a **large number of interacting factors**, including:

- the growing number of operators who intervene in the food chain between the primary producer and the consumer;
- inadequate hygiene controls at various steps of production and distribution, as well as in the consumer's own kitchen;
- a change in the way food is prepared and consumed: shorter cooking times, more consumption of raw products either for taste or to save time, less canning and more freezing, more fermented products, cold-smoked fish, and so on;
- more consumption outside the home in restaurants, canteens, etc.;
- more preparation of food, ready-to-cook or ready-to-eat;
- greater sensitivity of products to spoilage (e.g.: less salt or sugar used);
- increased demand for meat or fish, which are more prone to contamination;
- longer food preservation periods due to the complexity of the food chain and greater distance between the field and the consumer's table;
- a larger quantity of food involved as a result of industrialization of the agri-food chain and centralization of distribution systems;
- more international trade, more transport and storage, which offers fewer guarantees that the cold chain has been maintained;
- better detection of bacterial contamination (more cases are reported);
- more exotic products in the diet;
- less respect for growing seasons.



**Food hygiene** is regularly cited as a cause of food poisoning. Those who produce and distribute food obviously must respect rules of hygiene, but individuals should also be concerned about the food they eat.

#### **Main factors leading to foodborne illness outbreaks (FBI) in France**

(Source: "Conserver mieux", CTCPA, 1997)

Contamination of raw materials:	54%
Non-respect for the cold chain during meal preparation:	40%
Error in the preparation process:	35%
Too much time between preparation and consumption:	25%
Contamination by equipment:	21%
Contamination by employees:	17%
Non-respect for the hot chain:	14%



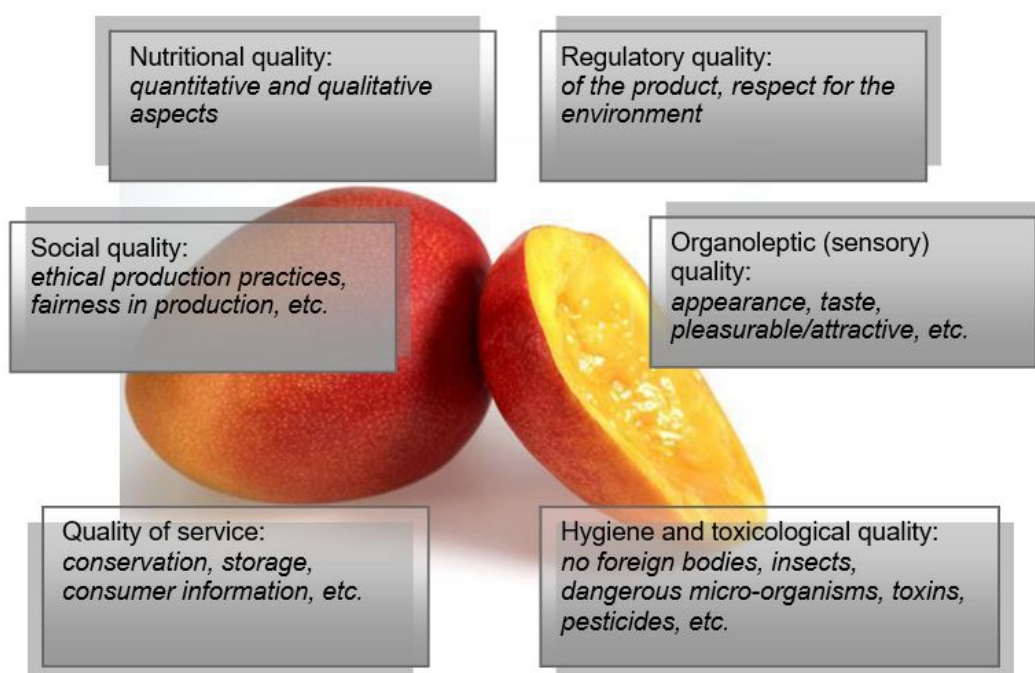
Nonetheless, food poisoning is not **caused solely by insufficient hygiene but also by** various types of **contaminants** which, at certain concentrations, can be toxic for the consumer. Despite the recognized health benefits of regular fruit and vegetable consumption, recent studies on consumer exposure to pesticide residues point to an identifiable risk of poisoning for **some groups** such as children (W. Claeys *et al.*, 2010).<sup>1</sup>

Risks for the average consumer, however, remain low, but they can be reduced further when simple and efficient hygiene rules are applied and all operators implement food safety management systems based on an analysis of the hazards linked to their professional practices and the type of product they handle.

### 1.1.3. Evolution of the concept of product 'quality'

The international standard ISO 9000 defines terms related to quality. Quality is defined as the degree to which a set of inherent characteristics fulfils requirements. Quality comprises multiple characteristics, or components, that depend on the product or service under consideration.

**Quality requirements** for food products have **multiplied considerably** in the past years. They cover not only aspects relating to a product's food safety, but also to the way it was produced or related services related to it (e.g.: information about the product). For instance, **quality elements** can include:

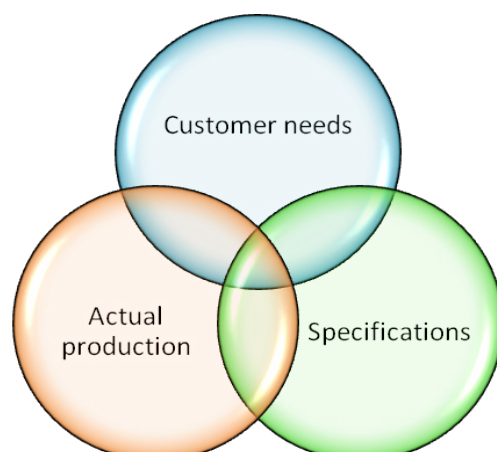


The concept of 'quality' can be illustrated by **3 circles** (Venn diagram) representing:

1. **Customer needs:** which are variable and never totally expressed;

<sup>1</sup> W. Claeys, J.F. Schmit, C. Bragard, G. Maghuin-Rogister, L. Pussemier and B. Schiffers, "Exposure of several Belgian consumer groups to pesticide residues through fresh fruit and vegetable consumption", *Food Control*, No. 22, 2011, pp. 508-516.

2. *Specifications*: both internal (never perfectly defined) and external (better defined, for example regulations);
3. *Actual production*: in the actual production process a gap often appears between the real conditions and those foreseen in specifications (in particular for agricultural products: inclement weather, materials, seasonal workers, etc.).



The final objective of any “*quality strategy*” will be to reconcile “needs/specifications/actual production” in all circumstances – for **controlled quality** is found at the center where the three circles intersect!



**Food safety and traceability** requirements reflect the desire of buyers and consumers to know **where, how, and when** the food on their plate was produced in order to have a guarantee that it is safe.

#### 1.1.4. Significant evolution in retailers' approach

Food safety **cannot be used as a sales argument** because it is illogical to sell foods that are 'safer' than others (they are either safe or not!). This aspect is nevertheless promoted by some retailers who oblige suppliers to apply **their own private standards** in the place of regulations such as MRL (maximum residue levels authorized for pesticides).












In Germany, for example, after the Greenpeace campaigns in the retail sector on pesticide residues in fruit and vegetables ('Eating pesticide-free') the main supermarket chains imposed MRLs well below those authorized by the EU, even though reducing the limit considered as acceptable by 20 to 30 % has no effect on the consumer's level of risk!

Campaign in the Netherlands (with the 'Hypermarket C1000' label): Mandatory limit of 80 % of MRL and maximum of 3 detectable residues authorized in products.



**Examples of residue requirements set by various supermarket chains:**  
**Maximum % of the European MRL considered as acceptable**

 	  		
80% MLR	70% MLR	33.3% MLR	50% MLR

Moreover, the above list does not include retailers that impose their own lists of authorized active substances for use on crops, which are more restrictive than official authorizations.

Food safety and quality have become a major concern for the **European retailing and distribution industry**, which uses it as a marketing argument to address consumers' concerns and calls for change from some pressure groups. Retailers have thus also become 'standards developers' and given their economic clout they can easily take the place of regulations.

In this context, it is clear that the **retail industries are particularly keen to know** whether ACP fruit and vegetable producers master production and packaging techniques, especially as regards food hygiene and the use of pesticides!



**Whether food is sold locally or exported** it must be produced in accordance with general principles of hygiene that are recognized throughout the world (such as those laid down in the *Codex Alimentarius*).

Food exported to the European Union from other countries, however, must also comply with the general requirements of European regulations. This is because the **regulations of the destination market apply *de facto*** to ACP producers. They cannot ignore these requirements if they wish to access these markets or merely to keep their present share of the market. For this reason, even

though the **regulations of the place of production apply as a priority**, this handbook will regularly refer to European regulations.

### 1.1.5. Restoring the confidence of stakeholders and consumers

One connotation of the word 'safe' is '*trustworthy, reliable*'. A series of food crises, however, has shaken European consumers' trust in the safety of their food. Despite efforts deployed in the European Union since 2000 to revise its regulations and operator monitoring systems, the latest opinion polls show that consumers still worry about food safety. The latest 'Eurobarometer',<sup>2</sup> published in 2010 after a survey of 26,691 individuals in all 27 Member States, shows for example that:

- 79% of those surveyed stated they were deeply concerned about the safety of their food (much more important than dietary matters);
- 48% worry about food affecting their health (compared to 44% for road accidents);
- 72% are worried about pesticide residues. **This is the number one 'risk'** (freshness ranks fourth and GMOs rank sixth)!

To ensure that food is harmless and restore consumers' confidence and sense of security, it is necessary:

- **to reinforce and continually update the regulatory framework** to reflect technical changes and the results of risk analyses;
- **for operators to organize self-evaluation and risk control systems** based on HACCP principles;
- to identify the data to be recorded to **ensure product traceability**: to be able to trace the history, destination or origin of a product;
- to guarantee application of these measures through **inspections, monitoring plans, and internal and external audits**.

<sup>2</sup> Eurobarometer, 2010,  
[www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/reporten.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/reporten.pdf).

Confidence can only be restored when:

1. **Food hygiene is guaranteed** (by taking measures and organizing the conditions to prevent hazards and ensure that food products are suitable for consumption).
2. **Food safety is guaranteed** (by using production modes that assure that the food is not harmful to health: good practices and quality strategies).
3. Efforts are taken to **provide correct information** to all stakeholders and the population in general (information, traceability, withdrawal and recall procedures).
4. All actors in the food chain adopt an approach towards food safety that entails a **continuity** of responsibility through the whole life cycle of the product, in other words from **farm to fork**.



## 1.2. Food safety – key concepts

### 1.2.1. The concepts of ‘hazard’, ‘risk’ and ‘crisis’

In order to meet food quality and safety requirements, agricultural businesses must identify all aspects of their activities that are decisive factors for the safety of their products. They must be able to **control all hazards at all stages** of product life cycle (development, production, storage, transport, marketing) in order to meet specifications (regulatory and market) and assure consumers that their food is safe.

The operators must therefore be able to **identify all hazards** (physical, biological or chemical) that can potentially contaminate their products at different stages of production. They must also be able to **assess the level of each risk** (probability) according to their working conditions, procedures and practices. On the basis of these analyses, the appropriate control measures, adapted to the type and level of risk, can be adopted. The company must then make sure that these measures are effectively implemented, complied with and regularly reviewed.

**It is important to understand the difference between the terms ‘hazard’ and ‘risk’:**

**Hazard:** a physical or biological agent or substance with the potential to cause a proven adverse effect on health.

**Risk:** probability of an adverse health effect. The degree of risk is a combination of the probability and the severity of the effect (type of harm, number of people affected, etc.). ‘Risk’ refers to exposure to a hazard, in other words to consumption of a contaminated food (quantity and frequency of consumption).

Risk analysis at every stage of production and packaging is thus indispensable and must precede any preventive action. **The analysis method must be one that has been tested and validated.** In the agri-food sector, HACCP (Hazard Analysis Critical Control Point) is considered to be the most efficient and is the most widely used. It is generally **mandatory by regulation** for all food processing firms. The *Codex Alimentarius*<sup>3</sup> recognizes HACCP as the benchmark for identifying hazards and controlling risks in the food sector.

Many private standards also recommend and encourage application of HACCP principles. For primary production,<sup>4</sup> however, at present it is only **recommended** (in the framework of European regulations). On the one hand programmes to control hygiene

<sup>3</sup> The *Codex Alimentarius* is a set of internationally recognised laws and standards applicable for processes, guidelines and recommendations on food, food production and food safety. The *Codex* standards are the authority in the agri-food sector and most of the recommendations issued by this body have been integrated into European and other regulations.

<sup>4</sup> Primary production: The set of steps taken in the growing and harvesting of fresh fruits and vegetables such as planting, irrigation, application of fertilizers, application of agricultural chemicals, etc.

conditions (or PRP) must be introduced before a HACCP plan can be implemented, and on the other HACCP alone cannot guarantee food safety.

It is also important to clarify the meaning of the term '**food crisis**'. According to terminology accepted by experts, a 'crisis' is a situation in which a **real or hypothetical risk** can lead to **collective misgivings** throughout a population group. It is clear that a crisis can occur even if the risk never materializes.

The crisis occurs when a **malfunction** is measured or when a gap between reality and expected standards is either measured or suspected. This can occur, for example, when **results of an internal or external control** (including documentary controls) or **of analyses** reveal that insufficient mastery of a process has resulted in non-conformity with a standard (e.g.: MRL exceeded) or product contamination (e.g.: traces of dioxin in eggs, avian flu virus detected etc.).

A crisis is also a situation where organizations, private firms and competent authorities (ministries, inspection agents, laboratories, etc.) strive to cope with a situation considered as 'critical'. For a given period of time they find themselves in the forefront where, under **heavy external pressure and acute internal tensions**, they enter into conflict with one another, often under the media's watchful eyes!

Europe has gone through a series of 'crises', all with repercussions among the public, regardless of how serious the crises actually were. Over the past decade alone we can cite:

1997	Numerous cases of BSE (mad cow disease)
1999	Listeria – Illegal dioxin levels in chickens – Contaminated Coca-Cola
2001-2002	Foot and Mouth disease, GMOs, various meat origin frauds
2004	Avian (bird) flu
2006	BTV – Catarrhal fever (blue tongue disease)
2008	Melamine-tainted milk powder in China

To restore consumer confidence, private firms and public authorities alike must prepare **crisis management procedures**, establish mutual trust and get into the habit of communicating together when a malfunction is observed.

### 1.2.2. The concept of 'hygiene' and respecting the cold chain

It is up to each actor in the food production and distribution chain to take all steps to make sure that products placed on the market are free of all risks to consumers' health.

Many of the hazards attributed to food originate in the **failure to respect hygiene rules at the place of production**. This can be in the field or on the packaging line, or during storage or transport. For this reason general rules of hygiene applicable to the food industry are also valid for primary production. As a large portion of **fruit and vegetables are eaten raw**, hygiene is an essential requirement for the conformity of these products.

Simple or cross-contamination of fruit and vegetables, either before or after harvest, can have **several causes**. Growing areas, soil, inputs (manure), equipment and staff are all potential germ vectors. Each producer or firm should organize hygiene measures and



practices that are adapted to the specific conditions of their production area, type of products, methods and techniques, and staff in order to monitor and control risks to food safety and promote the production of wholesome fruit and vegetables.

Following basic principles of hygiene considerably reduces risks that food will be contaminated with germs.

**Preservation conditions** during storage and transport also have a **considerable impact on food quality**. Fruit and vegetables must be handled with care to avoid injuries that make the products more vulnerable to pathogens.

Failure to keep food at the right **temperature and relative humidity** can lead to spoilage and favour the development of pathogenic micro-organisms. The 'cold chain' must be respected absolutely!



*To ensure the stability of physiological and organoleptic properties of fresh produce, the **optimal temperature and relative humidity of storage must be known for each product**. If required, fruit and vegetables must be harvested, transported and preserved at low temperatures (examples: green beans, tomatoes etc.).*

### 1.2.3. The concept of 'product'



'Product' is understood to mean the **result of production**, in other words a coherent sequence of operations (the term 'process' is discussed below).

In the broad sense of the term, products are all foods of plant or animal origin that a producer **places on the market**.

*When we speak of a 'product' we are referring to products that have been harvested, possibly processed, and packaged.*

Other foods are not considered to be '*products*' in the strict sense of the term, even though they are marketed. This is the case for products that have been picked or collected in natural conditions, such as mushrooms, berries, small fruits, aromatic herbs, edible insect larvae or gastropods snails, or even honey produced by colonies in the wild. This is also the case for food that has been fished or hunted.

Despite the fact that these foods were not produced under someone's responsibility, but were merely 'collected', **the person selling these foods nonetheless remains**

**completely responsible** for ensuring that they do not harm consumers' health.  
**Conformity** with health and safety standards **must be ascertained**.

Each type of food product is associated with different types of risks due to their:

- **nature** (origin, composition, sensitivity);
- **production mode**;
- **preservation mode**;
- **mode of preparation and consumption** (raw or cooked).

It is thus important for the producer to be fully aware of the **characteristics** of the products and processes in order to **evaluate the risks**.

Some types of food can be considered as '**high-risk foods**'. A majority of cases of food poisoning are in fact caused by:

- eggs and egg-based products, which account for about one third of foodborne illness outbreaks (FBI);
- poultry, in particular chicken and minced chicken meat;
- food **eaten raw** (fruit, vegetables, fish, meat or shellfish).

#### ❑ Eggs and egg-based products



According to the US Department of Agriculture (USDA) about 2.3 million of the 50 billion eggs produced each year are infected with *Salmonella* (primarily *Salmonella* Enteritidis).

The main means of prevention is to respect the **cold chain** and to pay scrupulous attention to use-by dates.

#### ❑ Poultry and poultry-based products

Chicken is often a *Salmonella* carrier. The mere presence of these bacteria does not pose any particular risk because chicken is almost always eaten cooked. However, *Salmonella* brought into the kitchen by this means can **contaminate other food items that are not cooked** (such as vegetables). Food can be contaminated:

- either **directly**: if the chicken directly touches other food, in the refrigerator for example;
- or through **surfaces** that later come into contact with other food.



The bywords therefore are strict hygiene – from hatching to slaughter and cutting – and thorough cooking.

## ❑ Foods eaten raw or only slightly cooked



**Fruit and vegetables**, even when eaten raw, should in principle not pose high risks for consumers, apart from allergies that some people may have to exotic fruit which is often allergenic.

Eaten raw, they are rarely harmful and are even highly recommended by nutritionists (*'eat five portions of fruit and vegetables per day'*).

Nonetheless they can pose **serious risks** for consumers due to the presence of:

- **pathogenic micro-organisms**, especially of faecal origin, through accidental contamination during production (e.g.: tainted irrigation water), harvest (e.g.: unwashed hands), transport (e.g.: insufficiently disinfected containers), or packaging (e.g.: insufficient hygiene);
- **'toxins'** (mycotoxins) caused by poor storage conditions and overlong preservation;
- chemical residues (nitrates, pesticides, biocides) or heavy metals which contaminate the food.

Prevention essentially means respecting Good Agricultural Practices and applying good hygiene measures during harvest and packaging.



**Meat and fish** in principle should be no more risky than other foods, since they are generally only eaten after cooking, which eliminates most parasites and pathogenic bacteria.

Nevertheless, with changing preparation and consumption habits (the sushi fad, for instance), these foods become more risky with respect to **food poisoning**.

When eaten raw they pose a much higher risk than other products for the following reasons:

- animals are **natural carriers of certain parasites** (such as *Anisakis*, which can reproduce or survive in the human intestine after being consumed in raw fish: herring, mackerel, tuna, salmon etc., or *Ascaris*, found in the intestines of many animals);
- animals are **naturally contaminated on the surface** (skin) by excrement and thus carry germs; even washing after slaughter cannot totally eliminate these germs.
- sale and distribution of meat and fish imply **cutting/slicing operations**, or mincing and mixing, all occasions where the food is liable to be contaminated by staff, equipment, work surfaces or the food products themselves. In the case of minced meat, contaminants spread all the way to the center of the mix and only thorough cooking can eliminate the bacteria.

Prevention does not require complicated measures: fish and meat must be cooked to 70 °C (at least). Fish can be eaten raw after it has been deep frozen for a few days at – 20 °C.

## ❑ Allergy-causing foods

In addition to risks of biological or chemical contaminants, there is also the risk of allergy that the presence (even traces) of certain foods or food components (such as egg yolks, celery, groundnuts) can pose for sensitive consumers. The producer must be aware of the risk of cross-contamination between products.

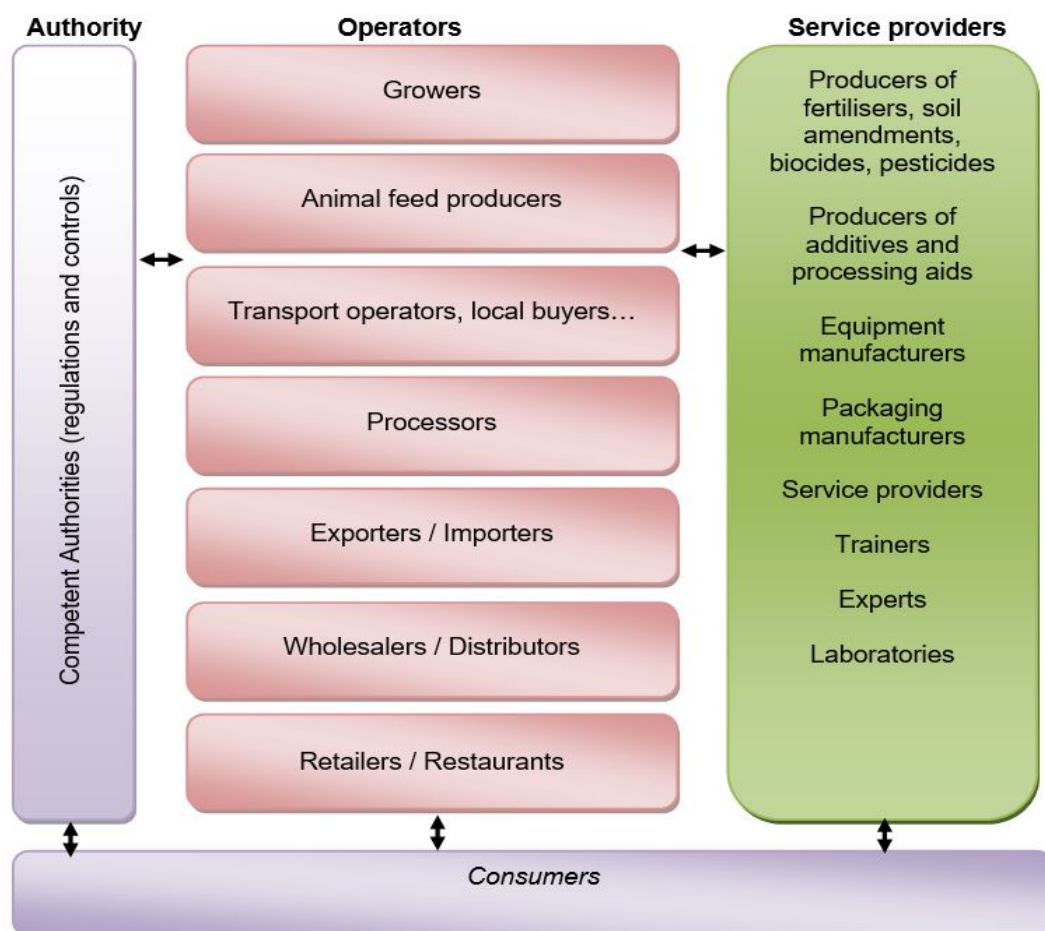
### 1.2.4. The 'food chain' concept



Ensuring food safety must be a goal for all 'actors' along the **food chain** (another term for 'actors' is **stakeholders**).

*Just like a real chain, it is the 'weakest link' that determines the sturdiness of the whole system. The image is totally appropriate.*

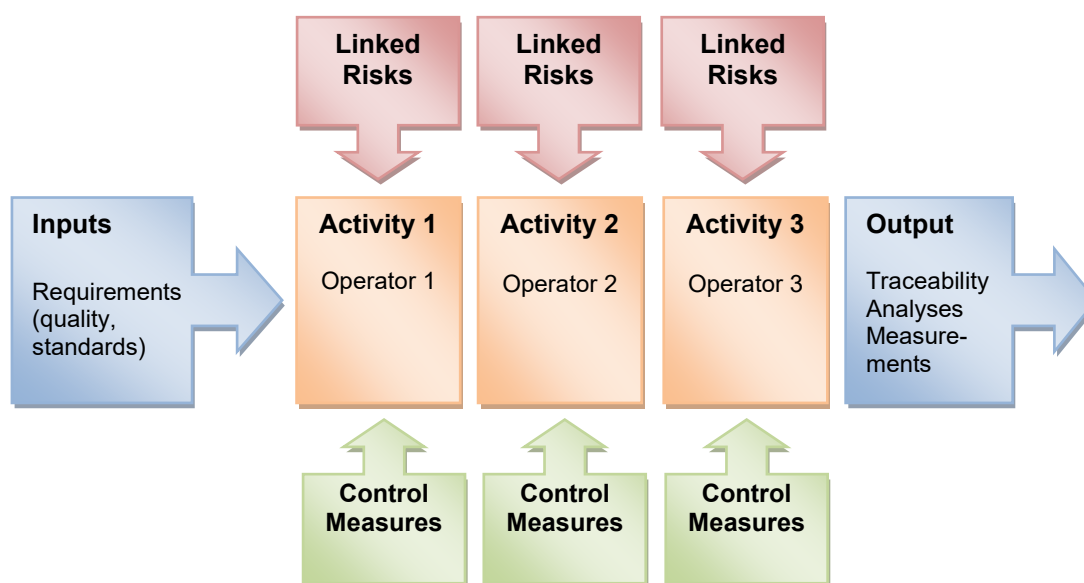
An approach that focuses on the food chain to manage food safety and quality recognizes that **all actors are responsible** for providing food that is safe, healthy and nutritious (FAO, 2010). The diagram below shows the parties involved in the food chain, and indicates the information flow:



### 1.2.5. The concept of 'process'

A process can be described as a **chain of activities** that transforms 'input data' into 'output data'. According to ISO 9000 a process is a sequence of activities accomplished by different players in order to meet an internal or external need by making a product or service available to the customer. Process inputs can be a product, raw material or information.

'Placing a food product on the market' is a **complex process** that requires the **involvement of several operators**. It is also one that requires a combination of **different skills** to attain an objective. A company's production process approach can be depicted as follows:



An objective and meticulous analysis of the processes is important in order to identify:

- The *sequence of operations* (steps in the process), and to be able to distinguish between **operations that can directly influence the safety** of a product and those that are production 'process supports' (which, although important, do not have a direct or indirect influence). This analysis is a crucial step in organizing hygiene measures, drawing up an HACCP plan and choosing the appropriate control measures. As each company has its own organization mode, this type of analysis **cannot be transposed** from one to another.
- The *risks linked to each operation* (e.g.: crop management, harvest, transport, cleaning, etc.).
- The *responsibilities of each entity involved* and the skills required for each.
- The *inspection measures* (records necessary for traceability) and *control measures* that are relevant for each step in the process.

Describing the overall process, in other words the chronological sequence of key steps and the operations carried out, **is something that must be validated on site**. The analysis consists of examining the whole process and methodically calculating the relative importance of each relevant parameter. This involves visits to the various process



sites, interviews with staff and customers, measurements and analyses, all of which in a fact-finding approach.

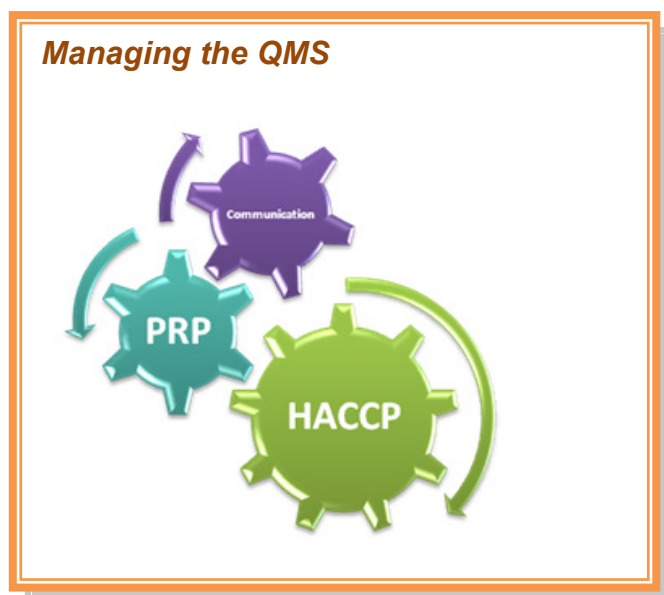
The **complete analysis of the process will yield a picture of how a company operates**. It will be used to ascertain its results in terms of quality and conformity of its products, and also to foresee the risks associated with its organizational and functional mode.

### 1.2.6. The concept of 'system'

Food safety must be **conceived as an 'organized system'** with the aim of meeting a regulatory objective (producing safe and suitable food) and, if relevant, other contractual objectives (complying with one or more private certification schemes). The industry refers to this as a **Food Safety Management System, or FSMS**.<sup>5</sup>

All food safety management systems must be grounded in the elements that the ISO 22000:2005 standard deems as essential to guarantee the safety of food at every link in the food chain:

1. interactive communication between all players in the food chain;
2. systemic approach (system-based management);
3. prerequisite programmes;
4. HACCP principles.



As for any system, a company's FSMS must be designed and prepared. It is then built, managed, evaluated regularly, adjusted and improved (principle of ongoing improvement).

Although a management system can be certified if the customer requires this or if it represents a competitive advantage, **certification in itself does not guarantee** that food safety objectives have been met. The company's objective should be quality and conformity of the products, not mere *certification*.

<sup>5</sup> In reality this system often covers management of *food and phytosanitary* quality. It deals with regulatory requirements concerning quarantine organisms in relation to phytosanitary certification for exports.

### 1.2.7. The concept of 'traceability'

Traceability of a product means the ability to identify:

- all stages of its manufacture,
- the origin of its components and their suppliers,
- where the product and its components have been stored,
- checks and tests on the product and its components,
- equipment used in manufacturing or handling,
- direct customers who bought the product.

Traceability aims to meet **two different yet complementary objectives**:

1. It must be able to **locate** the product in space and time. *Tracking* means the ability to physically follow a product consignment. This is especially useful in a food crisis, to locate products that have to be withdrawn or recalled.
2. Traceability, however, also means being able to *trace* information on the **history and composition of the product**: origin of the seed or plants, crop management practices, inputs used in production, plant protection treatments, processing methods and steps, and so on.

Setting up a 'traceability system' is a *sine qua non* for food safety and is also mandatory by regulation.

## 1.3. The key role of operators in ensuring food safety

### 1.3.1. The operator's responsibility is the cornerstone of the regulatory approach



There have been **fundamental changes** in the management of food safety over the past 20 years, through efforts to implement and extend a **new approach to food safety**.

The result of this evolution in Europe is the '*food hygiene package*', introduced in 2004, which was the foundation for the new European regulations.

**Before these innovations**, food safety was primarily based on the obligation for operators to respect a long list of '*requirements*' (laid down in laws and increasingly detailed and precise with each revision). These **requirements** (or control measures) ranged from compliance with hygiene measures to **details** relating to equipment and installations (such as the height of tiled walls in slaughterhouses), mandatory inspections and registrations etc.

These requirements stemmed more from the accumulated experience of agri-business professionals (producers and inspectors) about which requirements were effective, than from a true *a priori* risk analysis. Over time and with the need to adopt new preventive measures as a result of real incidents, measures were reinforced and new requirements were set out in legal texts and ever more voluminous professional guides.<sup>6</sup>

The concept of food safety at the time was based on the hypothesis that strict compliance with all requirements would guarantee the production of safe and suitable food (**best endeavor obligation** to guarantee a satisfactory result).

This approach was **reassuring for producers**, who merely had to apply the regulations strictly to be absolved of all responsibility. It also made it **easy for inspectors to assess conformity** because it was enough to follow predefined checklists, without worrying about the importance or usefulness of a given hygiene measure in the context of the company being inspected, or the usefulness of their records on the safety of the product in the context of the process. Under this approach, the risk analysis was deemed to be definitive and the measures required therefore applied to all operators in a given sector, regardless of the size of the company, the nature of its products, the qualification of its staff or the characteristics of the natural or work environment.

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<sup>6</sup> The US and Canada's approach to food safety is still based on the principle of 'written food protection guidelines for industry' (according to Eric Poudelet, DG SANCO, in a personal memo, 2010). It is not surprising that this 'diagnosis and solutions' approach developed everywhere, because veterinarians were the first professionals to adopt a health policy for the meat and fish industry.

This approach **carried the seeds** of what would later bloom into the '*food crises*' of the late 1990s that shook Europe's faith in its food safety system. As the whole system revolved around the *inspection* of operators, producers who passed these inspections were not held responsible. The concept at this time – precisely those years when '*quality assurance*' was the hot topic – can be grossly summed up as follows: the inspector, and thus the administration responsible for controls, on signing the certificate of conformity, assumed responsibility for the safety of products placed on the market by the producer.

Furthermore, under this system, the need for stronger safety guarantees equates with more controls. However, simple statistical analysis shows that, for substances with a low accepted prevalence level, the absence of a micro-organism can only be guaranteed with a sufficient level of confidence by analyzing a very large number of samples, which is neither economically feasible nor manageable given the capacity of laboratories. So this approach quickly reaches its limits.

The **current approach** to food safety has completely reversed the role of each party.

The 'new approach' is **non-prescriptive** and **focuses on the operator's accountability**. It sets general objectives without imposing methods. It is up to operators to define means (for example in Good Practice Guides) and apply them. Operators now have the **duty to achieve a given result**, in contrast with the earlier best endeavour obligation.

- **Safety objectives** are regulatory, thus **mandatory**!
- The **means** to attain these objectives are guidelines, therefore their **application is voluntary**!

The defining feature of the 'new approach' is **greater liberty and margin of maneuver for operators**, who bear prime responsibility for food safety management: this is the principle of active accountability (Bolnot, 2008).

It is based on the principle of guiding the development of control measures and monitoring such measures, based on **analysis of the risks linked to the production processes employed in the producer's context**, with the company's own realities, means, resources, equipment, staff qualifications, regulatory requirements for its products and for its customers, and so on.<sup>7</sup>

'*Risk analysis*' is at the heart of the system, and producers are held accountable for organizing efficient health quality management systems, based on **HACCP** and **self-evaluation of their practices**.

The HACCP method establishes 7 basic principles that the producer must respect:

1. Identify the hazards relevant to its activities and product.
2. Identify the 'critical points' where control is absolutely essential. These are called Critical Control Points, or CCP.
3. Establish critical limits (that must not be exceeded) for each control point.
4. Establish CCP monitoring requirements (self-evaluation).
5. Plan corrective actions in case of malfunction (which can occur in the best of

<sup>7</sup> See for example: SAFE FOODS - *Promoting Food Safety through a New Integrated Risk Analysis Approach* - EUFIC, The European Food Information Council.

companies).

6. Establish procedures to verify and validate that the system is working as intended (internal audits).
7. Document its activities, record data on its procedures and keep this information on file.

It is worth noting that the risk of a 'mistake' is not excluded under this approach. What is unacceptable is not the malfunction itself, but rather the failure to identify it or to react immediately when a problem is detected.

Traceability must enable the operator to show that the problem has been identified in time and that it was solved quickly and effectively.

This approach is less 'reassuring' for the producer (who will need advice, training and guides, since the **'critical points' are not pre-determined**). It is also less 'comfortable' for the control authority, who for each firm and each product must verify that the risk analysis has been correctly conducted and that control measures are appropriate and being applied. This approach goes well beyond the 'checklist' and 'inspection' logic, applying 'audit' principles instead!

Although Europe has deliberately moved towards simpler regulations with fewer constraints but more responsibilities, the major wholesalers and retailers have set up schemes to evaluate their suppliers on the basis of their own **reference standards** (such as GLOBALG.A.P. or TNC). Analysis of different specifications for such standards reveals a strong convergence of their basic requirements: in accordance with the '*due diligence*' principle, producers must prove that they have taken **all possible precautions** to make sure that their fruit and vegetables are not dangerous for the consumer. They tend to fall back on the principle of 'requirements' **but these are not based on an analysis of real risks in the producer's context**.

The plethora of *private standards* does not make it easy for producers to adopt a coherent approach to their food safety management systems: one that combines a 'responsible approach' in terms of regulations and a 'standards approach' in terms of market requirements.

### 1.3.2. Operators' responsibilities and obligations under regulations

**Regulation (EC) No. 178/2002**<sup>8</sup> (*General Food Law*) clearly defined the responsibilities of the various players (adapted from E. Poudelet, 2010):

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<sup>8</sup> Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJEC*, L31/1 of 1 February 2002.



### Operators must

- Ensure that food hygiene conditions are met at every stage of production
- Place on the market products that comply with standards
- Ensure the traceability of processes and products
- Be able to withdraw non-compliant products immediately and to warn customers.
- Keep the authorities informed and cooperate with them

### Competent Authorities must

- Establish the regulations and standards applicable to the products
- Evaluate sanitary and phytosanitary risks transparently and independently
- Define a food safety policy (objectives)
- Draw up a programme for official controls and set up these controls
- Communicate information on food safety and risks

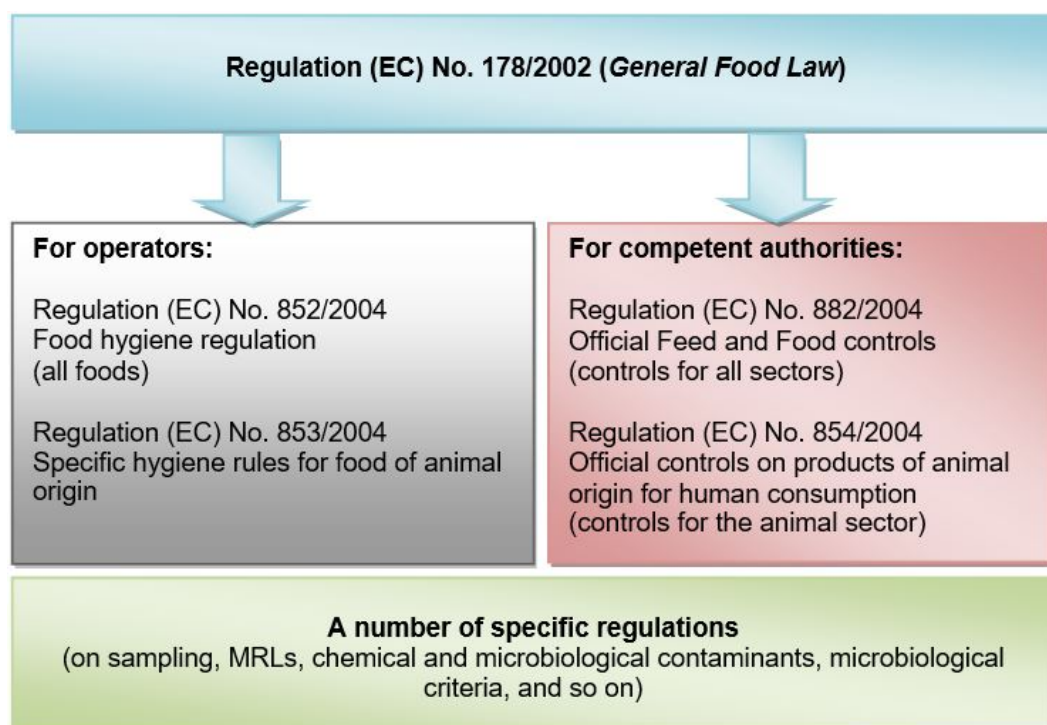


*European regulations on the safety of food and plant protection products grew from the 84 recommendations laid out in the White Paper on Food Safety (published in January 2000).<sup>9</sup>*

*At present, 99% of food hygiene and pesticide legislation has been harmonized at the European level!*

<sup>9</sup> In January 2000 the Commission adopted a White Paper on food safety. It was a response to the major food crises the EU had faced in the years leading up to this document, in particular 'mad cow disease' (1996) and the dioxin crisis (1999). The Prodi Commission, which inherited the trauma these events caused in the EU's executive branch (the Commission), quickly identified food safety as 'one of its main policy priorities'. The objective of the white paper was to re-establish and consolidate European consumers' trust.

The organization of European regulations can be summarized as follows:



This strong regulatory framework has been formulated on the basis of general international guidelines issued by the *Codex Alimentarius*.

Even if these regulations taken as a whole may seem somewhat complicated, it should be kept in mind that Europe has endeavored to set up rules **based on simplicity, flexibility and the responsibility of each stakeholder**, starting with the producers themselves.

The philosophy underlying these rules can be summarized quite simply as follows:

**Food safety** measures which fall under the producer's responsibility  
=  
Applying a minimum of **hygiene rules**  
+  
Setting up a **HACCP programme**

Europe sought rules that could be applied flexibly for small operators (flexible HACCP) and with less red tape in primary production (HACCP not mandatory, but compliance with general hygiene measures).



# Chapter 2

## General principles of food hygiene

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## 2.1. Importance of hygiene for product quality and safety

### 2.1.1. How is food hygiene defined?

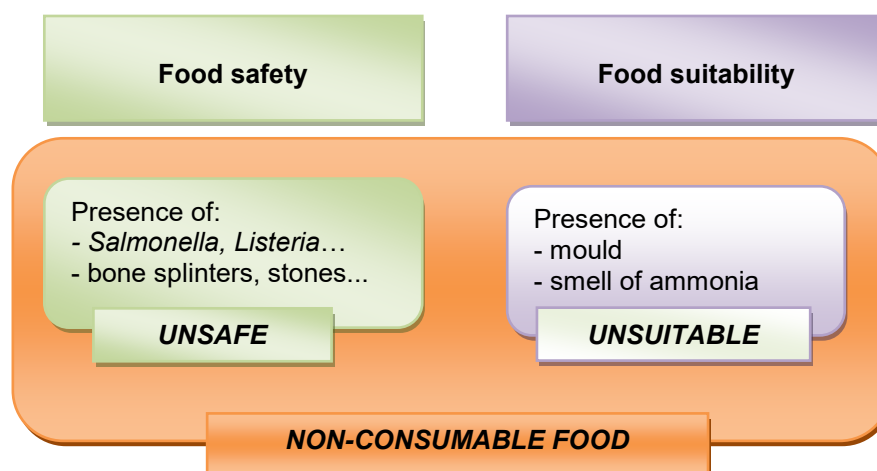
European regulations define hygiene as: *'the measures and conditions necessary to control hazards and ensure fitness for human consumption of a foodstuff taking into account its intended use'*.

Food hygiene comprises two components:

- **food safety**, which guarantees the harmlessness of food, the absence of adverse effects for the consumer's health when prepared and/or consumed in keeping with its intended use;
- **food suitability**, which concerns the intrinsic characteristics of the product, namely taste, smell, texture and presentation, characteristics that can change with the presence of spoilage microbes (bacteria, yeast and mould). Suitability is the assurance that the food is 'acceptable' for human consumption.

**Food safety** and **suitability** must be assured at every link of the food chain.<sup>1</sup>

*Food hygiene diagram (based on O. Boutou, 2008):*



The concept of safety is therefore stronger than that of suitability although both can have the same result: **losses of products** (unsuitable food) or **markets** (unsafe food). These

<sup>1</sup> A distinction should be made between 'food hygiene' in the sense used here and the dietetic concept of 'food hygiene', which refers to the deliberate selection of foods consumed in the daily diet: the latter concerns nutrition or dietetics, which relates to consumers' health and dietary habits. It should nonetheless be borne in mind that dietary habits are also related to 'food safety'. Exposure (to contaminants) is in fact related to consumption (nature, quantities, frequency).



two components of hygiene are inseparable and the consequences of a lack of hygiene can be very serious because fruit and vegetables can present numerous risks of:

- chemical origin (pesticides residues, excessive concentrations of nitrate, etc.);
- biological origin (food viruses, bacteria, pathogenic moulds or fungi);
- physical origin (glass shards, etc.).

### 2.1.2. Who is responsible for food hygiene?



*Food safety begins on the farm!*

*Applying effective hygiene rules reduces the risk of food poisoning for consumers.*

***Producers are the first who need to apply by these hygiene rules.***

**Regulation (EC) 852/2004** on the hygiene of foodstuffs<sup>2</sup> establishes (Article 3) the following general obligation: **'Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.'**

However, hygiene rules also concern exporters, wholesalers, transport operators, distributors and so on, and **in general any operator along the food chain**. In the end, the consumer is also responsible for ensuring that food remains edible and does not present any danger of food poisoning, by handling and storing it in suitably hygienic conditions.

Through a lack of resources or appropriate qualifications, **small producers** are often unaware of or inadequately evaluate the chemical, biological or physical **risks** that can occur at different stages of the production process.

Although certain sources of microbial or chemical contamination cannot be kept totally under control, such as airborne germs or air pollution, it is possible for operators to **limit risks to a large extent** during production and packing by applying a set of measures related to basic hygiene principles.

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<sup>2</sup> Regulation (EC) 852/2004 of 29 April 2004 on the hygiene of foodstuffs, *OJEU*, L139/1 of 30 April 2004.



## 2.2. General principles of food hygiene

### 2.2.1. The basic rules

Controlling sanitary risks in the production and packaging of fruit and vegetables requires **compliance with a few basic rules** related to the production environment and the staff and facilities available. The following rules should be kept in mind:

#### **Rule No. 1**

*Fruit and vegetables can be contaminated at any point in the process: during production, handling, transport, packaging or storage of products. Hygiene measures therefore apply at every link in the chain and concern all operators involved in the process, from the field to the consumer. Each is responsible for practicing the hygiene measures recommended where he/she can control the situation.*

#### **Rule No. 2**

*Concerning chemical, physical or microbiological contamination of fruit and vegetables, preventive measures are always preferable to corrective measures. For products consumed fresh, without cooking or post-harvest processing, the quality of the harvested product is absolutely crucial to the conformity of the finished product.*

#### **Rule No. 3**

*An effective food safety management system must include a monitoring and control programme covering the entire production process (farm, packing areas, storage areas, distribution center and transport sector). This requires the use of qualified personnel capable of observing recommended good practices and putting in place the necessary supervision.*

#### **Rule No. 4**

*The good hygiene practices of employees and sanitary practices at production sites are essential factors in preventing contamination of fresh fruit and vegetables. In terms of biological risks, human or animal excrements are the leading source of contamination of these products by pathogens.*

#### **Rule No. 5**

*Depending on its source and quality, water can contaminate fresh products that enter into contact with it. This risk of contamination must be kept to a minimum.*

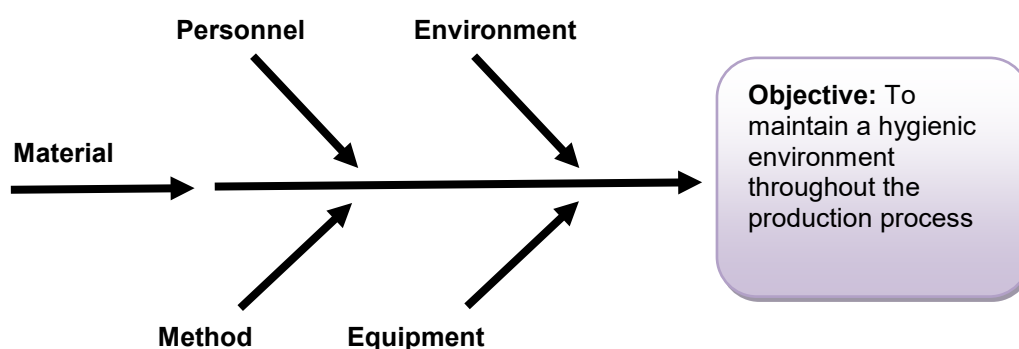
#### **Rule No. 6**

*The qualification of personnel is a precondition for controlling chemical risks. Where chemical risks are concerned, observance of good agricultural practices and correct use of inputs (fertilizers and plant protection products) are guarantees of compliance with standards.*

Hygiene and safety problems for fruit and vegetables are complex and **require an integrated approach** due to the multitude of risks to be managed<sup>3</sup>.

To analyze hygiene problems, the industry often uses the Ishikawa diagram. This method is used to answer the following question:

*Which elements of the process determine the risk of contamination?*



This method (material (products), personnel, work method, equipment and environment) consists of systematically reviewing the **factors** involved in the hygiene of the process:

- **Material (raw material)**  
A number of aspects have to be taken into consideration, for instance the products': origin, cleanliness, conformity, labelling and characteristics (e.g.: temperature, water content). For our purposes, this concerns not only **harvested products** (raw material to be prepared for market), but also the **inputs used** (seed, water, fertilizer, soil improvers, packaging, plant protection products, etc.).
- **Personnel**  
Every individual who handles products potentially carries **pathogenic micro-organisms transmissible through food**. Different precautions therefore need to be taken to minimize risks. The first essential step is for personnel to wash their hands. **Clothing** is another element to be considered. Most instructions on personnel hygiene have become common practice, such as having a **medical exam**, wearing an apron, using a hairnet and removing all jewelry before handling food.
- **Method**  
This concerns all **processes** used for production (**technical protocol**, from seed to harvest), harvest, transport and packaging up to consignment of the product. The aim is to follow **Good Manufacturing Practices** (GMP).
- **Equipment**  
All equipment (**implements, utensils and packaging material**) can contaminate food if not adequately maintained or suited to use. Washing it properly is not enough. The duties of personnel must also include the tasks of maintaining machinery, application equipment, means of transport and cold storage rooms (defrosting, cleaning and disinfection).

<sup>3</sup> Codex Alimentarius Commission - Code of hygienic practice for fresh fruits and vegetables, CAC/RCP 53, 2003.

➤ **Environment**

The workplace, whether a field or a packing station, must remain **clean and protected** from pests. It is essential, for example, to adjust and close doors and windows, check the hygiene of the premises and all work surfaces, maintain drain pipes and manage waste, ventilation and lighting.

### 2.2.2. General hygiene principles in the Codex

The *Codex Alimentarius* publication, '*General Principles of Food Hygiene*',<sup>4</sup> identifies the essential principles of food hygiene applicable throughout the food chain (from primary production to the final consumer) to ensure that food is safe and suitable for human consumption.

For both the production chain and packing stations, the general hygiene principles dictated by the Codex primarily concern the **following six points**:

1. hygiene measures related to **production conditions** (healthy operating premises and packing station);
2. measures for **personnel hygiene** (health status, personal cleanliness, clothing, access to facilities etc.);
3. hygiene measures related to **facilities**: cleanliness of equipment and apparatus (storage material, sorting devices, grading devices etc.);
4. aspects related to **handling**, transport and storage of products;
5. aspects related to **control of operations** (raw materials, water quality etc.);
6. aspects related to **maintenance, cleaning and waste** management.

Hygiene measures related to all these different aspects will be summarized below. General recommendations will also be added on **product traceability** and personnel **training**. Readers are advised to consult the Codex documents and codes of practice for further information. Lastly, the *Codex* 'general principles' recommend that producers use the HACCP system to improve the suitability of food and describe how to put hygiene principles into practice.

The *Codex* 'general principles' also provide instructions for drawing up specific 'hygiene criteria' that may be needed for certain sectors of the food chain, certain processes or certain products. There follows in this chapter a discussion of the usefulness for each sector of drawing up a 'Guide to Good Hygienic Practices' suited to its specific risks and appropriate implementing measures.

### 2.2.3. Hygiene measures related to production conditions

Production is to be avoided in areas where the environment poses a threat to food safety.

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<sup>4</sup> Codex Commission, Recommended International Code of Practice – General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4, 2003.



**Production areas** (fields, orchards, tunnels, nurseries etc.) and packing and storage areas (sheds, silos, cold storage rooms etc.) must be kept clean at all times. They should be located in areas that have not been used to bury waste (the operator should therefore have access to a soil history); otherwise, soil analyses are needed to demonstrate the absence of risks of contamination from germs or heavy metals, for instance.

*Example of clean fields (Photo B. Schiffers).*

Unhygienic production areas and packaging stations present greater risks of contamination. Pathogens can be present either in the soil or in sorting, grading and packing equipment. In the absence of appropriate sanitary measures, **any surface in contact with food is a potential source of microbial contamination.**



**Waste** (crop residues, fruit on the ground, straw not worked into the ground, empty cans, bags, cords, damaged crates, used irrigation tubes, etc.) must be collected and removed from production areas regularly. Areas where waste is deposited and composted must be located at a sufficient distance from production and packaging areas.

*Irrigation tubes abandoned in the field (Photo B. Schiffers).*

**Human and animal excrements** are the leading source of contamination of fruit and vegetables from pathogens. Sanitary facilities must be available both in fields and in packaging stations to reduce sources of contamination from faecal matter.

*Children should not be allowed in the fields due to the risks of faecal contamination from their excrements as well as risks to the children themselves!*

*Photo B. Samb*





**Toilets, compost** and heaps of **manure** or organic soil additives should not be located near a source of irrigation water or in an area that may flood during heavy rainfalls. Run-off from poorly built or poorly located toilets can contaminate farm workers and animals, the soil, water sources and fruit and vegetables. Personnel must be informed about the correct use of toilets in order to maintain hygienic and healthy facilities.



**Plant protection products** and **fertilizers** must be **stored** in areas that meet safety requirements (premises suited to this use) and be well managed (prevention of leaks) to avoid any accidental spills or spreading. Appropriate measures must be planned and implemented to dispose of chemical waste and effluents safely (empty packages, time-expired products and any product left in the bottom of tanks). Water must be available for workers to wash their hands (see photo).



*Photos B. Schiffers*

#### 2.2.4. Measures for personnel hygiene



The sanitary measures applicable to anyone working in the food sector also apply to those in primary production.

*Personnel hygiene begins in the field. Washing hands before and after harvesting decreases the risk of contamination of products harvested by the workers.*





*If products are sorted in the field in unsanitary conditions, their hygiene cannot be guaranteed!*

Personnel hygiene rules apply to those assigned to the task of harvesting and sorting the products as well as to those in charge of applying plant protection products and fertilizers. **Specific training** in this area is necessary for risk-free handling of these products.



Good hygiene concerns not only personal hygiene but also correct maintenance of protective equipment (clothing, hairnets, etc.) and safety equipment (personal protective equipment or PPE).

*Hair covered, no jewelry on the hands and ears, and fastened garments diminish the risks of transmitting a foreign body.*

*Photos B. Schiffers.*



*Personnel cloakroom, separate from the packaging rooms. Work garments must stay in the cloakroom. Personnel must remove them during breaks. The full equipment (headgear, apron and boots).*



Hand-washing facilities (Kenya). Note:

- tap is turned on by pressing a button under the sink with the knee (no contact with dirty hands) (see detail);
- liquid soap dispenser (bars of soap are sources of micro-organisms);
- paper towel dispenser for drying hands (and not a blower, which would project droplets carrying germs into the air).

Photos B. Schiffrers



Personnel must be reminded of hygiene rules at all times through the use of written instructions or pictograms. These must be placed in such a way as to be visible **where and when they are really useful** (for example, on the door, at the toilet exit).

It is essential to make sure that the personnel **understand the instructions**: some pictograms can lead to confusion. Before they are posted, they need to be **explained to personnel**.

It is also important to **motivate** personnel to follow the instructions by explaining why a given prohibition is applied (removing jewelry, for example), or why an obligation is imposed (such as washing hands).



Photos B. Samb & B. Schiffers.

The personnel's state of health is an important factor, but **difficult to control**. The aim is primarily to avoid contaminating products from pathogens from infected wounds, discharges from the nose or mouth or people coughing or spitting.

### 2.2.5. Hygiene measures related to facilities and equipment

Establishments must be **located far from polluted areas**, flood plains or industrial areas that could represent a threat of contamination of food (e.g.: release of dust or fumes).

Depending on the nature of the operations and the associated risks, **premises, equipment and facilities** must meet the following characteristics:

- The arrangement and layout of the premises must be such as to keep food contamination to a minimum. **'Workflow from dirty to clean areas'** must be preferred to keep finished products from coming into contact with raw materials. The same principle applies to the layout of storage areas, where **finished products must be separated** from raw materials.
- The **design and layout of facilities** and equipment for sorting, grading and packaging fresh products must accommodate suitable maintenance, cleaning and disinfection and minimize airborne contamination.
- The surfaces of walls, floors, doors and ceilings, as well as the materials used to build them, especially if they come into contact with food, must be non-toxic. They must be **smooth and impermeable**, allow easy drainage, and be **easy to clean and maintain**. Work surfaces that come into direct contact with food must be in good condition, durable and easy to clean, maintain and disinfect. They must be made of smooth and non-absorbent materials and remain inert upon contact with food, detergents and disinfectants (for example, no tiles on work surfaces because their joints are very hard to clean and disinfect).
- It should be possible to **control** temperature, humidity, air circulation, etc. where necessary.
- **Effective protection** must be installed to prevent pest access and harborage in the premises. Windows must be easy to clean, built to minimize the accumulation of dirt and if necessary fitted with removable and cleanable screens to keep out insects. If necessary, windows must be sealed.



These factors and the way equipment is used can help to reduce the risk of cross-contamination of fresh fruit and vegetables.



*A work surface in such poor condition it can no longer be cleaned effectively.*

*Photo B. Schiffers.*



*Tables have a smooth work surface, are made of metal, and are edge-free and easy to clean. The floor and walls of the work room are also smooth. (Packing station in Kenya).*

*The quality of the lighting (powerful and well protected to avoid glass debris) contributes to good working conditions.*



*Tables have a smooth metal surface that is easy to clean (an opening in the edge facilitates cleaning).*

*The concrete floor is smooth and easy to clean. Waste and dust cannot become encrusted.*

*Brushes used to clean the floor must not be used to clean the work surfaces.*

*Empty and clean packages are stored separately from products in a room fitted with a screen to prevent contact with animals.*

*It is preferable to stack the boxes on a pallet.*

*(Packing station in Senegal, photos B. Schiffers)*



*Stock of ready-to-use packaging.*

*The boxes are placed on pallets, not in contact with the floor.*

*Packaging storage takes a lot of room but flawless hygiene is essential, even when the boxes are empty.*

*It is important to make sure that birds cannot leave droppings on the boxes.*



*Another example of a packing station. In spite of more limited means for meeting hygiene requirements, the boxes are easily kept off the floor by being stacked on a clean pallet.*



*The finished products are stored separately, stacked on pallets in a cold room prior to consignment.*

*Photos B. Schiffers*



### 2.2.6. Controlling water quality

Water is used for **irrigation**, the **preparation of mixtures** for plant protection treatment and the application of fertilizers in fields. It is also used to **clean** not only **fruit and vegetables** but also **sorting tables, floors and harvesting containers**, and so on.

Two aspects therefore need to be considered:

- **water must be protected:** avoid polluting water during growing and packaging operations (discharges). Water sources in particular have to be protected: ground water, catchment areas, etc. The presence of livestock in direct contact with watering places (for instance, animals that enter the water to drink) increases the risk of contamination from faecal germs. Overuse of nitrate fertilizers leads to excessive concentrations of nitrates in ground water;
- **products must be protected:** avoid allowing water contaminated or polluted by pathogens or chemical products from coming into contact with products.

When **preparing mixtures**, avoid contaminating water points with plant protection products. Measuring and mixing tools, for instance, must be reserved for this use alone and water should not be drawn using a utensil contaminated by the products. The dregs of unused mixture, water used to rinse apparatus and protective equipment, and water used to wash protective equipment should only be poured out in a given area reserved for this purpose. Products should not be allowed to flow or penetrate deeply and pollute the water table.

Water in contact with fresh fruit and vegetables can be a major source of direct contamination. **It can spread many micro-organisms**, some of which are pathogens (*Escherichia coli*, *Salmonella*, etc.) and can survive on packaged products. It is essential to adopt irrigation methods that prevent or minimize contact between the water and fruit or vegetables (for example: use the drip method rather than sprinkling). **Caution is needed when using irrigation water:** the producer should assess the risk by analyzing the location and quality of available water.



Washing fruit (Photo B. Samb).

Only **potable water** should be used for food processing (when water is involved in the process). This also holds true for ice or steam made from this water. For certain stages of the process (for instance, washing of vegetables but not blanching) and in certain conditions, it is possible to use **clean water** (namely, microbiologically clean, but not meeting all potability criteria). **Regular water quality analyses** are essential.

### 2.2.7. Transport and storage hygiene

Special attention should be given to product **transport conditions**. Measures must be taken during transport to **protect food** from potential sources of **contamination**.



Loading platforms and containers must be **cleaned**. Products must be **protected** against damage that could make them unsuitable for consumption (**cover lorries with a tarpaulin**; package products correctly; protect them from the sun and rain, dust, smoke, birds and other animals; avoid bulk transport which can crush products; avoid the use of used bags etc.).

The same vehicle should not be used to transport fruit and vegetables, fertilizers and plant protection products, or even people!



*Transport vehicles must allow for effective separation of different foods or of food and non-food products.*



When **transporting bulk products**, containers and vehicles must be used **exclusively for food transport** and marked accordingly.

*Photos B. Samb*

Before each load, if the same vehicle or container is used to transport different foods or non-food items, it must be thoroughly cleaned and disinfected where necessary.



**Products must be stored** in an environment that prevents the presence of pathogens or micro-organisms that cause spoilage and produce toxins in food (order, cleanliness, maintenance of storage premises, organization/rotation of stocks).

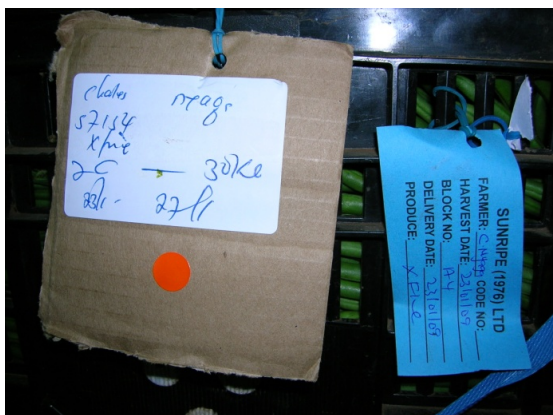
The premises must lend themselves to control of all required conditions of temperature, humidity, etc.

The identification of lots contributes to **effective stock rotation** (based on the 'first in/first out' or FIFO principle) and **helps avoid overly long storage** (e.g.: risk of spread of micro-organisms on/in the product or risk of leeching of sulphur into lychee pulp). For fragile products (such as those that have to be kept in cold storage), **clear labelling** of the products showing maximum storage temperature will make it easier for operators to handle and store them correctly (e.g.: **maintaining the cold chain**). A lack of information on a product distributed can contribute to the spread of biological contaminants and the production of food unfit for consumption, even when appropriate hygiene control measures have been taken before shipment.

Special safety rules are necessary for the transport and storage of plant protection products and fertilizers (see chapters 8 and 9 of the COLEACP Handbook "Operator safety and good crop protection practices").



### 2.2.8. Importance of a traceability system



The capacity to identify the origin and history of a product is a decisive factor for risk identification and control. Each container of food should **bear an indelible mark that identifies the producer and lot.**

*Photo M. Delacollette*

**Traceability makes it possible to trace the food products back to their source** (identification of producers, packing operators, etc.). Although it cannot always prevent an initial occurrence of microbial contamination and potential infection of consumers, it does represent **a valuable crisis management tool**. The information it provides can be used to **isolate and eliminate product lots that present a risk** to public health. Thanks to traceability, producers can withdraw or recall products not in conformity, where necessary. It therefore effectively supplements other preventive measures implemented in the field and in packing stations.

### 2.2.9. Personnel training

According to Codex, *“those engaged in food operations who come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform”*.

All personnel (team leaders, full-time and part-time employees as well as seasonal workers) must be aware of their **role** and **responsibility** in protecting food from contamination or spoilage. An **‘Awareness’** phase to motivate personnel is therefore essential prior to training per se. Food handlers must understand the risk of contamination to products that can result from a lack of foresight, or from negligence, unhealthy practices or poor personal hygiene.

All producers and employees must have **practical knowledge of basic sanitation rules and hygiene measures related to the work** they perform and the **responsibilities they hold**. ‘Training needs’ must therefore be analyzed in terms of the **skills required** for a given position and are determined with respect to the operator's duties. The skills acquired must allow operators to **assume their responsibilities**, especially their capacity to take decisions in the event of a malfunctioning or crisis.

A training programme must be set up for all operators based on identified risks and the ‘Good Practices’ that concern them. Those who handle cleaning chemicals or other potentially **hazardous chemicals** (e.g.: plant protection products) should be instructed in how to handle them without risk to themselves (Good Hygienic Practices), the

environment (Good Plant Protection Practices) or food products (Good Agricultural Practices).

It is important, for instance, to teach personnel: where and how to wash their hands properly; how to maintain premises and equipment; how to clean harvesting containers and work surfaces; how to calibrate equipment; when and how to wear personal protective equipment; how to keep them in good repair; how to keep records on the operations carried out; when to react in case of handling error or accident; how to store products; how to manage waste; precautions to be taken during transport of products etc.

Training programmes must be based on a **needs analysis**, validated by the company's management, **regularly reviewed** and updated where necessary.



## 2.3. Implementing food hygiene principles

### 2.3.1. Prerequisite programmes (PRP)

#### ❑ Origin and definition of PRPs

The concept of **prerequisite programme** or **PRP** has emerged recently as the Hazard Analysis Critical Control Points (**HACCP**) system has come into general practice.

HACCP is formalized by the *Codex Alimentarius* and applies to all food production, transport, storage and distribution sectors. It is used by operators to identify the hazards that exist at every stage of the production process, and at the points of this process for which control is critical to guarantee product safety and suitability, thus the term Critical Control Points (CCP). For each CCP identified, limits must be established and followed to ensure product safety. A single CCP can even have several critical limits (e.g.: temperature and length of the pasteurization process).

To be considered a 'CCP', a point in the process must be able to be **monitored continuously** so that the results of such monitoring can be compared to the critical limits set. Critical limits are criteria (quantitative or qualitative) used to distinguish between what is acceptable and what is unacceptable with respect to control of the food's safety and suitability. The cleanliness of operators' work garments, their knowledge of basic food hygiene rules or the effectiveness of a cleaning and disinfection plan **cannot be measured continuously**, however. Furthermore, it would be very difficult to set a critical limit for these factors. They are consequently not CCPs, yet their control is necessary **to guarantee food safety and suitability**. It consequently was important to **define a complementary concept**, namely prerequisite programmes (PRP).

With reference to ISO 22000, prerequisite programmes (PRP) are defined as the basic conditions and activities necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and food that is safe for human consumption.

The PRPs required depend on the type of business and the segment of the food chain in which it operates. As a general rule, the following terms are used to categorize PRPs: Good Agricultural Practices (GAP), Good Veterinary Practices (GVP), Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), Good Production Practices (GPP), Good Distribution Practices (GDP) and Good Sales Practices (GSP).<sup>5</sup>

PRPs refer in general to **control measures that are not specific to a given point in the production process**. They are cross-cutting measures which, in accordance with ISO 22000, cover as a minimum the following 10 points:

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<sup>5</sup> ISO 22000:2005, Food Safety Management Systems, Requirements for any organization in the food chain, ISO, 2005.

1. construction and layout of buildings and associated utilities;
2. layout of premises, including workspace and employee facilities;
3. supplies of air, water, energy and other utilities;
4. supporting services, including waste and sewage disposal;
5. suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;
6. management of purchased materials (such as raw materials, ingredients, chemical products and packaging), supplies (water, air, steam and ice), disposal (waste and waste water) and product handling (storage and transport, for example);
7. measures for the prevention of cross-contamination;
8. cleaning and sanitizing;
9. pest control (rodents, insects, birds);
10. personnel hygiene (personnel training, individual hygiene measures, dress rules, management of personnel work garments, etc.).

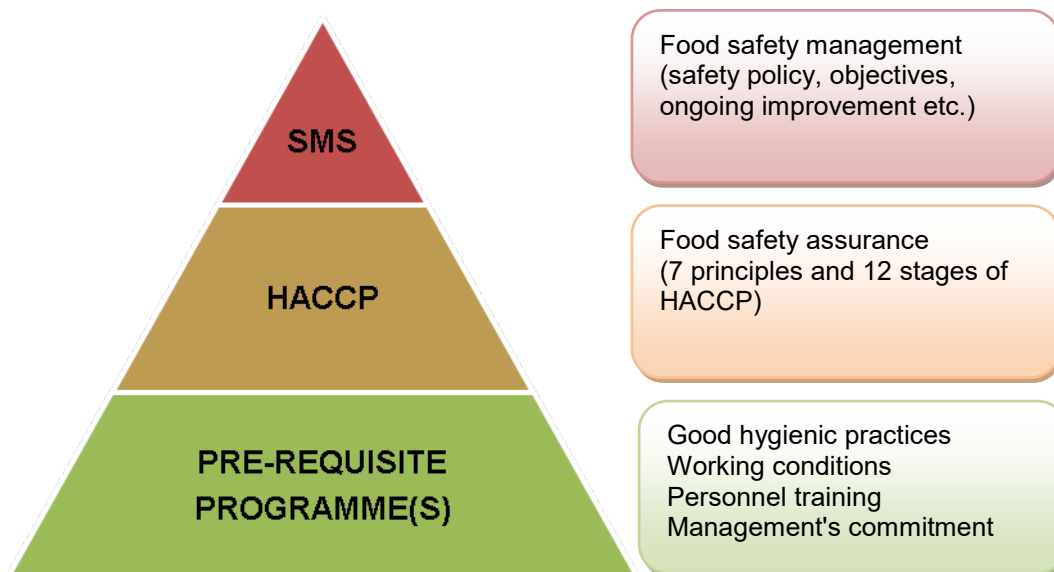
Although HACCP is the international reference for developing a food safety management system, its application **alone** in a company does not guarantee food safety control.

Before implementing the HACCP system in any food business, the operator must first have put in place the prerequisites based on the appropriate good practices (regulatory requirements in force and/or customers' commercial requirements), namely:

- the organization of good practices (Good Hygienic Practices, Good Agricultural Practices, Good Harvest Practices, Good Transport Practices, Good Manufacturing Practices, Good Handling and Packaging Practices, Good Storage Practices, etc.);
- a set of other conditions that are prerequisites to food processing (premises, training, work organization, personnel hygiene and health, water quality, maintenance of the cold chain, etc.).

PRPs constitute the basis for effective application of HACCP principles and must be organised before the HACCP system is developed.

PRPs and HACCP will work even better in the framework of a Safety Management System (SMS). The organization of a SMS requires the unreserved commitment of management and personnel, a policy, objectives, data analyses and periodical review of the management system.



PRPs are **the foundation** on which to base specific control measures resulting from the hazard analysis. These are prerequisites in the strict sense.

The hazard analysis also serves **secondarily** to identify relevant hazards to be controlled, the degree of control that ensures food safety and the corresponding combinations of control measures.

In some cases, the hazard analysis can lead to a correction of PRPs already in place. Effective implementation of PRPs facilitates the introduction and helps to reduce the number of CCPs during study of the HACCP plan.

#### ❑ Nature of PRPs

PRPs are divided into **two sub-categories**:

##### 1. **Infrastructure and maintenance programmes**

The company must **have the infrastructure necessary** to ensure the safety of products and must **maintain if in good condition**. This implies that the design and construction of buildings and facilities, especially employees' work stations and facilities, are suitable for the operations to be performed (receiving, washing, sorting, packing, storing, etc. of food products). It also implies that product safety will not be affected by air, water and energy supplies or by equipment (installation of equipment and accessibility for maintenance). The company must practice **preventive maintenance** and have a cleaning plan and a plan for disposal of waste and waste water. Where necessary, the infrastructures or equipment must be modified to take account of hazard analysis results or of the capacity to implement control measures and ensure correct maintenance of the premises and equipment.

## 2. Operational prerequisite programmes (or OPRP)

Control measures contained in the OPRP must ensure **control of all hazards that are not controlled at a given CCP** under the HACCP plan or where no CCP can be identified for a hazard (ISO 22000). The following elements must be taken into account in the OPRP:

- personnel hygiene;
- cleaning and disinfection;
- pest control;
- measures to prevent cross-contamination;
- packaging operating modes and management of purchased materials (such as raw materials, ingredients, chemical products), supplies (water, air, steam, ice, etc.), disposal (waste and waste water) and product handling (storage and transport, for example).

**Operational PRPs must be validated and documented in the form of instructions and procedures.**

**When the OPRP results in effective control of a hazard at an acceptable level, a CCP is no longer required for this hazard!**

For example, if there is systematic analysis of the microbiological quality of water used to wash fruit and vegetables at the packaging station, the CCP associated with this operation is removed from the HACCP plan.

In small firms where it is difficult and complicated to organise HACCP, conformity with OPRPs is a valuable solution for guaranteeing product safety.

However, **the OPRPs must be sufficiently effective** to control the hazard at an acceptable level.

### ❑ Putting PRP measures in place

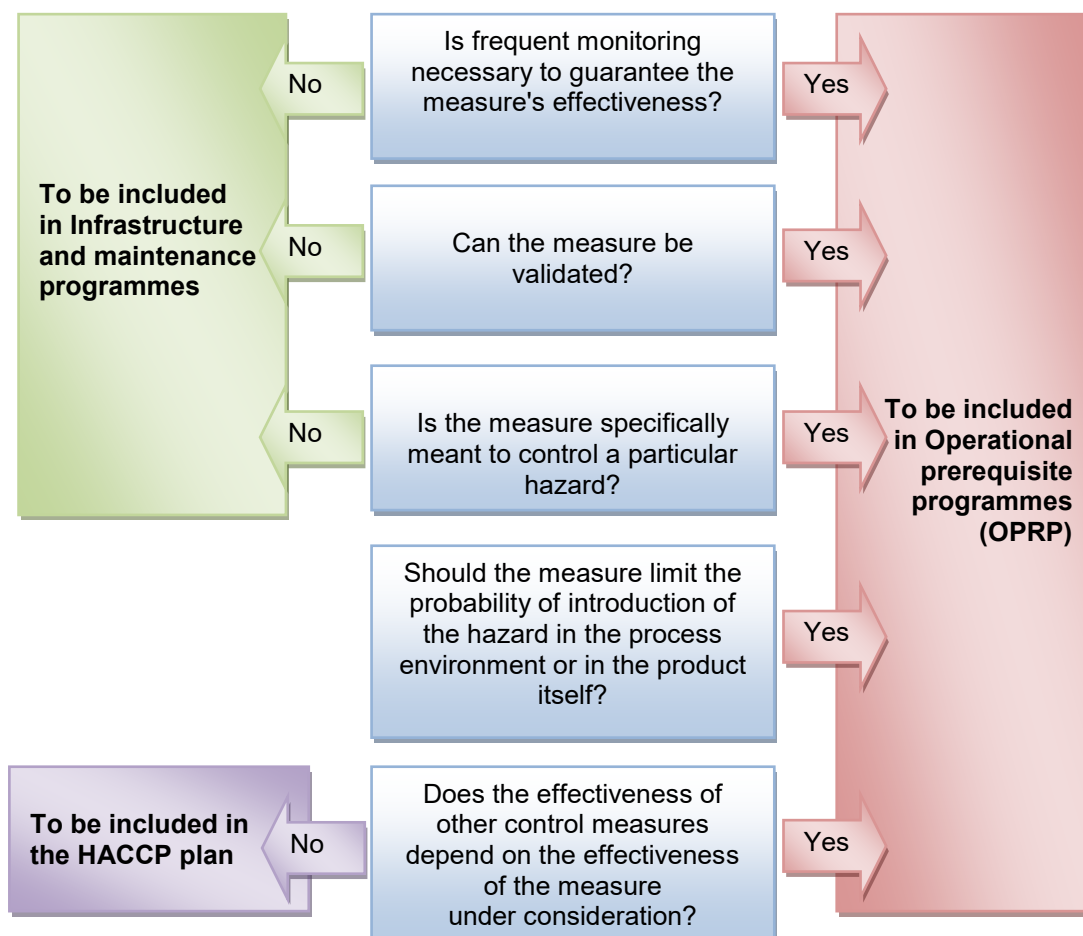
The PRP(s) must be designed and implemented **prior to** hazard analysis and organization of the HACCP system.

Operators are free to choose the measures to be contained in the PRPs. They are also free to analyze and choose, from among the measures being considered, what comes within '*Infrastructure and maintenance PRPs*' and what comes within '*Operational PRPs*' in their facilities and processes.

The main difference between the two types of PRP lies in the fact that operational PRPs involve in the workings of the system: OPRPs must therefore be systematically documented.

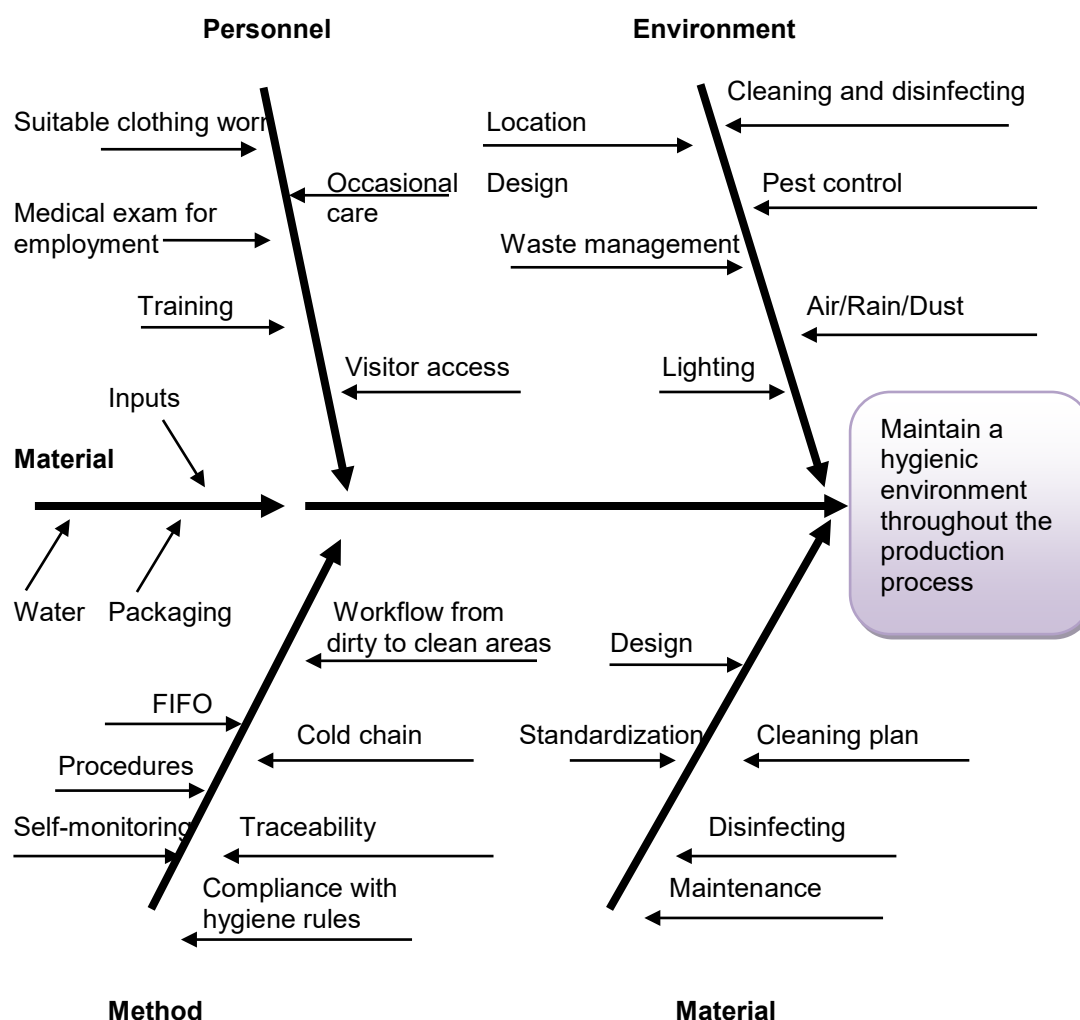
It is important to note that the PRPs that are categorized as infrastructure and maintenance programmes **are not based on hazard analysis and are not validated**.

**Decision tree for categorizing potential control measures in PRPs (based on ISO 22000):**





The Ishikawa diagram can also be used to identify PRP measures (based on O. Boutou, 2008):

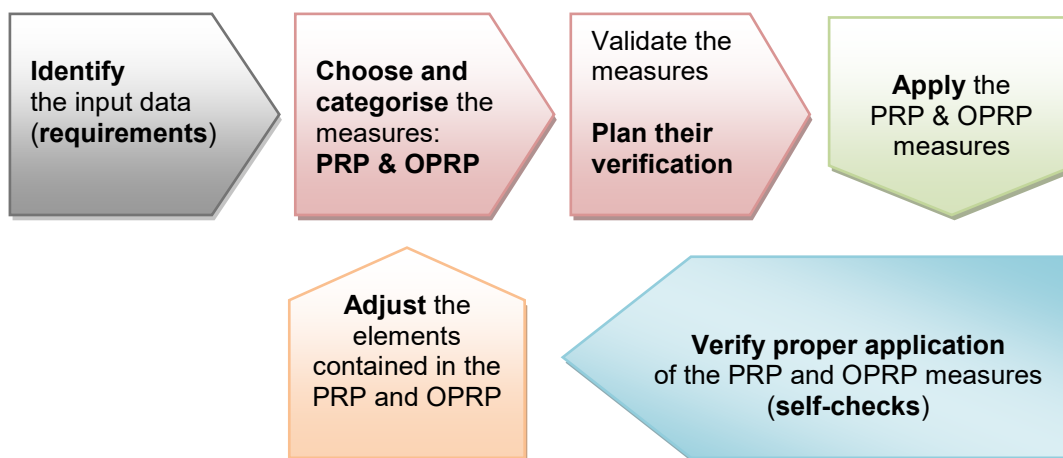


When setting up PRPs, the company must take account of and use relevant existing information (input data). For example: regulations (**requirements of Regulation (EC) 852/2004 on hygiene**), **customers' requirements**, food hygiene guidelines and general principles in the *Codex Alimentarius*<sup>6</sup> and all existing '**Codes of Good Practice**', national, international and industrial standards etc. (e.g.: ISO 22000).

It is therefore useful for producers to have '*Guides to Good Practice*' to help them to master PRPs.

PRPs must also form part of an **ongoing integrated improvement initiative** of the 'PDCA' type (*Plan – Do – Check – Act*):

<sup>6</sup> *Codex Alimentarius* Commission - Hygiene of Foodstuffs. Basic texts. Fourth edition, Rome 2009.



### 2.3.2. Guides to Good Hygiene Practices (GGHP)

#### Regulation (EC) 852/2004

*“The application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, **guides to good practice** should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides”.*

Article 1 of Regulation (EC) 852/2004 on the hygiene of foodstuffs states that: “*guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles*”. Part B of Annex I of the Regulation contains recommendations for the drafting of Guides to Good Hygiene Practice (GGHP) by operators. They must include **appropriate information on the hazards that may arise** in primary production and associated operations and actions to control such hazards.

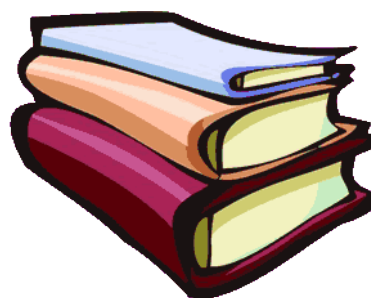
Among the hazards that concern **primary plant production** and measures that can be included are (*extract from the Regulation*):

- the control of contamination such as mycotoxins, heavy metals and radioactive material;
- the use of water, organic waste and fertilizers;
- the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
- protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;
- procedures, practices and methods to ensure that food is produced, handled, packed stored and transported under appropriate hygiene conditions, including effective cleaning and pest-control;

- measures relating to record-keeping.

Guides to Good Hygiene Practices (GGHP) and to application of HACCP principles are supplied as **voluntary guidelines, evolving in nature and developed by and for operators in a sector** with the aim of helping them to meet the requirements of **Regulations (EC) 852/2004** and 183/2005.

They can also help businesses to establish food safety management systems in the framework of certification under **ISO 22000:2005**.



Ideally, the '*Guide to Good Hygiene Practices*' must be **submitted for validation** to a local authority with responsibility for food chain safety. This authority's role will be to:

- **verify that the analysis of hazards** recognized as relevant in the Guide has been carried out correctly and thoroughly, and that the operators have not overlooked or under-estimated any aspects;
- **approve the control measures** (e.g.: type and number of analyses, control points, traceability, etc.) that operators in a sector propose to implement on a voluntary basis to prevent, reduce or eliminate risks.

To achieve the high level of food suitability and safety required by Regulations (EC) 178/2002 and 852/2004, the Guides should be easy-to-use, **pragmatic** and **educational** tools for producers and other food chain operators. They should aim to:

- **build consensus among operators** in a sector over food risks and appropriate control measures (effective and economically justifiable) required to bring risk down to an acceptable level;
- serve as a basis for discussion among operators and representatives of the national competent authority or even the authority of the market of destination;
- inform and draw the attention of all operators to relevant hazards (foreseeable and significant) for the sector concerned;
- describe the general hygiene rules to be observed by operators in the sector;
- facilitate the hazard analysis to be carried out by operators by serving as preparation for it, possibly in the context of introducing HACCP;
- **secure recognition**, for example on the basis of a history, **of practices recognized by the sector as effective** in terms of hygiene (traditional methods, **professional know-how** etc.);
- facilitate the organization and updating of professionals' PRPs and HACCP plans;
- help to demonstrate the operators' mastery of hygienic practices;
- serve as evidence of compliance with regulations when a GGHP **validated by a competent authority** is applied by a business, and where necessary, as evidence of conformity with ISO 22000, both for Good Hygienic Practices (prerequisite programmes) and for application of the HACCP system;
- **facilitate certification** of operators' Safety Management Systems (SMS) (private safety standards: BRC, IFS etc.).

### Safeguarding and adding value to professional know-how!

The text of Regulation (EC) 852/2004 (point 16) underlines the importance of applying hygiene rules with some degree of 'flexibility':

*"Flexibility is also appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments".*

**This point is especially important for small producers from ACP countries who encounter difficulties implementing HACCP.**

The intent of European law is that means deployed should be **proportional to risks** on the one hand, and on the other that the value of **control methods used traditionally** by producers should be recognized if they guarantee a sufficient level of food safety.

**The Regulation also states that "good hygienic practices can replace the monitoring of critical control points". This is the meaning given to the PRPs described above in this text.**

In particular for businesses that do not process food (primary production), hazards can be controlled through compliance with prerequisites alone.

The same regulation nevertheless stresses that *"flexibility should not compromise food hygiene objectives"* and, since all foods produced will be in free circulation throughout the European market, flexibility must be 'fully transparent'.

Thanks to 'Guides to Good Hygiene Practices' (or 'Guides to Self-Monitoring Systems') professionals can demonstrate their capacity to satisfy regulatory requirements **through measures adapted to their socio-economic context.**

## Annex: Guides to Good Practices

In parallel with the Guide to Good Hygienic Practices, the *Codex Alimentarius* makes official recommendations that apply to all stages of the product cycle. These concern:

- Good Agricultural Practices (GAP);
- Good Processing (and Packaging) Practices (GPP);
- Good Distribution Practices (GDP);
- codes of practice and guidelines.

### A.1. Recommended good practices

#### ❑ Good Agricultural Practices (GAP)

Objectives: to reduce the likelihood of introducing a hazard which may adversely affect the safety of food or its suitability for consumption at later stages of the process. Primary production should be managed so as to assure that harvested products are suitable for their intended use. Where necessary, this will include:

- avoiding the use of areas where the environment poses a threat to the safety of food;
- controlling contaminants, pests and diseases of animals;
- adopting practices and measures to ensure that food is produced under appropriately hygienic conditions;
- satisfying conditions for the use of plant protection products, in particular: dose, maximum number of applications, pre-harvest interval (PHI) and volume of mixture recommended per hectare.

#### ❑ Good Processing Practices (GPP)

##### • **Establishment: design and facilities**

Objectives: follow rules of good hygiene in the design and construction of buildings; appropriate location and adequate facilities are necessary to ensure effective hazard control.

Depending on the nature of the operations and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that:

- contamination of food is minimized;
- design and layout permit appropriate maintenance, cleaning and disinfection and minimize air-borne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable and easy to maintain and clean;
- where appropriate, suitable facilities are available for temperature, humidity and other controls;



- there is effective protection against pest access and harborage.

- **Establishment: maintenance and sanitation**

Objectives: to facilitate the continuing effective control of food hazards, pests and other agents likely to contaminate food. Effective systems must be established to:

- ensure adequate and appropriate maintenance and cleaning;
- control pests;
- manage waste and monitor effectiveness of maintenance and sanitation procedures.

- **Establishment: personal hygiene**

Objectives: people who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions, or who behave inappropriately can contaminate food and transmit illness to consumers. It must be ensured that those who come directly or indirectly into contact with food are not likely to contaminate it. This requires:

- maintaining an appropriate degree of personal cleanliness;
- behaving and operating in an appropriate manner;
- providing personal hygiene facilities (cloakrooms, sanitary facilities, hand-washing facilities).

- **Establishment: Control of operation**

Objectives: to reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards. To produce food that is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials, composition, processing, distribution and consumer use to be met in the manufacture and handling of specific food items;
- designing, implementing, monitoring and reviewing effective control systems.

## ❑ **Good Distribution Practices (GDP)**

Objectives: food may become contaminated, or may not reach its destination in a suitable condition for consumption unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain. Suitable measures should be taken where necessary throughout the transport and distribution process to:

- protect food from potential sources of contamination;
- protect food from damage likely to render the food unsuitable for consumption;
- provide an environment that effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

## A.2. Examples of Codex codes of practice and guidelines

### ❑ General

- CAC/RCP 1-1969, (Rev. 4-2003), Recommended International Code of Practice – General Principles of Food Hygiene; includes the Hazard Analysis and Critical Control Points (HACCP) system and guidelines for its application.
- Codes and guidelines for specific food products.

### ❑ Fruit and vegetables

- CAC/RCP 22-1979, Recommended International Code of Hygienic Practice for Groundnuts (Peanuts)
- CAC/RCP 2-1969, Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Products
- CAC/RCP 3-1969, Recommended International Code of Hygienic Practice for Dried Fruits
- CAC/RCP 4-1971, Recommended International Code of Hygienic Practice for Desiccated Coconut
- CAC/RCP 5-1971, Recommended International Code of Hygienic Practice for Dehydrated Fruits and Vegetables, including Edible Fungi
- CAC/RCP 6-1972, Recommended International Code of Hygienic Practice for Tree Nuts
- CAC/RCP 53-2003, Code of Hygienic Practice for Fresh Fruits and Vegetables

## A.3. Examples of PRPs for production and packaging of fresh fruits and vegetables

### ❑ Good production/processing practices

#### 1. Location, layout and equipment of establishments

- Environment
  - Potential sources of contamination from the environment should be considered when drawing up prerequisite programmes (PRPs) and proposing the HACCP system.
  - Primary production must not take place in areas where the presence of potentially hazardous substances would lead to an unacceptable level of such substances in food.
  - Site limits must be clearly defined and an adequate drainage system must be provided around buildings or areas where unprocessed food is stored or processed.
  - The following factors should be considered: previous use of the site, nature of the soil, erosion, quality and level of groundwater, existence of sustainable sources of water and impact on nearby surfaces.
  - Access to the establishment's site must be controlled and any potential pest harborage factors (burrows, substratum, rubbish) must be eliminated.

- Workflow layout
  - The internal layout and flow of production, products and personnel must be logical and designed to prevent contamination.
  - High/low risk areas (dirty areas, clean areas) should be determined and separated appropriately.
- Premises and rooms
  - Structures in food production establishments should be solidly built from durable materials and easy to maintain, clean and where necessary to disinfect.
- Storage
  - Adequate facilities must be available to protect food, ingredients and packaging material from dust, condensation, run-off, waste, pests or any other source of chemical, physical or microbiological contamination.
  - Storage areas should be dry and well ventilated.
  - Non-food chemical products (cleaning/lubricating products, fuel, plant protection products, etc.) must be stored separately and in holding tanks.

## **2. Basic facilities**

- Water supply
  - An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control should be available whenever necessary.
  - Irrigation water must be monitored and be of adequate quality; the use of untreated waste water must be prohibited.
  - Water used for post-harvest washing must be potable and, where necessary, monitored at appropriate intervals for the presence of contaminants.
- Lighting
  - Adequate natural or artificial lighting must be provided to enable the undertaking to operate in a hygienic manner.
  - Are bulbs used above sorting, weighing and storage areas unbreakable or fitted with a protective device?

## **3. Drainage and waste disposal**

- Drainage and waste disposal
  - Adequate drainage and waste disposal systems should be installed for the separation, storage and disposal of waste.

## **4. Adequacy, cleaning and maintenance of equipment**

- Equipment
  - Equipment in contact with food should be made of appropriate materials and designed and laid out to be easy to clean and maintain. It must be regularly examined and cleaned.

- Maintenance
  - Workplaces and equipment must be suitably maintained and kept in a state of good repair to facilitate all sanitation procedures.

## **5. Management of raw materials (inputs)**

- Incoming material
  - No raw material or ingredient should be accepted if known to contain parasites, undesirable micro-organisms, pesticides or toxic substances, or decomposed or extraneous substances that cannot be reduced to an acceptable level by normal sorting and/or processing procedures.
  - Any incoming material that may have an impact on food safety must be approved for the intended use (cleaning/lubricating products, fuels, pesticides and other substances).
- Selection and management of suppliers
  - Procedures to control food safety hazards should be set up for the selection, approval and continuous monitoring of suppliers.
- Stock rotation
  - Products must be managed on the basis of either the 'First In, First Out' (FIFO) or the 'First Expired, First Out' (FEFO) principle.

## **6. Measures to prevent cross-contamination**

- Separation and isolation of products
  - Different types of products must be separated to avoid cross-contamination.
- Microbiological cross-contamination
  - Buildings should be designed and built to minimize the accumulation of dirt and debris.
- Physical contamination
  - Appropriate measures determined on the basis of hazard analysis must be taken to prevent the contamination of food by foreign bodies (glass or metal shards, dust, etc.).
- Chemical contamination
  - Chemical products (pesticides, additives, cleaning products, etc.) must be stored separately in holding tanks and used by trained personnel.
  - Records must be kept on the use of chemical products in primary production.

## **7. Cleaning and disinfection**

- Cleaning
  - Cleaning and disinfecting operations performed to remove food residues and dirt should not represent a risk of contamination.
  - Chemical heavy-duty cleaning products must be handled and used carefully in accordance with the manufacturer's instructions.



## 8. Pest control

- Adequate measures for cleaning, inspection and monitoring of raw materials should be taken to minimize risks of harborage and consequently to limit the need for pesticides.
- Buildings should be kept in good repair and condition. Holes, drains and other places where pests may gain access should be kept sealed to prevent access and to eliminate potential breeding sites.
- A bait plan should be available.

## 9. Control of operation

- Time and temperature control
  - In terms of the nature of the operations, adequate systems should be available for heating, cooling or storage of food.

## □ Good hygienic practices

## 10. Personal hygiene

- Rules of hygiene and personal behavior
  - Food handlers should be correctly trained and maintain a high standard of personal cleanliness. Where necessary, they should wear appropriate clothing, headgear and footwear.
  - Documented hygiene rules based on the nature of the activities and potential hazards must be drawn up and communicated to personnel through pictograms and signs posted at the workplace.
- Sanitary facilities
  - Sanitary facilities that include appropriate hand-washing areas, toilets and cloakrooms must be available to guarantee an appropriate level of personal hygiene and to prevent the contamination of food.
- Health status and injuries
  - Medical surveillance procedures should be used so that persons known or suspected to be suffering from or to be a carrier of a transmissible disease or illness will not be authorized to enter any food handling area if there is a likelihood that they will contaminate food.
- Personal behavior
  - People engaged in food handling activities should refrain from behavior that could result in contamination of food (smoking, spitting, eating, chewing, sneezing or coughing over unprotected food).
  - Personal effects such as jewelry, watches, pins or other items should not be worn or brought into food handling areas and fingernails should be short, clean and unpolished.

- Hand washing
  - Personnel should always wash their hands before handling food, after handling contaminated material and after using the toilet to prevent contamination of the product.
- Visitors
  - Visitors to food processing, handling or manufacturing areas should wear protective clothing if there is a risk of contact with products.

#### ☐ **Good transport practices**

##### **11. Transport**

- Food must be adequately protected during transport to ensure its safety.
- Where appropriate, vehicles and containers should be designed and built to allow easy and effective cleaning.

#### ☐ **Good packaging practices**

##### **12. Packaging**

- Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage and accommodate proper labelling.
- Packaging materials must be non-toxic and not pose a threat to the safety or suitability of food under the specified conditions of storage and use.
- Reusable packaging should be suitably durable and easy to clean.

# Chapter 3

## Origin and nature of food risk

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## 3.1. Origin and nature of biological risks

Biological risks arise from contamination of food by pathogenic organisms (e.g.: worms) or micro-organisms, mainly **viruses, bacteria, fungi**, protozoa, prions<sup>1</sup> etc. These organisms are often **associated with humans** and **raw products** that enter the food production chain. Several form part of the natural flora of the environment where food is produced and grown.

Examples of biological hazards (Source: FAO training manual, 2010)	
Sporulating bacteria	Viruses
<i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Bacillus cereus</i>	Hepatitis A and E viruses Rotavirus Group of Norwalk viruses
Asporulating bacteria	Protozoa and parasites
<i>Brucella abortis</i> <i>Brucella suis</i> <i>Campylobacter</i> spp. Enteropathogenic <i>Escherichia coli</i> ( <i>E. coli</i> 0157, H7, EHEC, EIEC, ETEC, EPEC) <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. ( <i>S. typhimurium</i> , <i>S. enteridis</i> ) <i>Shigella</i> ( <i>S. dysenteriae</i> ) <i>Staphylococcus aureus</i> <i>Streptococcus pyogenes</i> <i>Vibrio cholerae</i> <i>Vibrio parahaemolyticus</i> <i>Vibrio vulnificus</i> <i>Yersinia enterocolitica</i>	<i>Cryptosporidium parvum</i> <i>Diphyllobotrium latum</i> <i>Entamoeba histolytica</i> <i>Giardia lamblia</i> <i>Ascaris lumbricoides</i> <i>Taenia solium</i> <i>Taenia saginata</i> <i>Trichinella spiralis</i>

Most are **destroyed** or **inactivated by cooking** and their number can be kept at a low level when product handling and storage conditions (hygiene, temperature and duration) are controlled.

Most cases of food poisoning associated with the consumption of fresh fruit or vegetables or those that have undergone initial processing (e.g.: trimming, washing, crown reduction etc.) are caused by **pathogenic micro-organisms**.

<sup>1</sup> For example, the infectious agent of BSE (bovine spongiform encephalopathy) is responsible for so-called 'mad cow disease'. BSE is a degenerative infection of the central nervous system of cows caused by a molecular infectious agent of a particular type (neither a virus nor a microbe) known as 'prion protein'. Prions are found in mammals (responsible for transmissible spongiform encephalopathies) and in certain fungi such as *Saccharomyces cerevisiae* (baker's yeast). This type of protein infectious agent, however, has to date never been detected in plants.



Micro-organisms, as their name suggests, are microscopic organisms. Some can be seen with the naked eye (mould, for instance) but others only under a microscope. They are found everywhere: in the air (transmission by draughts), in water, in the ground, on materials (work surfaces, packaging, etc.) and on living beings (humans and animals).

For risks of a biological nature, **two important elements** have to be considered:

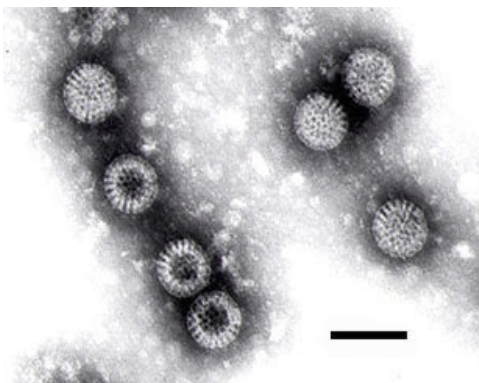
1. Their occurrence on or in food is primarily due to a **lack of hygiene and sanitary conditions**. Depending on the pathological nature of the biological agent, even a minor contamination can result in food poisoning that can have serious effects.
2. **Faecal matter is the main vector** and can contaminate food directly (e.g.: through contact with soiled hands) or indirectly (e.g.: **through the water used**).

**The operator therefore has a large measure of responsibility** in this area: **poor practices** are the source of most contaminations, via the soil, water or the employees' hands!

### 3.1.1. Foodborne viruses

#### ❑ Origin of foodborne viruses

Viruses can originate in food or in water or be transmitted to food by humans, animals or other contacts. Unlike bacteria, viruses are incapable of reproducing outside a living cell. Consequently, they **cannot multiply in food** but can merely **be carried** by food.

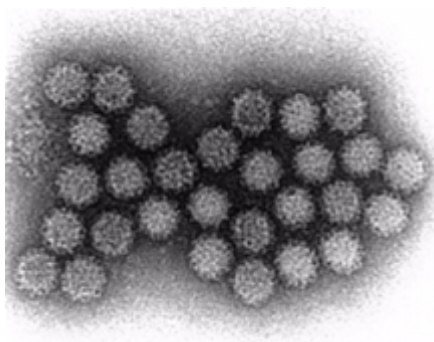


Viruses on leaves or on fruit and vegetables, often identified through symptoms or yield losses, are not dangerous for consumers. On the other hand, some foodborne viruses are pathogenic for man because they can cause serious digestive or liver problems (the **Norwalk virus, hepatitis A virus, Rotaviruses**, etc.). These viruses are **transported by water**.

*Rotavirus*

The **control of hygiene and of the quality of water** used for irrigation and to wash fruit and vegetables is therefore essential to reduce this type of risk.

#### ❑ The Norwalk virus (norovirus)



The Norwalk virus causes an infection and mainly infects **consumers of raw or undercooked products**, generally following contamination from **faecal matter**. The virus does not multiply in food, so the infections are not related to food storage conditions (e.g.: the cold chain).

Symptoms include vomiting, diarrhea and cramps that appear suddenly after a day or two. The illness is not serious and usually lasts from one to three days, but it does not confer immunity. Ingestion of a small number of viruses is enough to cause the illness because the infectious dose is very low (a single virus is enough).

The virus is transmitted mainly by affected persons who do not take proper hygiene measures and directly contaminate raw or undercooked food. Ill employees must not be allowed to work and it is also essential to ensure personal hygiene and sanitary conditions in growing areas. The virus resists freezing and disinfectants.

#### ❑ Rotaviruses

Rotavirus infection is the result of **contamination by human faecal matter** and causes gastro-enteritis. Symptoms are generally more serious than in the case of the Norwalk virus. The fever, diarrhea and vomiting can lead to severe dehydration. These symptoms appear after two to four days and the illness lasts two to ten days. The illness does not confer immunity and can be carried by healthy subjects.

Rotavirus is the **leading cause of severe acute diarrhea in young children** worldwide. The virus is highly concentrated in human faecal matter and survives for a long time in the environment. A person with diarrhea caused by a rotavirus excretes a large number of viruses for around ten days.

Infectious doses can be caught quickly from **contaminated hands**, objects, **food** and **water**. Ingestion of a small number of viruses (100 or so viral particles) is enough to cause illness. Personal hygiene (first and foremost) and full cooking of food eliminate most problems.

#### ❑ The hepatitis A virus (hepatovirus)

Hepatitis A (formerly known as infectious hepatitis) is an acute infectious disease of the liver caused by the hepatitis A virus, **generally through orofaecal transmission from contaminated food or water**. The hepatitis A virus primarily affects individuals who eat raw or undercooked products. It is resistant to the cooking of food and survives for long periods in the environment. It also resists freezing and disinfectants and survives for several weeks in water.

Hepatitis A is a two-stage liver infection:

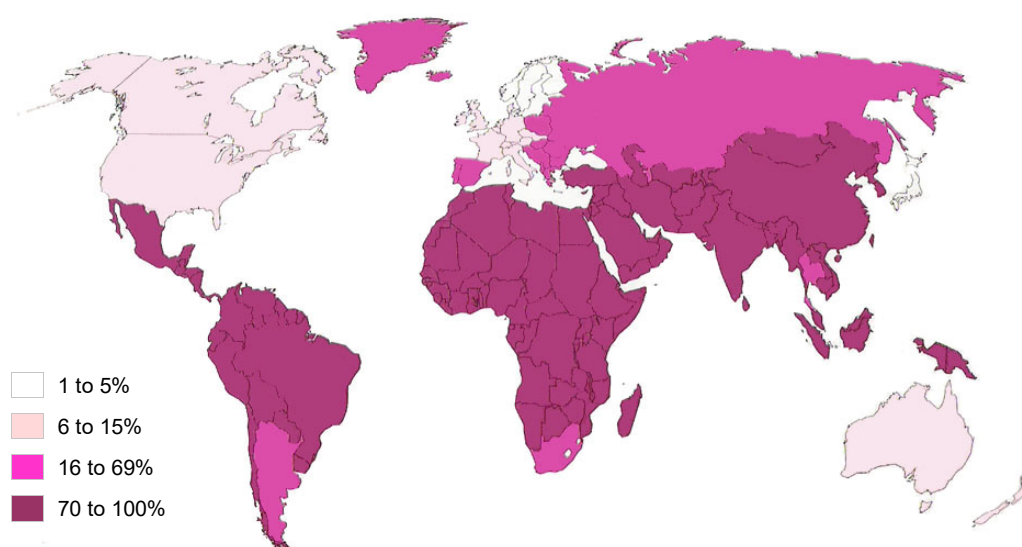
1. around 15 to 45 hours after ingestion, a gastro-enteritis appears and lasts one to three days;
2. the victim is contagious for two to four weeks, during which the virus enters the bloodstream and attacks the liver (hepatitis). The presence of bile is observed in the blood and urine, which become dark (jaundice); in rare cases the disease can degenerate into cirrhosis of the liver and be fatal. Other symptoms are vomiting, anorexia, fever, nausea and fatigue.

Ingestion of a small number of viruses (one to 100) is enough to bring on the disease. Ingestion of products contaminated from polluted water is associated with a high risk of infection. In regions with poor hygiene conditions, the incidence of infection with this virus is close to 100% and the disease is generally contracted in early childhood.

Detection methods are difficult because the virus multiplies slowly and results are often not available until the foods have been consumed.

HAV epidemics still occur because of **poor hand hygiene** among infected persons. Sometimes restaurant employees with symptoms fail to wash their hands after using the toilet. The most serious epidemic of hepatitis A in the USA affected at least 640 people (killing four) in north-eastern Ohio and south-western Pennsylvania at the end of 2003. The epidemic was attributed to **contaminated green onions** in a restaurant in Monaca, Pennsylvania.

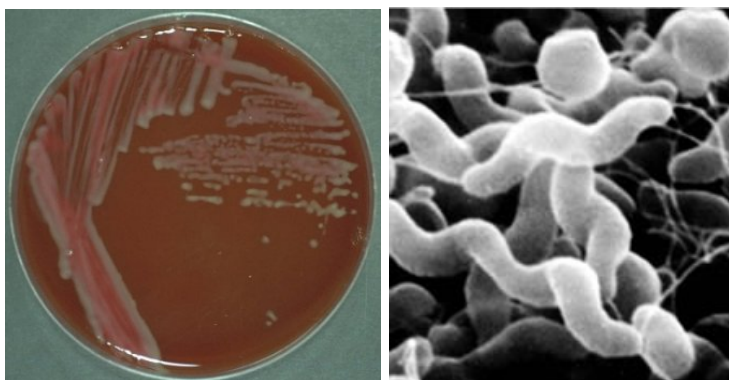
*Prevalence of hepatitis A worldwide:*



**Preventing ill employees from working** and ensuring appropriate personal hygiene and sanitary conditions are the best ways to prevent infections.

### 3.1.2. Bacteria (microbes)

The majority of foodborne infections reported are caused by pathogenic bacteria. Certain raw foods contain such bacteria naturally. Poor handling and storage conditions foster their proliferation in food. If not properly handled and stored, raw food is often a fertile culture medium for the growth of these undesirable germs.



Colony of *Campylobacter jejuni* in a culture medium. On the right: the bacteria.

**Bacteria are therefore the most important biological food risk.** They are at the root of the majority of cases of foodborne illness outbreaks (FBI).

In Europe, the micro-organisms most often mentioned in reports from Member States are, by order of importance: *Salmonella* (e.g.: in 2007, 8,922 persons concerned, 1,773 hospitalisations and 10 deaths), viruses, *Campylobacter*, *E. coli*, *Bacillus*, *Clostridium*, *Staphylococcus* and bacterial toxins (Source: EFSA).

Foodborne bacteria that are pathogenic to man are regularly detected in routine analyses carried out on apparently wholesome products.

In general, the bacterial flora present in fruit and vegetables can be broken down into **three groups**:

1. **Saprophytic or spoilage flora**: enterobacteria (*Erwinia* etc.), *Pseudomonas*, *Bacillus* and lactic bacteria. This flora develops to the detriment of the quality of fruit and vegetables.
2. **Phytopathogenic flora** (pectinolytic): certain species of *Erwinia*, *Pseudomonas* and *Clostridium* or other species that cause leaf spot (plant diseases). This flora is responsible for the deterioration or alteration of the taste, appearance, etc. of fruit and vegetables.
3. **Flora of animal origin** (coliform bacteria, enterococci) and land-based origin (earth, water, sewage sludge). **The pathogenic germs responsible for food poisoning, if developed beyond contamination levels, are found in part of this flora.**

### ❑ Spoilage microbes (food 'suitability' aspect)

Strictly speaking, these do not represent a 'danger' to man, but they have a negative impact on food conservation and consequently affect the product's commercial quality. These microbes can **alter the product's taste, smell, texture and general appearance**.

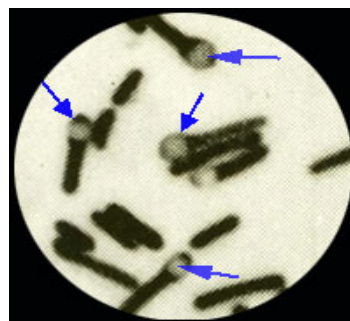
A typical example is the mould that can grow on the surface of jam, or the stickiness and off-color appearance that meat can develop in a home refrigerator. The product is not commercially presentable but does not present any risk in terms of consumption (disregarding the potential risk of mycotoxins).

### ❑ Pathogens (food 'safety' aspect)

**Infectious** microbes, through **intensive multiplication** in the body, lead to **serious illnesses** by altering the tissues of certain organs (e.g.: brucellosis, bovine tuberculosis, typhoid fever). They cause foodborne infectious diseases (**FID**). **Toxinfectious** microbes are **both toxic** (releasing toxins) **and infectious**. They are consequently the cause of foodborne toxinfections. The emergence of several cases of toxinfection is described as a foodborne illness outbreak (**FBI**).

Bacteria are found **naturally** on and in food. In limited numbers their impact on health is generally negligible for consumers. There are nevertheless differences between pathogens in terms of the speed of their development in the consumer's body and whether or not a toxic secondary metabolite (toxin released by the bacteria) is produced.

Certain pathogenic bacteria (of the *Bacillus* and *Clostridium* genera) are **sporulating**. The 'spores' present characteristics of resistance (e.g.: to heat) and can survive for long periods in unfavorable conditions (cold, dehydration). The spore's thermo-resistance is due in large part to its dehydration (vegetative form = 80% water, spore = 10 to 20% water). When favorable conditions reappear (e.g.: thawing of products), the spore, which is the bacteria's form of resistance, can develop into a vegetative form through germination.

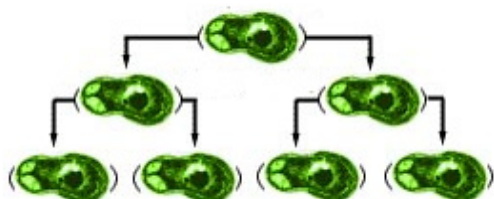


A few facts to bear in mind:

- **Salmonella** (*Salmonella enteritidis*) is the cause of 60 % of cases of FBI with a confirmed causal agent (deaths observed).
- **65% of CFTI outbreaks occur in group catering.**
- **19% of CFTI outbreaks** are attributed to the **consumption of eggs** and products containing eggs (e.g.: chocolate mousse and uncooked products).

### ❑ Bacteria multiplication and the importance of hygiene

**Classic diagram of bacteria multiplication:**

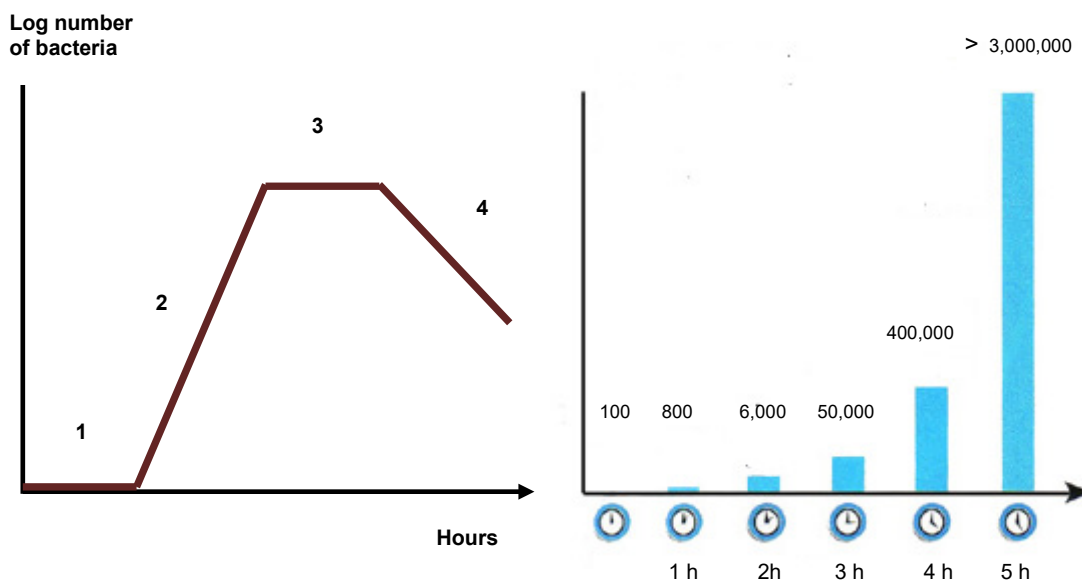


**The population doubles with every generation.** When conditions are



favorable, the population's development is exponential (it doubles on average of every 20 to 40 minutes *in vitro*, and every 2 to 5 hours *in vivo*).

**Characteristic growth curve for a population of bacteria in a non-renewed medium and consequence of the proliferation phenomenon:**



The following **four successive phases** can be observed:

1. Lag phase, the bacteria accumulate nutritive reserves. Acceleration phase, the bacteria reproduce through binary fission.
2. Exponential growth phase.
3. Stationary phase due to lack of nutrients (in a non-renewed medium the bacteria use all nutrients and produce toxic waste, leading to the stationary phase followed by death).
4. Decline phase, exhaustion of nutritive reserves and accumulation of toxic substances.

The generally exponential growth of bacteria in a contaminated product explains the **importance of observing hygiene rules** during food handling and storage.

➤ **The importance of hygiene!**

Let's consider a food that will be cooked but in the meantime is left at ambient temperature for four hours before being prepared. For the product to be edible, the number of bacteria at the exact time of consumption must be no greater than 50 germs/100 g (authorized limit).



**Let's compare two situations:** a food that has been produced in keeping with hygiene rules, with a bacteria count at the time cooking starts of 10 germs/100 g (Case No. 1), and a food produced without regard to basic hygiene rules, with a bacteria

count of 100 germs/100 g (Case No. 2). Is this initial contamination difference really important since the food will not be eaten until it has been cooked?

Considering that an initial population doubles every 20 minutes when conditions are right (substratum, temperature and humidity), the development of bacteria in the product can be roughly estimated as follows:

$$N_t \text{ (number of bacteria in the product at time } t) = N_0 \times 2^{(3 \times t)}$$

Where  $N_0$  = initial number of bacteria  
t = time in hours

	$N_t$	$N_t$
If $N_0$ is:	Case no 1 10 (germs/100 g)	Case no 2 100 (germs/100 g)
After 1 h	80	800
After 2 h	640	6,400
After 3 h	5,120	51,200
After 4 h	40,960	409,600

*If the product is cooked and the cooking process reduces the bacteria population by 99.9%, is the food still edible?*

In the first case, the population counted after cooking will be around 41 bacteria/100 g, which ensures **risk-free consumption**. In the second case, in spite of cooking, the final number of germs/100 g exceeds 400, which is still around **10 times above the authorized limit!**

**This example underlines the importance of Good Hygiene Practices to limit initial contamination of products:** even processes that are 99.9% effective are unable to offer the desired safety guarantees. Often the contamination difference between hygienic and non-hygienic productions will be much greater than a factor of 10. Furthermore, the development of bacteria on the product leads to other consequences such as greater product spoilage, the presence of toxins (that remain after cooking) and so on.

## ❑ Origin of pathogenic bacteria and conditions for their development

Origins and growth conditions of a few pathogenic bacteria:

Bacteria responsible	Origin of the bacteria	Foods often contaminated	Growth conditions
<b>Salmonella</b>	Intestines, animal or human stools (ill or healthy carriers) Dirty hands Manure Purification station	Eggs, egg products, meat-based products, poultry, raw milk, prepared meat products Vegetables (especially pre-cut) Fruit juice Seafood Ice cream	Min. T°: 5 °C Optimal T°: 37 °C Min. Aw: 0.94 Min. pH: 4  Max. T°: 65 °C
<b>Listeria monocytogenes</b>	Work environment Floor, water, intestines, excrements, dust	Prepared dishes, smoked fish (salmon!) Vegetables Raw milk-based dairy products, Prepared meat products	Min. T°: 0 °C Optimal T°: 37 °C Min. Aw: 0.89 Min. pH: 4  Max. T°: 70 °C
<b>Staphylococcus (Staphylococcus aureus and S. epidermis)</b>	Abscesses Saliva, throat, nose, wounds and infections (animal or man) Dirty hands Animals	Meat products (minced meat), prepared meat products, desserts made from eggs and milk, ice cream, pre-cooked dishes, slow reheating	Min. T°: 6 °C Optimal T°: 37 °C Min. Aw: 0.90 Min. pH: 4.5  Max. T°: 65 °C (thermal-resistant toxins)
<b>Clostridium perfringens</b> (sulphite-reducing anaerobe)	Intestines, animal or human stools Spores in nature, soil, dust Plant sediments	Vacuum-packed foods, cooking in large quantities, in broth, leftover sauce, foods cooked the day before, dishes cooled too slowly, etc.	Min. T°: 12 °C Optimal T°: 45 °C Min. Aw: 0.95 Min pH: 5
<b>Clostridium botulinum</b> (sporulating anaerobe, fatal)	Spores in nature (soil, air, water) and intestines of animals Plant sediments	Preserved or semi-preserved food Prepared meat products	Min. T°: 10 °C Optimal T°: 37 °C Min. Aw: 0.94 Min. pH: 4.6

<b><i>Escherichia coli</i></b>	Human digestive tract, water contaminated by excrements Treatment plant Evisceration Droppings	Fruit, salads and raw vegetables Minced meat Raw milk, dairy products	Min. T°: 10 °C Optimal T°: 37 °C Min. Aw: 0.95 Min. pH: 4.4  Max. T°: 65 °C (thermal-resistant toxins)
<b><i>Bacillus cereus</i></b> and <b><i>Bacillus mesentericus</i></b>	Plant seedlings Cereals, rice Cocoa	Bread Crumb (inside) of bread Rice dishes	Min. T°: 10 °C Optimal T°: 37 °C  Max. T°: 65 °C

There are other important pathogenic bacteria but they are specifically **associated with animal products** or products of animal origin. For example, the ***Campylobacter*** genus (*C. jejuni* and *C. coli*) includes some of the most frequent and most pathogenic bacteria, which come from the intestines of wild or farmed animals and contaminate chicken, duck and turkey meat, pre-cut poultry, etc.

To develop in food, bacteria need:

- **Water in any form** (liquid, steam, mist, etc.). The availability of water (described as 'water activity', Aw) is a **critical factor** for bacterial growth.
- An appropriate **temperature** (N.B.: some bacteria can develop in cold storage and refrigerators, despite temperatures below 5 °C.).
- **Nutrients** (sugar, fatty substances, vitamins).
- **A neutral or low-acid pH** (5 to 8).
- **Oxygen** as a rule, but this varies depending on the species, and some bacteria are even anaerobic (e.g.: *Clostridium botulinum*, responsible for botulism, is a strict anaerobic bacterium).



There are risks when preserving food at home, because factory production theoretically provides protection against poisoning by *C. botulinum*.

Infection can be avoided when preparing food if simple hygiene rules are observed. Checking temperature, salt concentration and pH is essential to prevent the formation of *C. botulinum* spores.

*Clostridium botulinum*, **bacteria** responsible for botulism.

## ❑ Microbiological cross-contamination

Microbiological cross-contamination is a **major problem**, especially for certain bacteria like *Listeria monocytogenes*. It can occur through direct contact with **dirty unprocessed products** (e.g.: vegetables pulled from the ground or picked fruit), personnel wearing **dirty clothes, sprays** (e.g.: produced by a pulsed-air hand dryer), **contaminated instruments** (e.g.: using a knife that was used to harvest products), unwashed material, etc. The problem is even more serious when cross-contamination occurs at the end of the process (just before shipping) and for products that will **not be cooked** before being eaten (e.g.: lettuce contaminated by soil).

Cross-contamination can occur at any stage of the process when the product is exposed to the environment, including harvest, transport and processing. **Traffic** flows of employees, raw materials and material must be limited and controlled between product 'reception areas', 'processing areas', 'storage areas' and 'finished product areas' in order to prevent the transfer of pathogens from unprocessed (or raw) products to processed products.<sup>2</sup>

It is therefore important to apply the principle of a **workflow from dirty to clean areas** (the 'processing chain' should be designed on the basis of this principle to **prevent unprocessed and finished products from crossing paths** on entry or exit) and measures to prevent contamination of products that have already been sanitized (e.g.: use different colored containers/baskets for unprocessed and finished products).

## ❑ What are the acceptable limits?

Regulation (EC) No. 178/2002 establishes general food safety requirements, in particular that food cannot be placed on the market if it is unsafe. The general aim is to ensure consumer safety: food must not contain micro-organisms or their toxins or metabolites in quantities that would present an unacceptable risk to human health.

Food business operators are obliged to take unsafe food off the market. To contribute to the protection of public health and to **prevent different interpretations**, regulations therefore establish, on the basis of scientific findings, **harmonized safety criteria** for food acceptability, particularly with respect to the presence of certain pathogenic micro-organisms (**Regulation (EC) No. 2073/2005** on microbiological criteria for foodstuffs).<sup>3</sup>

These '**microbiological criteria**' serve both as **references** for authorities in charge of food controls and as **objectives** for food business operators (e.g.: the HACCP plan can be 'gauged' to these criteria).

<sup>2</sup> Cross-contamination is also possible via the work surface (e.g.: cutting vegetables on a work surface used to cut up poultry) or even in refrigerators (e.g.: liquid dripping from meat onto vegetables) if germs are transferred from carcasses to cut vegetables. It is therefore recommended to use different work surfaces for meat, fish and vegetables, to perform tasks in a certain order (cutting vegetables first) and to avoid using hard-to-clean wooden chopping boards or instruments.

<sup>3</sup> Regulation (EC) No. 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, *OJEU*, L 338/1, of 22 December 2005.

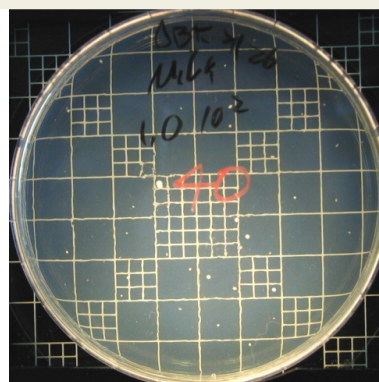


The 'microbiological criterion' defines the acceptability of **a food product** (or a food lot) or **a process**, based on the absence or presence or number of micro-organisms, and/or the quantity of their toxins/metabolites per unit of mass, volume, area or lot.

It should nevertheless be kept in mind that **food safety cannot be guaranteed merely by meeting criteria** but that it also requires compliance with 'Good Hygiene Practices' and use of HACCP, where necessary.

There are **two types** of microbiological criteria:

- **imperative standards (safety criteria):** these are public health criteria. Failure to observe an imperative standard results in action on the product lot concerned (e.g.: withdrawal, recall, destruction) and in corrective action on production/processing.
- **other criteria (process criteria):** these serve to verify good hygiene practices and processes in general. Failure to observe these criteria does not result in specific action on the products concerned but the origin of the weakness must be identified and corrective actions introduced.



A microbiological criterion is composed of the following elements:

- indication of the micro-organisms and/or their undesirable toxins/metabolites;
- analytical methods used to detect and/or quantify them;
- a plan defining the **number of samples to be taken (n)**, as well as the **size** of the analytical unit (25g, 20 g, 10g or 1g). The number and size of analytical units per lot tested should be as stated in the sampling plan and must not be changed.
- **acceptable limits** for the micro-organisms or toxins considered appropriate for the food, expressed either qualitatively (presence/absence) or quantitatively (e.g.:  $10^4$  cfu/g of product);<sup>4</sup>
- **the number of analytical units that should conform to these limits.**

The microbiological criterion must also define:

- the point in the food chain where it applies;
- the actions to be taken when the criterion is not met.

The values of the '**acceptable microbiological limits**' that will be set should **take into account the risks** associated with the micro-organisms and the conditions under which the food is expected to be handled and consumed.

<sup>4</sup> cfu: *colony-forming unit*. Unit used to count bacteria in microbiological analysis: every live bacterium isolated during sorting of the sample on a medium creates a 'colony' that appears in the Petri dish as a spot. Every spot, or colony, originates from one microbe that has divided. The measure is given in cfu/ml (liquid sample) or cfu/g (solid sample).

Microbiological limits should also take account of the likelihood of uneven distribution of micro-organisms in the food, and of the variability inherent to the analytical method. If a criterion requires the absence of a given micro-organism, the size and number of the analytical unit (as well as the number of analytical sample units) should be indicated.

The following values are examples of acceptability levels (acceptable limit value: no sample must exceed this value):

Hepatitis A	Absence
Rotavirus	Absence
Norovirus (Norwalk Like)	Absence
<i>Salmonella</i>	Absence in 25 g or ml
<i>Listeria monocytogenes</i>	Absence in 25 g or ml
<i>E. coli</i> O:157 enterohaemorrhagic	Absence in 25 g or ml
Toxins of <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Clostridium perfringens</i> , <i>Clostridium botulinum</i>	Absence

Microbiological analyses, wherever possible, must only employ sampling and analytical **methods** whose reliability (accuracy, repeatability, inter and intra-laboratory variations) has been statistically established in the framework of comparative or interlaboratory studies. Preference should also be given to **methods validated for the product concerned**, especially when these are reference methods developed by international organizations. Chapter 3 of Regulation (EC) No. 2073/2005 describes rules for sampling and preparation of test samples.

Although methods must offer maximum sensitivity and repeatability for the intended aim, tests conducted in companies often partially sacrifice sensitivity and repeatability to speed and simplicity. They must nevertheless be tested methods, capable of giving a sufficiently reliable estimate of the information required (Hygiene of food, *Codex Alimentarius*, 2009).

### 3.1.3. Mould, yeast and fungi



**Mould** and **yeast** found on fruit and vegetables are primarily spoilage flora.

Certain moulds (e.g.: *Alternaria* spp., *Aspergillus favus*, *Fusarium* spp. etc.) are **toxigenic**, in particular due to the **production of mycotoxins**. They also present a risk for product quality<sup>5</sup>.

**Yeasts** are **normal micro-organisms** on fresh fruit and vegetables. The majority of yeasts present on fruit and vegetables are spoilage micro-organisms. They are not a source of food poisoning.

*Grey mould on onion*

The following are examples of acceptable limits to be applied to ready-to-eat food placed on the market:

Mould	10 <sup>4</sup> /g
Yeast	10 <sup>4</sup> /g

### 3.1.4. Animal parasites

The specific hosts of parasites are often animals. However, the hosts can also include humans during the parasite life cycle. Parasite infections are usually associated with eating **undercooked meat products** or ready-to-eat food, but **fruit and vegetables can also be carriers** of some of these parasites. Effective freezing can get rid of this type of parasite in food that will be eaten raw, marinated or partially cooked.

#### □ Protozoa

Protozoa are small single-cell organisms less than a millimeter in size, which can form colonies. They live only in water or damp ground. They are known to cause many diseases such as malaria, certain forms of dysentery such as **amoebiasis**, and **toxoplasmosis**.

The pathogen responsible for amoebiasis is a rhizopod, *Entamoeba histolytica*. It is the only amoeba that is really pathogenic to humans. **Contamination by this amoeba is oro-faecal**, i.e. through ingestion of its cysts present in **soiled water or food**.

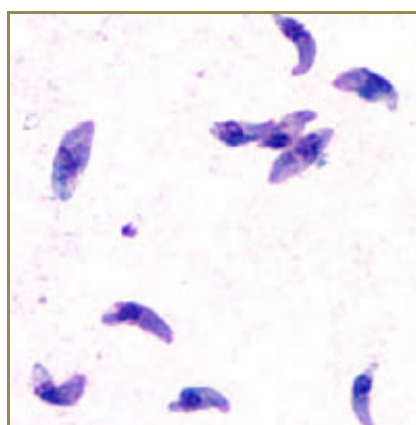
Toxoplasmosis is a parasite infection caused by the protozoan *Toxoplasma gondii*. The parasite usually infects warm-blooded animals, including man, but its definitive host is a felid (including cats). The oocysts are present on **plants or ground soiled by animal droppings** (cats in particular). From there, they can contaminate food, hands or drinking

<sup>5</sup> The health risk associated with the presence of 'mycotoxins' will be developed further in this chapter.

water and then be ingested. The presence of cysts in **meat** is frequent: 80 % of adult small ruminants are contaminated, while pork is generally contaminated in less than 40 % of cases. Other animal species can all be contaminated, but the extent is not known. When meat is eaten raw or undercooked, the cysts are not destroyed and develop in the host organism. In the case of an infection during pregnancy the risk is greatest to the fetus and the effects are particularly serious if the infection occurs during the first two months of pregnancy.



Photo of an amoeba



Tachyzoites of *Toxoplasma gondii*

**Lambliasis** is an infection (due to *Giardia intestinalis*, also called *Giardia lamblia*) that often goes unnoticed. However, the parasite that causes it is one of the most frequent in Europe, especially among children. It is a major oro-faecal disease, probably the most widespread intestinal parasitosis in the world. It is a frequent cause of **travelers' diarrhea**.

#### ❑ Intestinal worms<sup>6</sup>

Dozens of different types of worms and the other intestinal parasites that infest humans are present in every country in the world. They are more frequent, however, in tropical and sub-tropical regions and are widespread during the rainy season. Parasitic diseases caused by roundworms or nematodes that live in human intestines are called *intestinal helminthiases*.

The eggs of these parasites are introduced into the human system **through food or water** (e.g.: fruit and vegetables soiled by impure water). Food soiled by earth or washed with non-potable water therefore represents a major source of contamination from intestinal worms.

The transmission of intestinal worms to man is due to **poor hygiene conditions**:

1. A person infected by the parasite contaminates the environment by **excreting stools** in nature that contain worm eggs. The soiled ground and plants are contaminated by the parasite eggs.
2. Other people become infected by eating food soiled by the excrements or

<sup>6</sup> Other parasites that go through the skin, such as bilharziasis (schistosoma worms) found in stagnant waters in Asia, Africa and South America, or the larvae of ankylostoma, which penetrate the skin, will not be considered here.

through touching food with soiled hands.

3. In individuals infected by the parasite, the eggs or larvae develop into adult worms that produce large numbers of eggs, which in turn will be excreted.

The most widespread infections of this type in the ACP countries are:

- ascariasis, caused by roundworm;
- trichocephalosis, caused by whipworm (*Trichuris* sp.);
- ankylostomiasis, caused by hookworm.

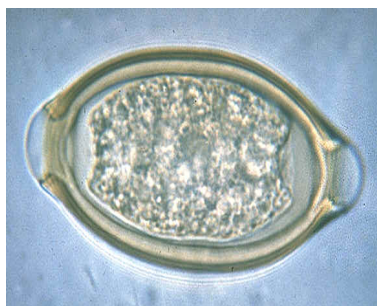
There are many others, however, and we describe below the main characteristics of the parasites encountered most often.



Roundworm (*Ascaris lumbricoides*) is a parasite that causes ascariasis.

**Roundworm** lives in the intestines of humans and animals and can grow to a length of 17 centimeters. It is transmitted through soiled water or **poorly washed fruit and vegetables**.

*Ascaris lumbricoides*



**Trichocephalosis** is a parasite infection caused by the nematode *Trichuris trichiura*. It is more frequent in warm and damp regions, and in areas where **untreated human faecal matter is used as fertilizer**.

Contamination is oral, and caused by ingestion of fertile eggs that soil hands or food or pollute drinking water.

*Egg of the Trichuris trichiura nematode*

**Pinworms** are small white worms measuring around one centimeter long and found **in the ground**. Children, who place their hands on the ground and come into contact with the eggs of these parasites, are infested much more often by intestinal worms than adults, because they then touch their mouths and the eggs enter the body. The parasites develop in the intestine and during the night the females migrate to the anus. They lay eggs, which causes the itching typical of this infection. Eggs are also found in underwear, bedding and even on the floor. If the child scratches himself and then touches his mouth, the contamination continues and the parasites can be transmitted to other family members.

The worms can cause an inflammation of the intestines and lungs, nausea, vomiting, major weight loss and fever. In some cases, the parasites can cause intense itching in the area around the rectum. Most of these parasites are not serious for people in good health, but some can have after-effects, particularly when they develop in the brain or lungs. Among immunodeficient individuals, such as AIDS patients, the parasites can be fatal.

To be complete, we will mention other parasitic worms that can be found in food, but **only in meat**.



*Trichinella spiralis* or **threadworm** is a parasitic worm (nematode) that causes trichinosis in man and in many mammals. The worm can develop in the small intestine and its larvae then migrate to the muscles where they encyst. Humans can be infected by eating the parasite-infested meat of pigs, warthogs or any other mammal.

Fish and meat can also be infected, with **tapeworm** for example. This parasite (cestode) attaches to the intestines of pigs and cows using its hooks. It is made up of a series of rings that enclose highly resistant eggs that will develop into worms. In cows and pigs, tapeworm can encyst in muscles. Humans can therefore be contaminated by eating **raw or undercooked meat**. Three months later, the first rings are excreted in the stools, a process that can continue for years!

## 3.2. Origin and nature of physical risks

### 3.2.1. Origin and gravity of physical risks

Physical risks, which seem to pose fewer problems than chemical and biological risks, can nonetheless have a serious impact on consumers' health when caused by hard, cutting or sharp objects. They also result every year in a significant number of product withdrawals and recalls<sup>7</sup>. Foreign bodies have also become the leading source of consumer complaints in the agri-food industry.

The origin of physical risks is the **unintentional presence** in a food product of either a foreign body (e.g.: metal fragments in minced meat) or of natural objects (e.g.: fish bones, bits of mussel shells, bone shards in salami, hard bits in packs of potato crisps, etc.) that are dangerous to consumers. A food can be contaminated by such agents at any stage of the production or packaging process.

*Example of a recall notice (AFSCA (food safety authority) website, Belgium, 2009):*



Press release  
Londerzeel, 17 April 2009

La William recalls Américaine Maison sauce 650 ml as a precautionary measure.

A shard of glass was discovered in a jar. La William asks its customers to return to the place of purchase any 650 ml jars of Américaine Maison sauce bearing the code 19/02/10 1F4A, 19/02/10 1F4B and 19/02/10 1F4C. La William applies the strictest quality and safety criteria and has decided to recall this product without delay as a precautionary measure.

La William asks its customers not to consume this product and to return it to the place of purchase. Returned products will be reimbursed. This recall does not concern any other La William products.

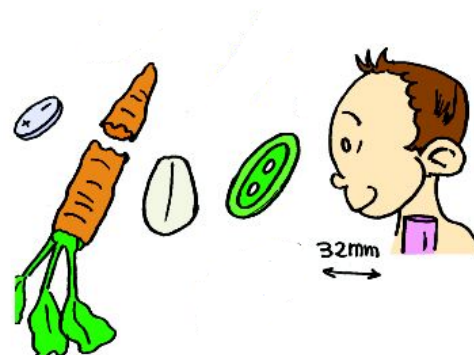
La William apologises to its customers for this inconvenience



<sup>7</sup> Many recalls for products sold in jars result from the presence of shards of glass in the product. Such shards can result when the screw thread is crushed during the process of screwing on the cover (excessive twisting due to poor adjustment of the machinery, poor quality glass or a manufacturing flaw in the jar).

The gravity of the occasional danger depends on the **nature** and origin of the foreign body, but also on the consumer's **age and state of health**.

A child can choke more easily by swallowing objects (this type of accident mainly concerns children aged 1 to 3 years. Any object with a diameter of less than 32 mm can go down the windpipe rather than the esophagus).<sup>8</sup>



Foreign bodies also pose a risk of choking for the elderly or the ill who have difficulty swallowing.

The intrinsic danger of foreign bodies also comes into play: **glass** or **metal fragments** are the most dangerous because they can cause:

- cuts in the mouth or throat;
- injuries to the intestines;
- injuries to the teeth or gums.

Synopsis of possible health effects:

Dangers	Harmful effects on health
<b>Glass</b>	Cuts, bleeding – can require surgery to find and remove the object
<b>Wood</b>	Cuts, infection, choking – can require surgery to find and remove the object
<b>Stones</b>	Choking, broken teeth
<b>Metal</b>	Cuts, infection – can require surgery to find and remove the object
<b>Insulating material</b>	Choking – long-term effect for asbestos
<b>Bone</b>	Choking
<b>Plastic</b>	Choking, cuts, infection – can require surgery to find and remove the object
<b>Personal effects</b>	Choking, cuts, broken teeth – can require surgery to find and remove the object

The consequences of ingesting a foreign body range from a broken tooth to intestinal occlusion (e.g.: a Belgian girl had to have surgery in 2010 because of a piece of mussel

<sup>8</sup> Groundnuts cause 50 % of choking incidents among children. Sometimes it is not until weeks later, when the groundnut or other object caught in the bronchial tubes becomes infected, that the tragedy occurs. The foreign body has to be removed as a matter of urgency, but the child dies in 10 % of cases.

shell attached to the intestinal wall) or perforation of the stomach, which in the most serious cases can be fatal.

### 3.2.2. Most frequent physical risks

The main sources of physical risks in food are as follows:

- **glass**: frequent sources in food processing establishments are light bulbs and glass containers (jars, bottles);
- **metal**: frequent sources of metal are fragments from the equipment used (shards, blades, broken needles, pieces of used utensils, staples, etc.). The intensification and modernization of agriculture is such that the production of fruit and vegetables is increasingly motorized (tractors, grading equipment etc.). If technical specifications for use, maintenance, hygiene and sanitary conditions are not sufficiently mastered, **machinery** can be a potential source of direct or indirect contamination from foreign bodies: bits of metal, pieces of blades etc.;
- **plastic**: frequent sources of hard or soft plastic are: packaging material, gloves worn by employees, utensils used to clean equipment or tools used to remove products stuck to machinery blades;
- **stones**: field crops, such as green peas or beans, for example, may contain small stones collected during harvest; stones can also come from the establishment's structures and concrete floors;
- **wood**: splinters from wooden structures and pallets used for storage and transport of ingredients or products;
- **natural parts** of foods that are hard, sharp, cutting: shards of bone in meat, fish bones, pieces of pits etc.

In **fresh fruit and vegetables**, physical risks are mainly associated with the presence of **foreign bodies** such as:

- earth or sand;
- pebbles (gravel);
- insects or insect debris, or even certain rodents;
- pieces of wood (e.g.: splinters from boxes);
- straw, stems or roots of weeds;
- glass debris or metal fragments (e.g.: staples, nails, jewelry etc.);
- pieces of cardboard, paper, cigarette butts etc.;
- bits of bandages or 'grafting' (natural or synthetic locks of hair affixed to natural hair);
- pest excrements (droppings);

In principle, it might seem difficult to ingest accidentally a foreign body like earth, sand, a pebble or glass debris, because as a general rule fruit and vegetables are washed as part of the packaging process and/or before being eaten.

However, precautions are needed to ensure the product's hygienic and marketable quality. The impact of a foreign body can be more or less serious depending on whether the food is eaten by a child or an adult, a person in good health or an ill person etc.

### 3.2.3. What are the acceptable limits?

The values considered as 'acceptable' for foreign bodies in food vary from one sector to another, one industry to another and one product to another. The following is an example of acceptable levels for physical hazards:

Physical hazards		
Honey	Insoluble matters < 0.1% Debris < 500 µm Absence of exogenous elements	Legal standards Customer requirements (tender specifications)
Fruit pulp	Absence of metallic and non-metallic foreign bodies with diameter > 1 mm	Internal requirement (private specification)

In the absence of another source, we can refer to the guidelines of the Food and Drug Administration (FDA, USA) for the presence of hard and sharp objects in food. The FDA states, for example, that there is a physical risk to consumers' health for:

- hard or sharp objects measuring **7 to 25 mm**;<sup>9</sup>
- natural parts of food that are hard or sharp (such as shells): these represent a physical risk because consumers can be injured if they are not aware of their presence;
- hard or sharp objects that have been incompletely removed from food (e.g.: pits in pitted cherries, walnut shells, etc.).

These conclusions are based on the practical experience of the FDA Commission which, from 1972 to 1997, ruled on more than 4000 cases of foreign bodies discovered in food (in most cases, glass or metal). The *Keuringsdienst van Waren* (Netherlands) applies the FDA conclusions. The Dutch inspectorate considers the presence of hard or sharp objects measuring 7 mm or more as an unacceptable risk to consumers. For food for small children or other high-risk groups, the inspectorate applies a limit of 2 mm.

<sup>9</sup> Foreign bodies measuring 7 to 25 mm can be a potential danger to the average consumer in ready-to-eat foods or those which, according to package instructions, simply require reheating, since this operation does not eliminate or neutralise foreign bodies before consumption of the food. Foreign bodies larger than 25 mm are visible enough and are therefore noticed by the consumer. Smaller objects (2-6 mm) are only a danger for people who depend on the care and attention of others for their food and drink; this is the case of small children, the ill and the elderly.



## 3.3. Origin and nature of chemical risks

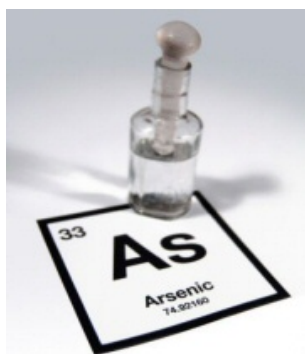
Food production and processing entails **a large number of chemical hazards**. Chemical contaminants can exist **naturally** in food, **be added to it** during processing (technological additives), **migrate from packaging** or even **form** during cooking (e.g.: acrylamide). In high doses, harmful chemicals are associated with acute food poisoning, and in repeated low doses they can be responsible for chronic diseases such as cancer.

Examples of chemical hazards (Source: FAO Training Manual, 2010)	
<b>Toxic compounds and elements</b>	Lead Zinc Cadmium Mercury Arsenic Cyanide
<b>Natural chemical compounds</b>	Mycotoxins Allergens Scombrottoxins (histamine, in fish) Ciguatoxin Fungal toxins Shellfish toxins
<b>Industrial chemical contaminants</b>	Dioxins and polychlorobiphenyls (PCB) Agriculture products (pesticide residues, fertilizers, antibiotics, growth hormones) Food additives Vitamins and minerals Contaminants (lubricants, cleaning and disinfecting agents, protective agents, coolants, paints, water and boiler treatment agents, rat poison, insecticides)
<b>Contaminants from packaging</b>	Plastic compounds (e.g.: bisphenol A) Banned products: vinyl chloride Label/coding ink Adhesives Lead Tin

European regulations apply to most of these chemical components and limits have been set for amounts that can be contained in food.

### 3.3.1. Risks associated with 'heavy metals'

#### ❑ Definition and origin of heavy metals



Metals are minerals. The term '**heavy metals**' refers to their **high density** (greater than 5) but this term has no scientific basis or legal application. The main 'heavy metals' are **lead** (Pb), **cadmium** (Cd), **mercury** (Hg) and, to a lesser extent, **chromium** (Cr) and **nickel** (Ni). Following adoption of the *Heidelberg Protocol* (1986), other elements were classified with heavy metals, including arsenic (As, a non-metal), selenium (Sn) and antimony (Sb), or even certain organic compounds that have a significant impact on health. So it is preferable to speak of 'trace elements' or **metallic trace elements (MTE)**.<sup>10</sup>

MTEs found in the environment have basically two origins:

- **natural origin:** rocks in soil that contain such elements (arsenic, lead, etc.), volcanic eruptions, forest fires and slash-and-burn technique, etc.
- **human origin:** contamination varies depending on the zone: industrial (or peri-urban), agricultural, urban, or road and motorway zones. The origins of these metals are numerous and varied depending on the elements: air pollution (lead, cadmium, etc.), fertilizers (cadmium, lead, arsenic, etc.), urban sewage sludge (mercury, lead, cadmium, etc.). Lead (Pb) comes from exhaust gases, accumulator batteries (particularly in cars), piping, welded seams, old paints, anti-corrosion paints (red lead) and hunting ammunition. Mercury (Hg) is used for many purposes, including dental amalgams, the extraction of gold and electric batteries. Chromium (Cr) is used as a red pigment and for chromium plating of coins. Zinc (Zn) is used to galvanize steel and in moulded vehicle parts, while nickel (Ni) is used for stainless steel.

Many MTEs are useful in biological processes: iron, for instance, is an essential component of hemoglobin, and zinc and copper are essential trace elements.

#### ❑ Effects on health

However, their presence in the environment at excessive concentrations poses real problems for public health because they are not degradable and can therefore accumulate in the ground. These heavy metals **can be absorbed by plants or animals** (in drinking water, fodder, etc.) and enter the food chain, producing **chronic** or **acute effects**:

- they replace or serve as a substitute for essential minerals;
- they have an antibiotic effect, which increases bacterial resistance;
- they produce free radicals and affect our genetic code;
- they neutralize amino acids used for detoxification;
- they cause allergies;
- they damage nerve cells.

<sup>10</sup> In European law, some of these elements are included among 'hazardous substances'.

As a general rule, the unborn, followed by infants and children, are much more sensitive and more exposed to MTEs than adults because they absorb them in much larger quantities.

Saturnism is the name of the condition corresponding to acute or chronic lead poisoning. Absorbing too much lead by eating contaminated products can cause headaches, anemia, blindness, kidney disease, paralysis and even brain damage. Severe lead poisoning can sometimes be fatal. Young children are most affected by lead because their bodies are small and growing. Lead is absorbed more easily during periods of fast growth.

Cadmium (Cd) is an element that has the property of accumulating in the body and it is toxic to the organism. Chronic ingestion (at small repeated doses over a long time) of cadmium disrupts the functioning of the liver, kidneys and blood pressure and causes pain in the joints.

#### ❑ Accumulation of heavy metals in plants



It has been demonstrated that **plants, both wild and cultivated, are good 'collectors'** of these elements. Certain species have a specific **propensity to accumulate certain elements** present in soil, water or air. Soil pollution clean-up techniques have even been developed on this principle (the MTE is 'trapped' with the aid of specific plants that are then eliminated using controlled processes to clean up contaminated industrial sites, for example).

This property of plants is also used to measure air pollution indirectly through the presence of metallic trace elements.

So it is easy to understand the importance of making sure that toxic elements (such as **lead, mercury and cadmium**), which may be present in soil (industrial use of site) or added to soil (via fertilizers, sewage sludge, settling from the air, fires, etc.), cannot accumulate in cultivated plants. Producers are advised to find out the **history of the cultivated soil**.

**Lead (Pb) and cadmium (Cd)** are two elements that should be **monitored most closely** with regard to **fruit and vegetables** (e.g.: potatoes). These two elements are covered by Regulation (EC) No 1881/2006<sup>11</sup>.

<sup>11</sup> Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs, OJ L 364 of 20.12.2006. Maximum levels for certain contaminants in foodstuffs such as Pb and Cd.

The maximum levels for the EU are as follows:

For lead	Maximum levels (mg/kg fresh weight)
Vegetables (excluding brassica vegetables, leaf vegetables, fresh herbs and fungi. For potatoes the maximum level applies to peeled potatoes).	0.10
Brassica vegetables, leaf vegetables and cultivated fungi	0.30
Fruit (excluding berries and small fruit)	0.10
Berries and small fruit	0.20

For cadmium	Maximum levels (mg/kg fresh weight)
Vegetables and fruit (excluding leaf vegetables, fresh herbs, fungi, stem vegetables, pine nuts, root vegetables and potatoes).	0.050
Leaf vegetables, fresh herbs, cultivated fungi and celeriac	0.20
Stem vegetables, root vegetables and potatoes (excluding celeriac; for potatoes the maximum level applies to peeled potatoes).	0.10



During summer 2006, the European Union's rapid alert system was triggered for unacceptable levels of cadmium in preserved pineapples originating in Kenya. In October, the first lots were taken off the market in Switzerland. Eight samples of preserved pineapples imported from South Africa and sold in Switzerland were contaminated by cadmium. Three boxes from the same lot had cadmium levels of between 0.11 and 0.12 mg/kg, exceeding the limit value of 0.050 mg/kg.

The source of the contamination was probably the **use of a fertilizer** (phosphate) that was overly rich in cadmium. Part of the cadmium, a labile element, migrated from the soil into the fruit.

### 3.3.2. Risks associated with mycotoxins

#### ❑ What is a mycotoxin?

The term mycotoxin comes from the Greek *mycos* meaning fungus and from the Latin *toxicum* meaning poison. It refers to toxic chemical substances produced by certain moulds that develop on certain foods, in particular on cereals but also on dried fruit and vegetables.

Mycoflora is estimated at between 200,000 and 300,000 species. Moulds (*Fungi imperfecti*) present two aspects (Dupuy, 1994):

- a **beneficial aspect: the transformation** of food raw material (especially during fermentation), the production of antibiotics, enzymes, condiments, flavoring agents and proteins that can be useful to human health and used widely in the agri-food industry. However, a strain used by the food industry is not necessarily atoxic and can become toxigenic in certain media.
- a **harmful aspect: the spoilage of food**, since imperfect forms of pathogens cause mycoses, allergies and the production of metabolites (mycotoxins) that are toxic to man and animals. Mycotoxins are **secondary metabolites**, meaning that they are not necessary for the development of the fungus, unlike amino acids, fatty acids, nucleic acids and proteins. Around **360 species** of fungi produce **mycotoxins**: primarily the genera *Aspergillus*, *Fusarium*, *Penicillium*, *Alternaria*, etc. Other genera also include toxigenic species: *Stachybotrys*, *Trichoderma*, *Trichothecium*, *Cladosporium*, *Claviceps* etc. Around **25% of foods are contaminated** by mycotoxins, the secondary metabolites of various moulds.

#### ❑ Main mycotoxins<sup>12</sup>

Mycotoxin group	Mycotoxins	Conditions for emergence	Moulds	Substrata
<b>Aflatoxins</b>	Aflatoxins B1, B2, G1 and G2	Tropical and subtropical climates	<i>Aspergillus parasiticus</i> , <i>Aspergillus flavus</i>	Groundnuts Sorghum Spices and condiments Fruit Dried fruit Cereals and cereal products
<b>Ochratoxins</b>	Ochratoxins A, B, C and D	Damp climates During storage	<i>Aspergillus ochraceus</i>	Maize, rice, cocoa, tea, coffee, spices Flour Dried fruit

<sup>12</sup> Mycotoxins are also found in other matrices. For example: Aflatoxins M1 in milk products, mycotoxins in products used in feed, in meat etc.



<b>Zearalenone</b>	Zearalenone	Ubiquitous moulds	<i>Fusarium</i> sp.	Maize Sorghum Flour Cereals and cereal products Oilseed products
<b>Deoxynivalenol</b>	Vomitoxin (DON) Nivalenol, Fusarenon X (Trichothecene B)	Ubiquitous moulds	<i>Fusarium</i> sp.	Maize Flour Bread and pasta Cereals and cereal products
	T2 toxin, HT2 toxin, Diacetoxyscirpenol (Trichothecene A)			
<b>Fumonisin</b>	Fumonisin	Temperate and warm climates	<i>Fusarium moniliform</i> , <i>Fusarium proliferatum</i> , <i>Fusarium</i> sp.	Maize Flour Cereals and cereal products Bread and pasta

Also worth mentioning are:

- the mycotoxin that was historically the most widely known in Europe and the world: **rye ergot** *Claviceps purpurea* (rye and other cereals). Thanks to the sorting of seed and the use of fungicides, this cereal disease has almost completely disappeared, although it is still endemic.
- **patulin**, a mycotoxin that forms during the storage of apples infested by the fungus *Penicillium expansum* and that is consequently found in apple juice.

The same toxin can be produced by different species of fungi but not necessarily by all strains belonging to the same species. Similarly, in some cases, a single species of fungus can produce several mycotoxins.

Ongoing research shows that many other toxins, produced mainly by the genera *Penicillium* and *Aspergillus*, may also come into consideration. The list of mycotoxins continues to grow, but data are usually lacking for serious exposure studies.

#### ❑ Special case of *Alternaria* mycotoxins

*Alternaria alternata* and *A. radicina* are two moulds that can develop on cereals, sunflower seeds, pepper, sesame, olives, different fruits, tomatoes, carrots and celery. These moulds produce various secondary metabolites (alternariol, alternariol methyl ether, altertoxin, radicin etc.). These metabolites in food can be dangerous to humans. Some have demonstrated embryotoxic and teratogenic effects in mice and hamsters and

cytotoxic effects for bacteria and mammal cells. Certain extracts of *A. alternata* are mutagenic for different microorganisms and mammalian cells.



Mould spores. Tomato and pepper infected with *Alternaria alternata*.

For the moment, there are no limits or guide values for *Alternaria* mycotoxins because human exposure through food is limited. Attention should nonetheless be drawn to specific groups of products such as vegetable juices and baby food (made from carrots or apples). Action may be taken in the future if further information suggests a need.

#### ❑ Factors promoting the appearance of mycotoxins

Mycotoxins can appear in different circumstances, for example during **fermentation, processing, refining, removal from storage** of foods, etc. In fact, mould spores often contaminate food that has not been sterilized or pasteurized because one of the common characteristics of fungal species found in foods that are not highly hydrated is sporulation or rapid dispersal.

The development of mycotoxins is closely linked to **conditions in their environment**. The many factors that influence their dissemination can be grouped into two categories:

1. **Biological factors:** the dissemination of mycotoxin depends on their infectious potential: some have high sporulation intensity and very long-lived spores that are disseminated faster and more easily than others, through the air (*Aspergillus*, *Penicillium* etc.) or water. **Mites or insects** help disseminate them and alter the natural defenses of substrata through the lesions they cause. The local spread of mould depends on **speed of growth**, which varies considerably from one species to the next. Growth is generally around a few millimeters per day. In terms of nutrition during the growth phase, a mould can encounter competitive fungal micro-organisms such as *Trichoderma viride*, an exclusive species because it does not tolerate the

presence of other species<sup>13</sup>, or bacteria, which multiply much more quickly than moulds when they have optimal physico-chemical conditions, especially water activity (Aw).

2. **Physico-chemical factors:** moulds and toxins develop in certain specific conditions of humidity, temperature and gas levels. Each strain has specific conditions that promote its development. **Humidity** contributes to the development of mould on a given substratum. Spores can germinate from a certain degree of **relative humidity of the ambient air**. To survive and continue to grow, however, the mycelium must find '**available water**'.<sup>14</sup> Mould can develop at the usual food storage temperatures (between 0 and 35°C). They need oxygen to develop since they are **aerobic organisms**. Some can nevertheless more or less tolerate partial pressure of low oxygen, high concentrations of carbonic gas, or a combination of the two (a relatively frequent situation in food preservation).

There are also concerns that **organically farmed products** may be more susceptible to contamination by mycotoxins because of the **absence of fungicide protection** (or insecticide for stored cereals). A number of research projects have explored this issue. The findings show that situations and results vary in terms of the type of mycotoxin and the foodstuff. In Belgium, studies have been carried out on levels of **ochratoxin A** (OTA): fairly high levels have been detected in organic products (e.g.: in cereals used to make beer). The same observation has been made for **patulin** in apple juice, suggesting that higher levels can occur in organic products (but only if the apples are stored before being juiced).

**For fruit and vegetables**, there is a **host specificity** for parasite species: *Penicillium expansum* on apples and other pome fruit trees, *Penicillium digitatum* on lemons, *Phytophthora infestans* on potatoes, *Trachysphaera fructigena* on bananas, etc.



Mould due to  
*Penicillium expansum* on apple



*Trachysphaera fructigena* on banana

#### ☐ What damage is caused and what are the health risks?

Mould and mycotoxins pose economic problems for grain merchants (poor quality grain, low yield for cereal production), poultry and livestock producers (poor animal performance

<sup>13</sup> It is therefore easy to understand why the use of certain fungicides (strobilurins group) that destroy antagonistic flora on cereals during the period close to ear emergence increases the level of mycotoxins on grains.

<sup>14</sup> There is a relationship between water activity (Aw) and the product's water content. Available water is measured by establishing a sorption curve for the substratum concerned. This point will be covered in chapter 4 on preservation of products.

and diminished reproduction, losses due to disease) and industries that produce feed and food.

Indirect economic drawbacks are the production of unmarketable substances (due to the food's change of appearance, alteration of organoleptic or chemical characteristics), a higher net price for detoxification (protection through fungicides) or destruction when substances are too contaminated. For stock farmers, this implies a higher price for non-contaminated feed or costs to decontaminate feed or treat affected animals. At a global level, this leads to losses estimated at 5 to 10%.

Mycotoxins only represent a potential risk to human and animal health if absorbed in large quantities. The food safety problem therefore only arises in case of massive infection of cereals, generally due to **poor cultivation and storage conditions**.

#### ❑ Acceptable limits

Since the discovery of aflatoxins in the 1960s, many countries have adopted regulations to protect consumers from the harmful effects of mycotoxins that can contaminate food and also to ensure fair food trade practices. Regulations are based mainly on known toxic effects for the mycotoxins currently considered as the **most significant** (e.g.: aflatoxins, ochratoxin A, patulin etc.). The European Union set **maximum levels** for mycotoxins in food with Regulation (EC) No 1881/2006<sup>15</sup>, adopted in 2006. Acceptable levels vary depending on the mycotoxin, the mycotoxin group (sum) and the food.

### 3.3.3. Risks associated with residues of plant protection products

#### ❑ Plant protection products and Good Practices



Plant protection products (commonly known as 'pesticides') are used to combat crop enemies and protect harvests.

The products used most often are fungicides, herbicides and insecticides applied by **spraying on the plants** during their growth, or sometimes even after harvest (e.g.: to prevent fruit rot or infection of grain during storage).

Plant protection products used by farmers are available in different 'commercial forms' (referred to as **formulations**: solid – powders, pellets – or liquid – emulsifiable concentrates, aqueous solutions, aqueous emulsions, concentrated suspensions in water or oil). These commercial products contain one or more **active substances** responsible for the product's biological activity and have their own properties.

<sup>15</sup> Annex (section 2) of Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs, *OJEU*, L 364 of 20 December 2006. The annex lists maximum levels for aflatoxins (B1, sum of B1, B2, G1 + G2 and M1), ochratoxin A, patulin, deoxynivalenol, zearalenon, fumonisins and toxins T2 and HT2.

Before being placed on the market, each commercial product undergoes an **evaluation of its effectiveness and risks**, particularly for the operator, consumers and the environment. The criteria laid down in regulations vary somewhat depending on geographical areas, but the principles and even the evaluation methods are relatively comparable and increasingly convergent.

After evaluation, each product is authorized by law:

- for a given use (crop to which it can be applied, with possible use restrictions or specific application arrangements);
- at an established maximum dose (usually expressed as g or ml/ha);
- for a maximum number of applications to the same crop during the season;
- for an application in accordance with given arrangements (volume/ha, stage, etc.);
- and with an interval to be observed between final application and harvest (PHI: pre-harvest interval, in days).

All these elements, which must be detailed on the product label, make up what is known as GAP or '**Good Agricultural Practices**' (within the regulatory meaning). The producer's **compliance with GAP** offers a **guarantee** of the treatment's **effectiveness** and the **conformity** of the harvest with established residue standards (MRL – maximum residue limits, in mg/kg food).

In Europe, Regulation (EC) No. 1107/2009<sup>16</sup> lays down rules for **applications for authorization to place on the market** plant protection products used in agriculture. **Only products containing one or more active substances shown in an 'approved list' can be used in Europe and a maximum residue level is set for each active substance for a given crop** (different from the limit of determination).

Authorization criteria for biocides (products used in the area of hygiene) are detailed in Directive 98/8/EC.<sup>17</sup>

Unlike other chemical compounds resulting from involuntary or accidental contamination (e.g.: dioxins, Bisphenol A, mycotoxins, etc.), residues of plant protection products result from **voluntary introduction of these compounds into the food chain**.

Producers who use chemical products are therefore **particularly responsible for the risks** they can cause to consumers by using an **unauthorised substance** or by **failing to observe the conditions of use** for these products (GAP) laid down by regulations!

<sup>16</sup> Regulation (EC) No. 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, *OJEU*, L 309/1 of 24 November 2009.

<sup>17</sup> Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market, *OJEC*, L 123/1 of 24 April 1998.



### ❑ Origin and definition of residues of plant protection products

After application, the amount of the plant protection product that remains on the plant **tends to diminish over time** under the combined effects of the environment and the characteristics of the plant.

This process entails two **phenomena**:

- **physical dilution** (through plant growth) and **transport** (leaching, volatilization);
- **biological and/or physico-chemical transformation**. In the first case, this results from metabolism by the plant itself or of micro-organisms (metabolization); in the second, photolysis and/or hydrolysis alter the molecule (degradation).

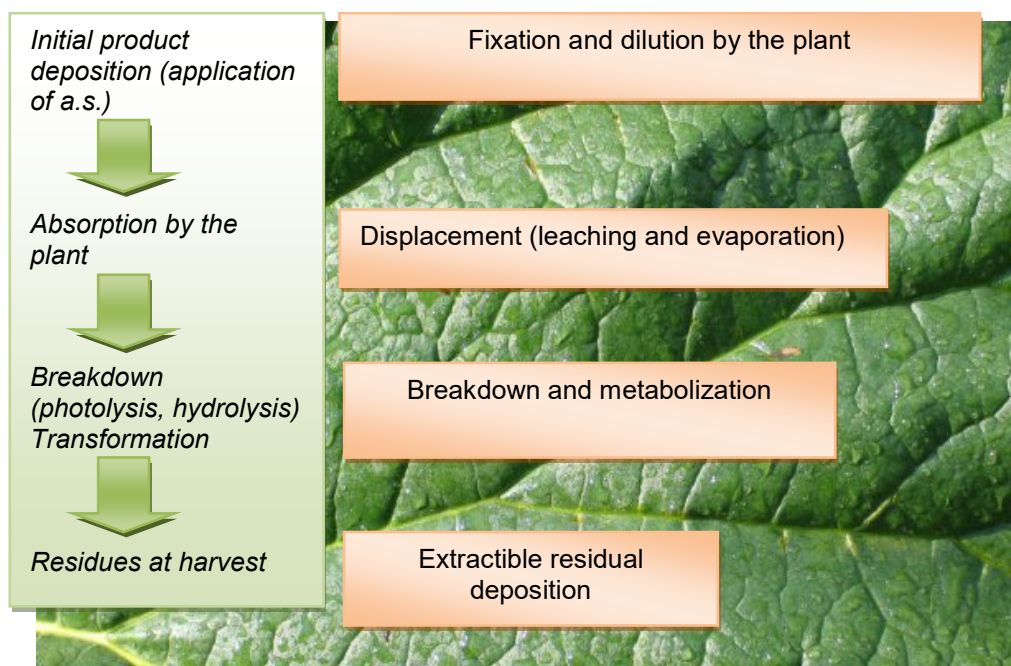


Every active substance, depending on its properties (polarity, solubility, affinity for fats), reacts in its own way with the plant surface. Some of the substance can become affixed to the surface of the leaves upon contact with the cuticular wax, some can penetrate the superficial layers of the cuticle and some can penetrate more deeply, reaching the parenchyma (the internal tissue of leaves) or even spreading throughout the rest of the plant (the 'systemic' nature of the active substance).

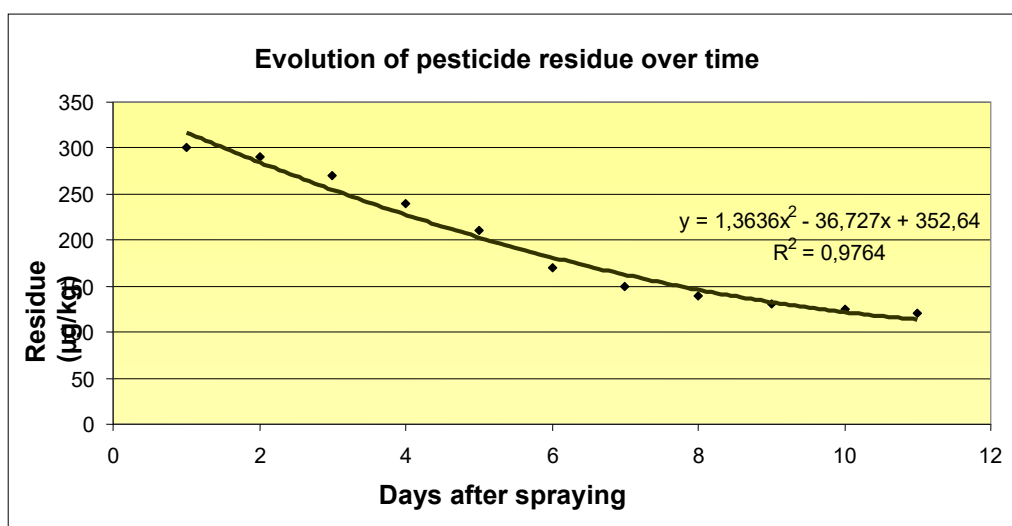
'Residues' from an application **can therefore be either superficial or found on and in the leaves, stems, fruit and even the roots or tubers** of treated plants, even if they are not directly exposed. Residues represent the part of the active substance that can be extracted and measured.

Since the cuticle of every plant has different properties that can vary depending on the stage of vegetation or in terms of the upper or lower leaf surface (the latter contains openings called 'stomata'), it is easy to understand the **complexity of the phenomena involved** and the impossibility of foreseeing the evolution of the active substance (a.s.) that settles on a crop without carrying out tests in different environmental conditions (temperature, rainfall, light, relative humidity etc.) and growing conditions (density of vegetation, varieties grown, use of fertilizer, irrigation etc.).

Diagram of the evolution of a plant protection product applied to a crop:



By conducting field trials and **sampling and analyzing** the residual deposits at regular intervals, the quantitative evolution can be monitored and the **decay curve** of the residues over time can be determined.



- **Photolysis** and **hydrolysis** are the two main physico-chemical processes responsible for the breakdown of residues (the compounds obtained by these processes are referred to as '*breakdown products*').
- **Metabolization**, the transformation of the active substance through the plant's metabolism action, concerns **penetrating and systemic** substances. By altering the

structure of the initial molecules, breakdown and/or metabolic processes contribute to the decay of the initial deposition and can generate new substances with different properties (the compounds resulting from this process are known as '*metabolites*').

The use of active substances can result in the presence of '**residues**' in **treated products**, in **animals feeding on these products** and in **honey** produced by bees exposed to these substances. Regulation (EC) No 396/2005<sup>18</sup> defines 'pesticide residues' as '*residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant production products*'.

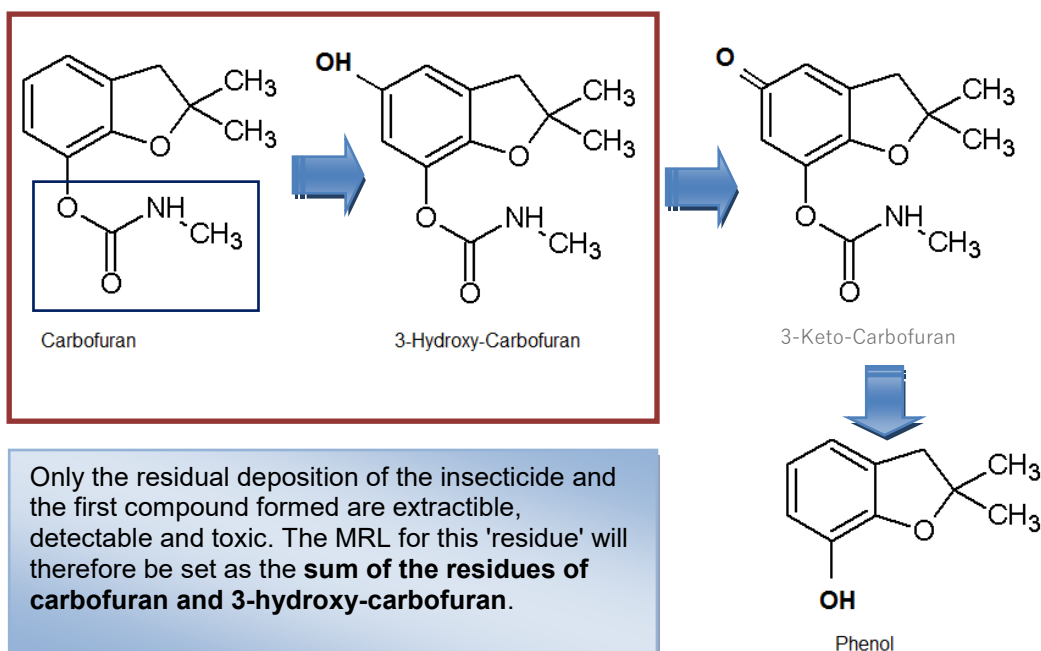
#### ❑ What is the definition of 'residue'?

The **definition of 'residue'** in the *Codex Alimentarius* (FAO/WHO) or in European regulations **is limited to the initial molecule and specific derivatives**, such as breakdown products and metabolites **that present a fair degree of toxicological importance**. It does not correspond to the chemical definition, which refers to all breakdown products of the initial molecule or metabolites that form, but that do not have recognized toxicity.

Every active substance has **specific properties**: toxicity, solubility, persistence of action, environmental persistence, photosensitivity, volatility, adsorption capacity, effects on fauna and flora, etc. The same can be said for breakdown products and metabolites that form upon contact with plant substrata. Some of these compounds conserve the chemical groups responsible for the biocide effect (e.g.: the N-methyl-carbamate group, which can interact in the nervous system with acetylcholinesterase), but others do not (e.g.: phenol).

An example is the evolution of a systemic insecticide of the carbamate family: carbofuran (also called 'furadan'). Its toxicity (for insects but also for man) is associated with the presence of the N-methyl-carbamate group (outlined in blue in the diagram below) in the molecule. After penetrating the leaf, the molecule is transformed into *3-hydroxy-carbofuran*, then into *3-ceto-carbofuran*. The latter compound is not stable and evolves very quickly to generate a *phenol derivative*.

<sup>18</sup> Regulation (EC) No. 396/2005 of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJEU, L 70/1 of 16 March 2005.



#### ❑ What are the risks to consumers' health?

The risk associated with residues depends on the following **three parameters**:

1. the **toxicity of the residue**: acute and chronic toxicity, severity of the active substance's effects on the organism and possibly of certain of its metabolites or breakdown products;
2. **contamination**: concentration of residues found in food, including drinking water!
3. **exposure**: which depends on consumption (quantity ingested and frequency of the residue in the diet).

Therefore, the **risk of exposure = contamination x consumption**.

The value obtained (estimate) can be compared to a reference toxicological value (scientifically established data).

To estimate the consumer's risk of exposure, two values must be known: the concentration of residues detected in the food (e.g.: results of a laboratory analysis) and the amount of food consumed. For contamination, the average value of the observed result (average residue) can be used, but it would not be accurate to use average consumption to calculate exposure, because some people can consume considerably larger quantities of a food than the average for the population, referred to as large portions (LP).

To cover the risk of exposure for all consumers, it is therefore preferable to use the value corresponding to the 97.5th percentile (P97.5) of the consumption curve.<sup>19</sup>

<sup>19</sup> Unfortunately, there is no reliable consumption survey for the ACP States, which represents an obstacle to a serious estimate of risk for local populations. In the absence of data, we refer to

**Examples for consumption (in g) of a few plant products (Source: Public Health Institute, consumer survey conducted in Belgium in 2004):**

Food	Average	P25	P50	P75	P97,5
Beans	83.4	57	77	103	175
Tomatoes	110.3	88	108	129	178
Bananas	143.9	118	134	160	267
Grapes	144.1	94	129	175	337

As this table shows, some people eat two to three times the average quantities ingested by the population.

There are different types of risks for consumers who ingest the residues of plant protection products used by producers:

- at **high concentrations**, a risk of acute poisoning exists;
- at **weak concentrations**, the risk is 'chronic' in nature (repeated exposure to traces of the product).



When the result of an analysis **exceeds the MRL**, a risk assessment must be conducted to check whether the food represents a risk to consumers' health.<sup>20</sup>

**Failure to conform to the MRL does not systematically result in a risk to consumers' health!**

Toxicological risk for consumers (adults and children) must be evaluated through a **calculation** that provides an estimate of the quantity of pesticide residues present in a food that can be ingested by a consumer **in a meal/day**: this is the **PSTI** or predicted short-term intake.

Calculation of the PSTI, which is fairly complex, is detailed in an annex to this chapter, and an example is given to show that, for the same residue value > MRL, the risk can be different for adults and children.

The PSTI calculated is compared to available toxicological reference data: acute reference dose (ARfD) or acceptable daily intake (ADI).

#### ➤ **Reference values for risk of acute poisoning**

**Acute poisoning** from the presence in food of a plant protection product residue is fairly exceptional since in principle residues are residual traces following a treatment applied several days prior to harvest. It cannot be ruled out, however:

the values of the *GEMS/FOOD Regional Diets*, WHO 2003. This document gives values, for example, for all of Africa, Europe, Latin America and so on.

<sup>20</sup> The analytical uncertainty of the residue value observed should be taken into account to avoid systematically conducting consumer risk assessments for every case of MRL non-conformity. For a result 50 % above the MRL, the only action to be taken should be notification to inform the producer and to request appropriate measures to improve production practices.



- in the case of plant protection products that present a significant risk of acute toxicity (products with a low LD<sub>50</sub> dose,<sup>21</sup> which act on the nervous system and are persistent). These are usually insecticides, acaricides, nematicides, rodenticides, etc. Most products with a high acute toxicity due to their mode of action have nevertheless been taken off the market gradually and replaced by less toxic products.
- in the case of short-cycle crops (e.g.: lettuce, leaf vegetables) for which harvested products are eaten fresh (e.g.: if the ARfD and/or recommended dose are not respected);
- for certain groups of particularly vulnerable consumers (e.g.: infants, children – whose body weight is lower than that of adults, making them more sensitive – and consumers of very large portions).

In this case, the **toxicological reference value is the ARfD (acute reference dose)**, expressed as mg of a.s./kg bw/day). ARfD is defined as the estimate of the amount of substances in food (expressed in body-weight) that can be ingested over a short period of time, usually in one day, without appreciable risk to the consumer on the basis of the data produced by appropriate studies and taking into account sensitive groups within the population (children and the unborn).

#### ➤ **Reference values for risk of chronic poisoning**

**Chronic poisoning** occurs after **prolonged exposure to low and repeated doses**. Certain harmful effects can take weeks or years to be diagnosed and can sometimes prove to be irreversible (e.g.: cancer). The signs of chronic poisoning appear because the poison accumulates in the organism or because the effects caused by repeated exposure accumulate.

For chronic risks, the **reference toxicological value is ADI (acceptable daily intake)**, expressed as mg of a.s./kg bw/day). ADI is defined as the estimate of the amount of substances in food, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk to the consumer on the basis of all known facts at the time of the evaluation, taking into account sensitive groups within the population (children and the unborn).

The toxicological reference values ARfD and ADI are set by international bodies: FAO/WHO committees or the European Food Safety Authority (EFSA) for the European Union.<sup>22</sup>

A toxicological risk to the consumer is considered to exist:

- if the PSTI calculated > ARfD (case where an ARfD value has been set for an active substance);
- if the PSTI calculated > ADI and if the risk is confirmed after consultation with a toxicologist in case where an ARfD has not been set for an active substance).

<sup>21</sup> Lethal dose 50. LD<sub>50</sub> is frequently used to express acute toxicity. The higher this indicator, the lower the product's toxicity.

<sup>22</sup> These values, and MRLs, are available in the European Commission database (*EU Pesticides Database*, DG SANCO) at the following address: [ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN).

## ❑ Acceptable limits

To ensure that residues of plant protection products do not present unacceptable risks to human beings and, where appropriate, to animals, **acceptable limits** for these residues or **MRLs have been set by regulations** for each pesticide and each foodstuff.

They have been set **at the lowest reasonably achievable level compatible with 'Good Agricultural Practice'**, in order to protect vulnerable groups of consumers such as children and the unborn.

MRLs are standards that have the **dual aim** of:

- protecting consumers' health;
- monitoring compliance with recommended Good Agricultural Practice (use of correct dose, respect for ARfD etc.). Non-conformity with these practices can lead to illegal residue levels that make the product non-compliant.

It is **prohibited to place on the market** foodstuffs containing: residues of unauthorized plant protection products (no MRL) or residues at levels above established MRLs.



*MRL values applicable to plant protection products<sup>23</sup> exist for unprocessed and processed food (e.g.: juices, jams, oils, etc.), for straw, fodder and animal feed, and for meat (animals that feed on plants), honey, milk fat, eggs, etc. They take into account the **transfer of residues from plants to animals**.*

For processed food for which no MRL exists, the level of pesticide residues may not exceed the MRL set for the unprocessed basic food, taking concentration or dilution into account. For mixed foods, the residue level may not exceed the maximum level authorized for the individual unprocessed foods contained in the mixture, taking account of their proportion in the mixture.

A number of countries (USA, Russia) and international organizations have set MRL values in line with these principles. The most important for ACP trade are the values set in the *Codex Alimentarius*<sup>24</sup> and the European Union's values.

The MRL value to be taken into consideration is always the value **applied on the market of destination!**

At European level, **MRL values are harmonized** for the 27 Member States under **Regulation (EC) No. 396/2005**. In the interest of free movement of goods, equal terms of competition between EU Member States, and to ensure a high level of consumer

<sup>23</sup> Values also exist for residues of medicinal products in food of animal origin. They are set in Regulation (EC) No. 2377/90.

<sup>24</sup> Available on [www.fao.org/fao-who-codexalimentarius/standards/pestres/en](http://www.fao.org/fao-who-codexalimentarius/standards/pestres/en).

protection, it was essential for MRLs to be established at EU level while taking account of best available agricultural practices.

### 3.3.4. Risks associated with other chemical contaminants

Apart from residues of plant protection products, **many other chemical products** can contaminate food. Some (such as dioxins, PCBs, polycyclic aromatic hydrocarbons or PAH) come from **air pollution**. They are either natural in origin (e.g.: forest fires, volcanic ash) or result from human activity.

Many other contaminants come from cultivation operations, the use of mechanical equipment, materials used for product transport and packaging, etc. These include: fertilizers, antibiotics and growth hormones (in meat and fish), traces of **lubricants**, residues of **cleaning agents** and **residues of biocides** used to disinfect premises and work surfaces, pest control agents (fungicides, rat poison, insecticides), residues of coolants, paints, water and boiler treatment agents, products migrating from packaging, ink etc.

Maximum acceptable levels for certain contaminants are laid down in Regulation (EC) No 1831/2003. These include (inorganic) tin in canned foods, 3-monochloropropane-1,2-diol (3-MCPD, a product that occurs during fermentation), dioxins, PCBs, and polycyclic aromatic hydrocarbons.

Considering the huge variety of chemical agents and the complexity of conceivable contamination pathways, operators must conduct a **precise evaluation of chemical risks** on their farm, considering their production processes, machinery used, technical agents used, etc., to determine the possible origin and probability of contamination, and to take appropriate action as needed to reduce or prevent such risks.

The following are a **few examples** of some of the most frequently observed chemical contaminants and their source of contamination:

- Fruit and vegetables can be exposed to contamination from hydrocarbons, lubricants and different types of oil from the machinery used for cultivation and sorting operations. **Proper maintenance of engines, apparatus and conveying equipment**, together with an appropriate choice of lubricants and oils, make it relatively easy to prevent contamination of fruit and vegetables from hydrocarbons or oils.



- Fruit and vegetables can contain excessive concentrations of **nitrates** (excessive use of nitrate fertilizers or organic fertilizers). Carefully planned management of fertilizers (for example, fractioning of applications) and organic soil conditioners is needed to avoid the presence of residual concentrations of these products or of their by-products in harvests. Maximum levels of nitrates in certain foods (e.g.: spinach, lettuce) are also set in Regulation (EC) No 1831/2003.

- Biocides used to combat pests (insects, rodents) must be authorized for this use (**avoid products intended for agricultural use**). They must never be allowed to come into direct contact with food products. Insecticide treatments must therefore be applied when the packhouse is empty. Bait used to trap rodents must be placed in **closed containers** placed on the ground to avoid all contact.



- **Packaging materials**, such as **ink** used to print information (e.g.: best-by date, lot number), can contaminate the product by 'migrating' (passage of the substance or a fraction of the substance or of a material into the product by permeation through the packaging material). For example, 4-methylbenzophenone from printed cardboard packaging migrated into muesli containing chocolate chips. This substance is a photo-initiator used in UV inks and coatings for package printing. The components of the ink can migrate in various ways through the packaging in the absence of an effective barrier, such as aluminum. In this incident, the 4-methylbenzophenone migrated into the muesli through the external cardboard packaging and plastic packaging (Urgent opinion of the AFSCA, 2009). The nature of the packaging materials that come into contact with food is therefore strictly regulated on the basis of a risk assessment.<sup>25</sup>

- **Cleaning agents** (soaps, detergents) used in a packing station must be **carefully selected**. They leave an invisible 'film' on surfaces that can come into contact with products during sorting and packing. They must be stored in separate premises at the packaging station. Cleaning operations must precede and/or follow sorting and packing operations.



### 3.3.5. Risks from allergens

Most individuals eat a wide variety of foods without running the slightest risk. For a small percentage (around 2%) of the population, however, specific foods or ingredients can cause secondary reactions ranging from a slight redness to a severe allergic response.

An allergen is a substance that **triggers an allergy**, a set of reactions by the organism's immune system on contact, ingestion or even inhalation in the case of a food allergen. The allergen provokes a chain reaction in the immune system that results in the release of antibodies. These antibodies in turn lead to the release of other molecules, such as histamines, which cause a range of symptoms, from a runny nose to coughing, sneezing or itching. In its most serious form, the allergen triggers an extreme reaction (anaphylactic shock, Quincke's edema) which leads to respiratory insufficiency and death. An individual suffering from a recognized food allergy must **avoid consuming foods** containing the substance that can cause more or less serious disorders. The list of the main allergens (recognized by law) can be found in the annex to this chapter.

<sup>25</sup> Regulation (EC) No. 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJEU, L 338/4 of 13 November 2004.

Given the frequency of food allergies and their consequences on health, public authorities have adopted consumer information measures. **Labelling is mandatory** for any product containing allergens and the labels must indicate the presence of any allergens (even if only traces are contained). The ingredient must be shown on the label in the list of ingredients with a clear reference to the name of the allergen. For example, if the recipe for a food product contains **soy lecithin** as an emulsifier, this must be mentioned as such in the list of ingredients: 'emulsifier: soy lecithin', and not as 'emulsifier: lecithin' or 'emulsifier: E322'. **This emulsifier can also be added to waxes used on fruit (apples, citrus fruit etc.)** to disperse them in water. Another example is wine bearing the statement: 'contains sulphites (sulphite concentration > 10 mg/liter).

Labelling rules only concern ingredients **added intentionally by the manufacturer** to the product recipe. The adventitious presence of major allergens (involuntary contamination from contact with other products on the production chain or during storage or transport) is not impossible. The agri-food industry must therefore **evaluate the risks of cross-contamination** and make every effort to reduce them. Labelling of the type 'may contain traces of ...', or 'may contain ...' are a last resort in cases where it is not possible to control the risk of adventitious contamination.



In the sector of fresh (unprocessed) fruit and vegetables the risk of allergen-related poisoning is low, apart from celery (*Apium graveolens* L.) and celery-based products for which there is a proven risk of allergy. Caution is still needed when producing and marketing **novel foods** (fruit or vegetables not widely consumed, new varieties), since some groups of consumers can show unexpected sensitivity to such products.

### 3.3.6. Risks from processing additives and flavorings

To be complete, we will briefly describe the risks stemming from certain processing additives and flavorings. Although use of such compounds (anti-bacterial substances, preservatives, flavorings) is still limited in the fruit and vegetable sector today, their use is on the rise due to **rapidly changing types of presentation and packaging** of plant products (more sophisticated, raw and ready-prepared fruit and vegetable products).



#### ❑ Food additives and processing aids

Food additives and processing aids are substances **added intentionally** to food at the manufacturing, processing, preparation, treatment, packaging, transport or storage stage to meet certain technical functions, for example, to color, sweeten, improve the appearance of or preserve the product.



Food additives are defined in Regulation (EC) No 1333/2008<sup>26</sup> as '*substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose such as the preservation of food*'. Substances not consumed as food but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product, are processing aids.

**Food colorings, preservatives, emulsifiers**, thickeners, stabilizers, gelling agents, flavor enhancers and sweeteners are food additives.

The following are examples:

- antioxidants and preservatives: sodium, potassium and calcium benzoates, benzoic acid and other benzoates. Products used to prevent the oxidation of oils and fats used in pastries, broths, dried fruit, etc. Nitrites and sodium nitrate used mainly to preserve processed meats (all prepared meat products) and in certain cheeses. Sulphites (sulphur dioxide, sodium disulphite, potassium disulphite, sulphur dioxide) found in wine, lychee pulp, cider, beer, molasses, frozen fruit juice etc.;
- artificial sweeteners: acesulfame K (acesulfame potassium), aspartame etc.;
- taste modifiers (monosodium glutamate, used to enhance the taste of Chinese dishes);
- coloring agents: amaranth, erythrosine, cochineal A, tartrazine, chrysoins S etc.;
- emulsifiers (e.g.: lecithins, fatty acids, morpholine<sup>27</sup> etc.) **used to disperse waxes in water** and to facilitate the processing of fruit etc.

Certain additives are **hazardous to health** (in certain conditions benzoate can produce benzene, allergic reactions, hyperactivity in children, endocrine disruption, anemia or cancer) or **can be transformed in the organism** (e.g.: **nitrates** are transformed into nitrites, which form nitrosamines, carcinogenic compounds). They are consequently strictly regulated (prohibition or maximum authorized concentrations). Food additives are only authorized if:

- there is a technological need for their use;
- their use does not mislead consumers;
- they do not pose a safety concern to consumers' health.

The use of food additives must always be shown on the food package label by category (antioxidant, preservative, coloring agent etc.) with their name or 'E number'. Labelling requirements for additives in food and additives sold as such to food producers and consumers are laid down in EU legislation (Directive 2000/13/EC, Regulation (EC) No 50/2000 (Food Labelling) and Directive 89/107/EEC).

<sup>26</sup> Regulation (EC) No. 1333/2008 of 16 December 2008 on food additives *OJEU*, L 354/16 of 31 December 2008.

<sup>27</sup> Morpholine is added to certain waxes used to coat apples. It is usually added to the wax in the form of morpholine oleate. This substance dissolves and spreads the wax, making it possible to apply the coating in liquid form (water-based). When the wax is dried with hot air, the morpholine residues evaporate and only traces remain. Its use is authorised in South Africa, the USA and Canada, but not in the EU.



## ❏ Flavorings

**Flavorings** are substances used to impart taste and/or odor to foods. European legislation defines different types of flavorings, such as natural, nature-identical and artificial flavoring substances, flavoring preparations extracted from vegetable or animal materials, process flavorings that enhance taste after heating and smoke flavorings.

Regulation (EC) No. 1334/2008<sup>28</sup> contains the definition of flavorings, and sets out general rules for their use, labelling requirements and maximum levels for substances that raise concerns for human health. The latter substances occur naturally in the flavoring source materials (herbs, for example) and are therefore also present in the flavoring preparations. It is prohibited to add these substances as such to food. The word 'flavoring' must be shown in the list of ingredients on the packaging of foods containing flavorings.

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<sup>28</sup> Regulation (EC) No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) Nos 2232/96 and (EC) 110/2008 and Directive 2000/13/EC, *OJEU*, L 354/16 of 31 December 2008.



## 3.4. Emerging risks

### 3.4.1. Definition of the concept of emerging risk

According to the definition proposed by the EFSA (2006), *'an emerging risk is a problem that may pose a risk to the food chain in the future'*.

Emerging health risks are related to:

- 1) significant exposure to a **hazard not recognised** previously as relevant in the context of food chain safety;
- 2) **higher exposure to a known hazard** (referred to as a re-emerging risk);
- 3) **increased sensitivity** of the population to a known hazard.

In Europe, the EFSA is obliged by Article 34(1) of Regulation (EC) No. 178/2002<sup>29</sup> to establish monitoring procedures to systematically search for, collect, collate and analyze information and data with a view to the identification of emerging food risks.

Emerging risks projects have been organized<sup>30</sup> and **international networks of experts** and information systems have been set up on this topic<sup>31</sup>. The European Commission's RASFF – Rapid Alert System for Food and Feed – celebrated its 30th anniversary in 2009. Its annual report and the nature of the alert messages issued each year give an overview of the emergence of new forms of risks.



#### ❑ Significant exposure to a hazard not recognized previously

- Progress of science and knowledge:
  - Acrylamide (which forms in fried potatoes and in biscuits during cooking).
  - Benzene (which forms in soft drinks).
  - T2 and HT2 toxins in food and feed.

<sup>29</sup> Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. *OJEU*, L31 of, 1 February 2002.

<sup>30</sup> EMRISK is an EFSA project to develop an emerging risk identification system (ERIS) providing tools for the detection of emerging risks. The project involves assessors from many European countries.

<sup>31</sup> To mention a few: OIE -World Animal Health Information System international, WHO/GOARN - Global Outbreak Alert and Response Network, GPHIN – Global Public Health Intelligence Network, IFSS (Food Surveillance System), USDA/APHIS – Center for Emerging Issues, EPA/ORD Research on environmental futures including emerging pollutants (USA), INFOSAN (WHO, International Food Safety Authorities Network), and of course the European Commission's RASFF – Rapid Alert System for Food and Feed.

- Migration of packaging residues (plastic monomers).
- New production methods:
  - Use of benzoate, which can generate benzene, as a preservative in soft drinks.
  - Microbial decontamination of plant products using chlorine derivatives (hypochlorite).
  - Irradiation of packaging materials by gamma rays.
  - Behavior of packaging materials in microwave ovens.
- Entry into the food chain of industrial chemical products and other substances:
  - Perfluorinated substances (PFOS, PFOA).
  - Polybrominated compounds (PBDE).
  - Organotin compounds.
  - Phthalates (from plastic).
- ❑ **New or higher exposure to a known hazard**
- New exposure to a prohibited compound due to:
  - Fraudulent use (azoic coloring matters in chili powder, nitrofurans and malachite green in aquaculture products, melanin in pet food or milk powder contamination of milk in China).
  - Accidental contamination of products (by pesticides, fertilizers).
  - Environmental contamination (presence of DDT detected in eggs from free-range hens, malachite green in fish, traces of aldrin (insecticide) in farmed salmon etc.).
- Higher exposure to a known hazard due to:
  - Change in dietary habits (toxins and contaminants in food supplements, preparations made from plants and spices etc.).
  - Change in the level of contaminants in specific foods (aflatoxin in Hungarian peppers and Italian maize (polenta) etc.).
- Unexpected exposure to a known danger due to:
  - Contamination during the production process (dioxin in gelatin and fats due to HCl and dioxin contamination of feed through contamination of clays etc.).
  - Cross-contamination (allergens in specific foods, veterinary medicines in feed, etc.).
  - Environmental contamination (heavy metals and dioxins in food due to industrial activity; PCBs, dioxin and other environmental contaminants in eggs, fish etc.).
- Increased sensitivity of the population to a known hazard
  - Allergy to celery, lactose intolerance etc.

In fruit and vegetable production, **emerging chemical risks (pesticides, biocides or mycotoxins not yet regulated)** need to be considered.

In some cases, these are **re-emerging chemical risks**. Problems are seen as re-emerging when the toxin is already known but poses new problems as a result of its detection in new matrices, changes in cultivation practices, climate change, the development of international trade etc.

Kleter *et al.* (2006) also mention **pesticides of natural origin**, which can include plant extracts of microbiological origin (e.g.: viruses, bacteria, antagonistic fungi), as a standard case of 'emerging chemical risk' (ECR).

### 3.4.2. Classification of Emerging Chemical Risks (ECR)

Emerging Chemical Risks can be categorized as follows, for clearer understanding:

- Means of entry into the food chain:
  - Natural toxins (plants, fungi, marine, bacterial etc.).
  - Pesticides, medicines, unauthorized coloring agents and additives.
  - Environmental contaminants (heavy metals, dioxins, PCB, brominated and perfluorinated compounds).
  - Contaminants associated with processing, food preparation, packaging (acrylamide, furans, benzene, semicarbazide etc.).
- Toxicological mode of action:
  - Carcinogens and genotoxic substances (aflatoxins, polycyclic aromatic hydrocarbons, azoic colors, furans, alkyloxy-benzoate compounds, etc.).
  - Endocrine disrupters (medicines with hormonal effects, certain pesticides and environmental contaminants (dioxins), plant micro-constituents (polyphenols) etc.).
  - Allergens.
  - Other (nephrotoxic and hepatotoxic substances, immunosuppressants etc.).
- Type of risk:
  - Acute risk: plant toxins, phycotoxins, allergens (e.g.: marine algae in oysters)
  - Chronic risk: endocrine disrupters, carcinogenic products, bio-accumulating products etc.
- Type of factors that can influence the appearance of ECRs:
 

**Agri-industrial factors:**

  - Changes in processes involved in agricultural production and food processing and preparation. For example:
    - Variety selection (enrichment in potentially toxic substances (e.g.: solanine); problem of GMOs banned in Europe, soy's anti-nutritional factors).
    - Soil amendment and fertilization (sewage sludge, cadmium in phosphate fertilizers etc.).
    - Protection of crops and preserved foods (change in the nature of pesticide residues, botanical impurities, mycotoxins).

- Intensification of aquaculture (risks of accumulation of persistent pollutants, residues of medicinal products, toxins etc.).
- Intensification of fruit cultivation and horticulture in developing countries (e.g.: intensive use of pesticides for export).
- Non-containment of production branches (GMO, organic) and problem of undesirable residues (e.g.: banned GMOs in food and feed; contamination of organic production by residues of synthetic pesticides; contamination of medicinal plants by toxic wild plants).
- Economic constraints (economic pressure) and risks of more intense use of illegal products (pesticides, antibiotics in eggs imported from India, prohibited coloring agents).
- Use of inferior quality processing aids (contaminated clays, mineral acids etc.).
- New contaminants produced during a change of process (drying, heating, frying, autoclaving, etc.) and contact materials (packaging, cling films, ink – ITX, glue etc.)<sup>32</sup>;
- Low-sugar and low-salt products (e.g.: risk of spread of mould in light products).
- New waste streams from the agri-food industry and secondary substitution products (e.g.: rapeseed cake, corn gluten feed resulting from the production of bioethanol or biodiesel).

#### Societal factors:

- Travel and the craze for exotic and natural products (food supplements made from exotic plants, spices, medicinal plants, consumption of products that are less well known from the toxicological standpoint, such as herbal teas, essential oils, salads made up of different kinds of flowers etc.).
- Transcontinental trade (e.g.: greater import of seed contaminated by new microorganisms that produce mycotoxins).
- Consumers' limited perception of real risks (preference for 'natural' foods and medicines without considering possible toxicity and contaminants; preference for food supplements to make up for poor dietary habits with a risk of overdose for certain constituents, vegetarianism etc.).
- Preference for prepared foods (ready-to-eat) with greater risk of problems during processing (cross-contamination, use of inappropriate or secondary ingredients, contamination by products in contact etc.).

#### Geo-climatic factors:

- Introduction of new fungal species as a result of climate change and **greater risk of production of exotic mycotoxins** (e.g.: aflatoxin in Hungarian paprika and Italian maize; OTA (ochratoxin A) in cocoa).
- Increase in periods favorable to the development of cryptogamic fungi (heat and humidity) and increase in contamination of cereal production by mycotoxins (including aflatoxins).
- Introduction of new species of cultivated or wild plants due to climate change, with the risk of new cryptogamic agents (production of mycotoxins) and botanical impurities.

<sup>32</sup> Use of products categorised as non-food-grade chemicals.



The experts and professionals who analyse risks in a given sector (and who sometimes participate in drawing up a 'Sector Self-evaluation Guide') must take into account the possibility that **processes and practices** will evolve, creating new risks or heightening risks previously considered to be minor.

It is therefore **important to organise monitoring** that is both **regulatory** (because acceptable levels can change) and **scientific** (publication of scientific opinions, studies on the product, project reports, etc.).

# Annexes

## A1. Calculating PSTI (Predicted Short Term Intake)

According to DG SANCO 3346 & PSD (Pesticide Safety Directorate), the general formula is as follows:

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

where

- U:* unit (unit weight of the food) in kg  
*OR:* Observed Residue, result of the analysis (in mg/kg)  
*v:* variability factor = 1, 5 or 7 (depending on the weight of U)  
*t:* transformation factor, generally = 1, for lack of data  
*bw:* body weight of the group considered (adult: 76 kg – child: 14.5 kg)  
*LP:* large portion consumption data for the food in question over a one-day period (97.5<sup>th</sup> percentile) expressed in kg. If no data are available, British consumption data (PSD) or GEMS/FOOD 2003 data can be taken into account.

Value of U	Examples	Formula to be used depending on sampling conditions
U < 0.025 kg	Cereals, strawberries Peppers, cherries	$PSTI = \frac{LP * OR * t}{bw}$
U > 0.025 kg & U < LP	Apples, oranges Mangoes Tomatoes	$PSTI = \frac{(U * OR * v) + (LP - U) * OR * t}{bw}$
U > 0.025 kg & U > LP	Watermelons Pineapples Melons	$PSTI = \frac{LP * OR * v * t}{bw}$

### Comments:

The samples analyzed are composite samples. A variation can nevertheless exist in the level of residues among single units of the composite sample. This variability of the residues among single units of the food is taken into account by means of a variability factor that reflects the residue level in the single unit compared with the residue level in the composite sample. This factor depends on the food and its unit weight:

- food with high unit weight (>250 g): v = 5
- food with medium unit weight (between 25 g and 250 g): v = 7
- food with low unit weight (≤ 25 g): v = 1

**Processing factors  $p$**  are sometimes set for certain operations (washing, peeling, cooking, etc.). This factor is applied case by case in terms of the pesticide and the matrix and its processing (food eaten raw or cooked, peeled or not, etc.). The default figure is 1, but this factor can be higher or lower than this value (e.g.: for dried fruit or tomato paste, the value of  $p > 1$ ).

**The following example illustrates how the PSTI is calculated and its usefulness.**



*In November 2007, the following notice was published further to the results of an analysis carried out in an accredited monitoring laboratory:*

*NOTICE (published on the AFSCA (food safety authority) site, Belgium).  
Recall of tomatoes produced by Haesen. 20/11/2007.*

*As a precautionary measure, the tomato producer Rudy Haesen, based in Rummen, asks consumers not to use the following product: 612 kg of tomatoes packaged in bulk in 102 cases weighing 6 kg each, bearing the lot number (producer number) 10398 and registration number 34.884.*

*This lot of tomatoes was placed on the market during the period from 05/11/2007 to 12/11/2007 inclusive. The retailers concerned have been informed and asked to display this notice prominently in their sales area. A laboratory analysis revealed that this product contains an excessive level of residues of ethephon, a product that fosters ripening. Consumption of these tomatoes is not recommended.*

*The risk analysis gives the following results:*

- *The tomatoes contain an average concentration of 3.5 mg/kg. The use of ethephon on tomatoes is authorized and the MRL is 1 mg/kg. The producer failed to follow the PHI, which explains the non-conformity with the MRL.*
- *The EFSA has set an ARfD value for ethephon at 0.05 mg/kg bw/day.*
- *The average weight of a tomato is 85 g. The 97.5th percentile consumption is 283 g. The processing factor is 1 because the food may be eaten as such.*

*Does this residue present a risk for adult consumers?*

*The PSTI can be calculated as follows (for adults):*

$$PSTI = \frac{(0,085 * 3,5 * 7) + (0,2830 - 0,085) * 3,5 * 1}{76} = 0.0365 \text{ mg/kg bw/day}$$

*The PSTI calculated therefore represents 73 % of the ARfD.*

**Conclusion:** *there is no risk for adult consumers. However, for a young child with a body mass of 14.6 kg, the PSTI represents 380 % of the ARfD! So there is a real risk for the group of young children.*

## A2. List of allergens and allergenic substances

The list of allergens is revised periodically in terms of scientific assessments. The list includes the following (source: DGCCRF, Directorate-General for Competition, Consumption and Fraud Repression, France - 2010):

- Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut and their hybrid strains) and cereals-based products, apart from:
  - glucose syrups produced from wheat, including dextrose;
  - maltodextrine produced from wheat;
  - glucose syrups produced from barley;
  - cereals used to produce distillate or ethyl alcohol of agricultural origin for spirits and other alcoholic beverages.
- Crustaceans and crustacean-based products.
- Eggs and egg-based products.
- Fish and fish-based products, except for fish gelatin used as a base for preparations of vitamins, and carotenoids or isinglass used as a clarifying agent in beer and wine.
- Groundnuts and groundnut-based products.
- Soy and soy-based products, except for:
  - fully refined soy oil and fat;
  - natural mixed tocopherols;
  - phytosterols and phytosterol ester derived from soy vegetable oils;
  - phytanol ester produced from sterols derived from soy vegetable oils.
- Milk and milk products (including lactose), except for:
  - whey used to produce distillate or ethyl alcohol of agricultural origin for spirits and other alcoholic beverages;
  - lactitol.
- Nuts (almonds, hazelnuts, walnuts, cashews, pecans, macadamia nuts, Brazil nuts, Queensland nuts, pistachios and products made from these nuts), except for nuts used to produce distillate or ethyl alcohol of agricultural origin for spirits and other alcoholic beverages.
- Celery and celery-based products.
- Mustard and mustard-based products.
- Sesame seeds and sesame seed-based products.
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/l (expressed as SO<sub>2</sub>).
- Lupin and lupin-based products.
- Molluscs and mollusc-based products.

Certain ingredients and substances have been given a temporary exemption pending the results of scientific assessments. The allergenicity of the following nine substances and ingredients has been confirmed:

- lysozyme (produced from eggs) used in wine;
- albumin (produced from eggs) used as a clarifying agent in wine and cider;
- fish gelatin used as a flavor carrier;
- milk-based products used as clarifying agents in wine and beer;
- essential oil of celery leaves and seeds;

- celery seed oleoresin;
- mustard essential oil;
- mustard seed essential oil;
- mustard seed oleoresin.

These nine substances must therefore be mentioned on food labels.



# Chapter 4

## Handling and preservation of fruit and vegetables

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## 4.1. Importance of different factors for handling and preservation of fruit and vegetables

### 4.1.1. Objectives of handling and preservation operations

After harvest, the product's properties need to be preserved (cleanliness, appearance, freshness, absence of spots, unit weight, shine, skin color etc.) up until the time of consumption.

For regulatory and economic reasons:

1. **Products need to be protected during post-harvest operations:** packaging, consignment and distribution. The aim is to prevent the development of organisms that could pose a threat to consumers' health or alter the commercial quality of products. This constraint is imposed on all products and is key for being competitive in markets and conforming to food safety requirements.
2. **Products need to be stored to improve commercial management.** Storing fruit and vegetables is meant to help ensure supplies for consumers living far from production areas (export market). Products (e.g.: potatoes for human consumption) are also stored sometimes to **stagger the product's availability** to markets and thus to **support prices**.<sup>1</sup>

Products have to be distributed to consumption areas both during and outside of traditional harvest periods. Given the difficulty of controlling this flow of products, the use of intermediate storage is an extremely valuable tool.

This possibility is obviously **highly variable** depending on the fruit or vegetable. The **keeping quality** of each product results from a combination of two of its characteristics:

- natural preservation, which corresponds to the longevity after harvest of the vegetable's life;
- the effectiveness of appropriate techniques that can be used to slow down or prevent product deterioration.

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<sup>1</sup> For example, for the cultivation of potatoes from seedlings imported from Sahel, all production areas plant between 15 November and the end of December. The large majority of harvests therefore take place between 15 February and the end of March. Based on average yield of 22 tons/hectare, huge quantities are placed on the market, which brings down prices in the main production areas (Sikasso, Fouta Djallon etc.). By storing potatoes, market supply can be regulated and prices stabilized.

### 4.1.2. General principles

#### ❑ Product spoilage

Food spoilage or rotting is understood to mean any change that causes the food to lose its desired quality and to make it unfit for consumption.

As soon as fruit and vegetables are separated from their natural source of nutritive substances, their quality starts to deteriorate. This is due to a natural process that begins when the biological cycle is interrupted by harvesting. The product is then consumable for only a limited time ranging from a few days to a few weeks, after which it starts to spoil or rot.

In spite of 'ideal' (or recognized as such) conditions for preserving fruit and vegetables, **it is impossible to avoid the ultimate perishability and limited shelf life** of fresh produce.

The following table sums up the risk of loss for certain products (*Source: FAO, based on Kader, A.A. (1993) – see in the annex below the detailed table presenting the shelf life of many products under ideal conditions*):

Relative risk of loss	Potential shelf life	Products
Very high	Less than 2 weeks	Apricot, cherry, mushrooms, spinach, fig, lettuce, green onion, ripe tomatoes
High	2 to 4 weeks	Eggplant, banana, green beans, mango, melon, nectarine, peach, sweet pepper
Moderate	4 to 8 weeks	Carrot, pomegranate, orange, grapefruit, grape
Low	8 to 16 weeks	Garlic, lemon, dry onion, pumpkin
Very low	More than 16 weeks	Seed-fruit, dry fruit and vegetables

There are **several types of deterioration**, which are reviewed below:

1. physical deterioration;
2. physiological ageing;
3. chemical and enzymatic deterioration;
4. deterioration caused by insects, rodents and pathogens;
5. mechanical damage;
6. deterioration caused by spoilage microbes.

#### ❑ Physical, physiological, chemical and enzymatic deterioration

Physical deterioration is caused first and foremost by **dehydration**. **Physiological ageing** occurs as soon as the biological cycle is interrupted by the harvest. The physiological functions of the organ still on the plant do not stop at harvest but are considerably altered.

**Chemical and enzymatic deterioration** occur mainly when the fruit and vegetables are damaged upon falling or breaking, or **due to cold**. This releases enzymes that trigger chemical reactions. Tomatoes soften, for example, and other types of fruit turn brown.



*Banana cells have no defense against cold. When the fruit is kept at excessively low temperatures, the cells burst and release enzymes that cause the fruit to turn brown and soften very quickly.*  
(Don Glass, 2008 – Moment of science).



Lychee fruit left at ambient temperature deteriorates very quickly.

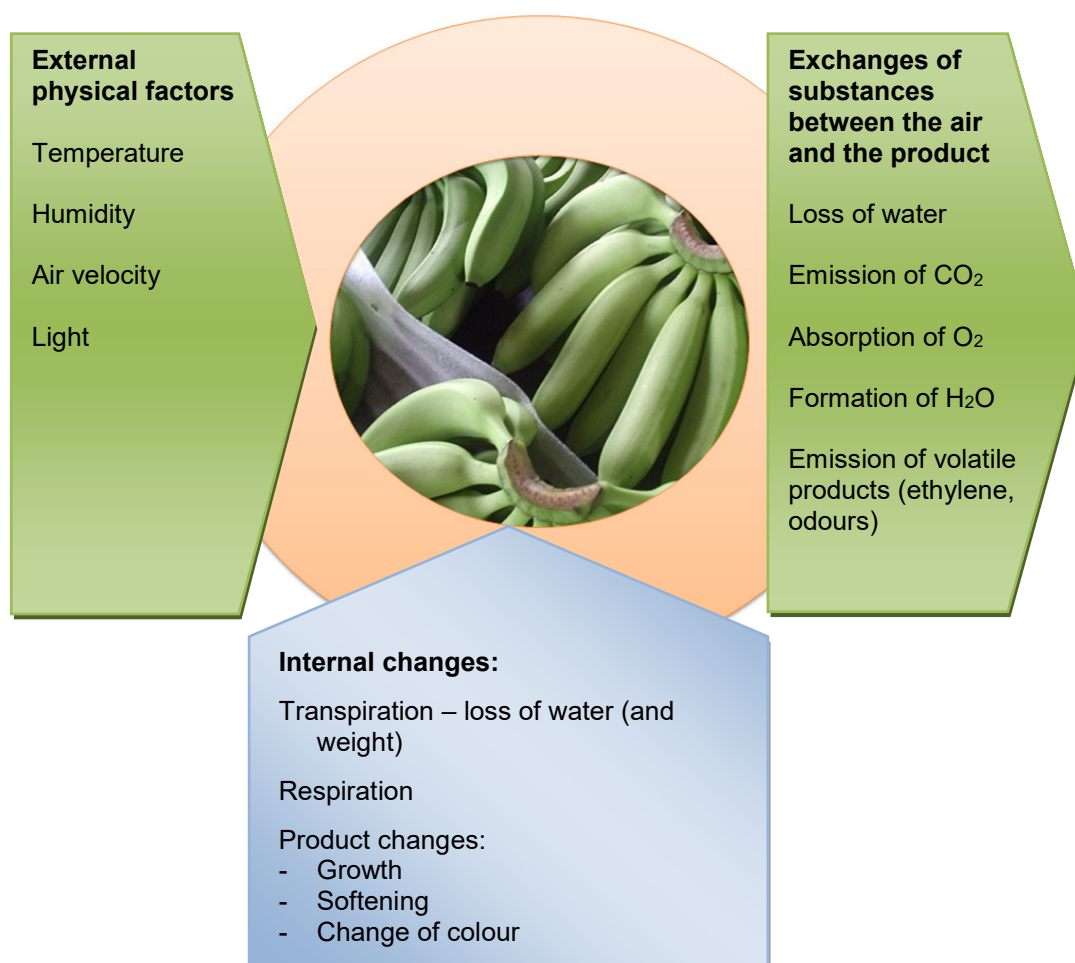
In two or three days, the shell turns brown and then dries out and becomes brittle. The loss of color is caused by the oxidation of anthocyanic pigments. The fruit is then more likely to burst and becomes susceptible to secondary contamination from fungi.

*Currently, sulphur treatment is the only product available, at an acceptable cost, that helps to preserve the color of lychee shells during a storage period of 30 days or more (which makes export possible). Sulphur dioxide keeps the pericarp from turning brown by acting on the shell pigments and preventing enzymatic reactions. The sulphuring of fruit presents many disadvantages, however: residues, exposure of workers and so on.*

Fruit can also go rancid.<sup>2</sup> **Insects** trigger the same process: they damage fruit and vegetables, which leads to the release of enzymes.

These processes are inevitable but can be delayed by storing agricultural products **in a dry area protected from draughts, at the lowest temperature possible**, and protecting them from pests before, during and after harvest.

The most important functions of the vegetable organs during this period are **transpiration, respiration** and **metabolism** of the plant tissues. The storage parameters (temperature, atmosphere, treatment and various types of protection) are chosen to act on these functions to obtain optimal stabilization.



<sup>2</sup> 'Rancidity' is due to the alteration of fatty substances leading to an unpleasant change in their smell and taste (unpleasant taste upon consumption). It mainly concerns dry fruit and nuts (e.g.: cashews) rich in fats.

### ➤ Transpiration

Transpiration is a **loss of water through evaporation**. It depends:

- on the one hand, on the organ's morphological characteristics, in particular the structure of the epidermis and of the surface in contact with the air;
- on the other, on the **difference in temperature** between the air and the product, **humidity** and **whether the ambient air is still or in motion**.

These **water losses add up** throughout the storage period and are responsible for a significant deterioration in quality: wilting, softening, alteration of appearance, etc. So it is very important to take this into account.

*% of water loss resulting in a harmful change of appearance (Source: Centre Technique Interprofessionnel des Fruits et Légumes (Fruit and Vegetable Inter-branch Technical Centre), France):*

Leaf vegetables, asparagus	3 to 4%
Fruit, fruiting vegetables	5 to 6%
Root vegetables	7%



*Comparison between green beans kept cool (left) and green beans left exposed to heat during harvest (right). There is a pronounced difference in appearance and color between the two boxes. The product on the right is no longer marketable (Photo B. Samb).*

### ➤ Respiration

Respiration is a cycle of complex biochemical reactions that is manifested principally in a loss of substrate (sugars, acids) burned to supply energy to the tissues. It absorbs oxygen, emits carbon dioxide and releases heat that must be removed through cooling:



**When respiration is reduced, shelf life is extended.**



The exploitation of these biochemical phenomena in holding rooms is the basis of **controlled atmospheres**. This technique was originally developed to extend the shelf life of a number of fruit and vegetables.

**Respiration is reduced by lowering the concentration of oxygen in the ambient air** and by increasing carbon dioxide concentration. Between 0 and 30°C, the respiration rate increases exponentially. However, even at 0°C, vegetable respiration continues.

**Level of respiration of various products:**

Very low	Dates, dry fruit, cashews
Low	Citrus fruit, garlic, grapes, kiwis, onions, potatoes, sweet potatoes
Moderate	Bananas, cabbage, carrots, lettuce, mangoes, tomatoes
High	Avocadoes, cauliflower, green beans, strawberries
Very high	Brussels sprouts, green onions, certain beans
Extremely high	Asparagus, broccoli, mushrooms, peas, spinach, sweet corn

➤ **Product changes**

The metabolism of plant tissues is a set of chemical reactions that characterize a living organism, which are the source of the changes observed during the plant's life and that continue after harvest.

The '**maturation**' of fruit and vegetables results from a complex set of reactions and biochemical and physiological changes that accelerate their development. It leads to the state of full maturity and gives the fruit its organoleptic characteristics.

**Maturation improves quality (especially texture and taste) but reduces storage time!**



Maturation can be controlled by environmental factors.

Temperature, oxygen, carbon dioxide (CO<sub>2</sub>) and ethylene are factors that influence the fruit ripening process.

*Maturation is accelerated by the ethylene content of the air. This gas is emitted by the fruit and vegetables themselves.*



#### ❑ Deterioration due to insects, rodents and pathogens

**Insects and rodents** cause a great deal of damage, not only by eating away at produce, but also by transmitting micro-organisms found on their hairs or in their excrement. The damaged parts of plants are particularly sensitive to infections from bacteria or mould.

Certain plant pathogens (diseases) can cause post-harvest alteration. The skin of the fruit or vegetable usually provides natural protection against micro-organisms, but **once damaged** after being dropped or receiving a shock, the risk of deterioration increases considerably. Shocks are produced most often when fruit and vegetables are harvested without care and stacked up in piles. The appearance of rot is associated with the production of enzymes that damage the cell walls. As fruit ripens, it becomes more sensitive to shocks and infections, causing spoilage, on the one hand because its production of antifungal components declines and on the other because of damage to cell walls.

#### ❑ Deterioration due to production, harvest, transport and storage conditions

Cultivation conditions are key in terms of the microbial flora present upon harvest of the product. Exposed surfaces are contaminated by soil, water, air, waste water, animals, insects, and then by contact with harvesting equipment. Pre-harvest fungal colonization is usually the main cause of post-harvest rot.

Certain fungi can penetrate the intact cuticle of leaves, stems and fruit. Other harmful organisms penetrate the fruit through mechanically caused injuries that occur during harvest, handling and packing or through natural openings in the cuticle, and attack the internal tissues.

Post-harvest changes can take the following forms: rot due to brown, blue, pink or grey moulds; superficial growth of moulds; tissue blackening (anthracnose); sour rot; stem end rot, rot due to yeasts and other forms of rot. Spoilage is also favored by high temperatures and high humidity after harvest.

Poor harvest and handling conditions result in product spoilage. **Harvest and transport conditions should therefore be such as to avoid accelerating the deterioration of products.** Fruit and vegetables must be handled **very gently** to avoid causing injuries that can contribute to physiological damage or the penetration of pathogens or moulds.

It is important to start with quality products for packing and preservation. The fruit or vegetable lot cannot contain damaged or diseased products. It is preferable to **sort products** as soon as they are harvested (preferably in a shady area) and before storage, to keep from introducing rotten or parasite-infested products into the storage station.

If possible, fruit and vegetable collection, transport and storage should take place at a low temperature (e.g.: for **green beans, tomatoes**, etc.). These products must be **placed in the shade** as quickly as possible.



*Providing a shady spot for the harvested products cannot be improvised and does not override the need to comply with minimum hygiene standards, such as keeping products off the ground.*



*Well ventilated sheds that can be built at the place of harvest, using light materials, so that harvested products can be brought into the shade quickly and thus retain their freshness, are valuable assets for quality.*

*Sheds offer shade and limit water loss from products. To be effective, they must be placed as close as possible to fields being harvested.*





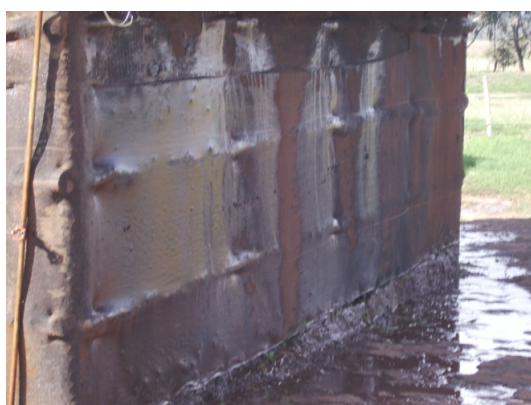
*Products should not remain in sheds for long periods. However, workers can perform an initial sorting of the harvest in such sheds, taking only those that can be validly processed to the packing station.*

*Sorting and weighing operations must be performed quickly and in a shaded area from beginning to end. It is important to observe minimum hygiene conditions during this initial sorting.*



*When the packing station is located at a distance from the production and harvest area, it is possible to keep the products in cool storage by building 'cold chambers' out of light materials. Products can then be stored for several hours before transport.*

*This small 'storehouse' has double walls made of two rows of wire-mesh between which charcoal is stacked. The wire-mesh and the charcoal must let air pass freely. The charcoal is watered abundantly and regularly to keep it saturated. The warm air goes through the walls. As the water that trickles down the walls evaporates, the temperature drops in the shed (evaporation removes heat from the water).*







*This system requires availability of water at the site, but it does not use electricity.*

*The roof is made of straw rather than sheet metal, which is much more resistant to bad weather but offers much less insulation than straw. The straw should be kept dry to keep it from rotting.*

*(Photos B. Schiffrers)*

The **means of transport**, condition of transport material, loading method and transport and storage practices play a role in successful product conservation. The '**containers**' (bins, crates, etc.) used are also important factors. If the recommended temperature and relative humidity are not maintained, product quality will decline. The 'cold chain' must be maintained during transport of products between processing and storage areas.



*Like cold chambers, refrigerated vehicles must also be fitted with **(calibrated) temperature regulation and control systems**.*

*During loading, products should be stacked carefully to avoid crushing and to ensure **good circulation of the chilled air** (the loading capacity should not be entirely used).*

### 4.1.3. Storage conditions

#### ❑ Importance of temperature and humidity on deterioration

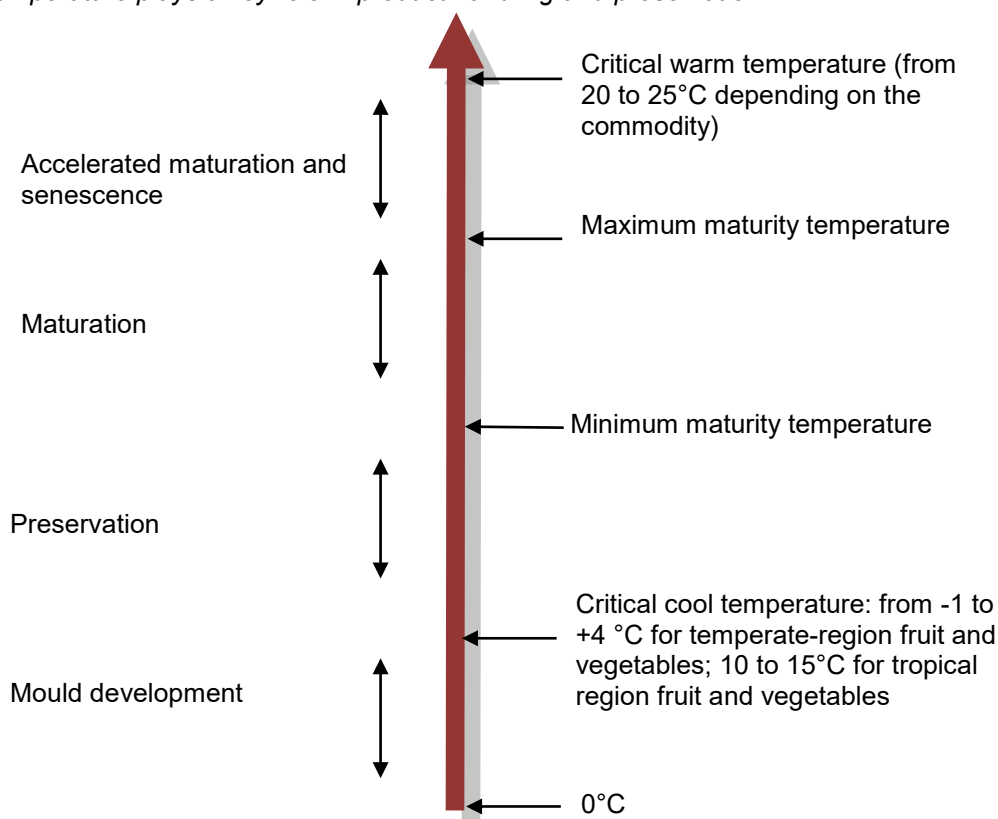
**Storage conditions** during harvest, transport and storage have a significant impact on the quality of foods brought to market.

Harvest, transport and storage installations must be designed to ensure maintenance of the cold chain and to **prevent damage** resulting from:

- the heat of outside air;
- heat released from product respiration;
- the accumulation of ethylene due to product maturation;
- the loss of heat in very cold temperatures;
- excess cold due to the functioning of the refrigerating installation.

It is important for the stability of physiological and organoleptic properties **to know the optimal temperature and humidity conditions for each product**.

*Temperature plays a key role in product handling and preservation:*



Optimal control of temperature and relative humidity is therefore essential. However, while very high humidity (sometimes over 95 %) has to be maintained, **the 'dew point'**<sup>3</sup> **must not be reached**, because this could result in **condensation and dampen** the stored products, creating conditions for infections to develop. Sophisticated storage installations, which ensure precise temperature and humidity control, significantly increase the shelf life of fruit and vegetables.

Most vegetables should ideally be stored at a temperature of 0°C.

**The lower the temperatures, the longer the vegetables can be stored.** Low temperatures slow down the metabolic activity of vegetables. An increase in temperature also affects **products' nutritional value**. Vitamins, for instance, are not resistant to high temperatures.

Most vegetables have a **high transpiration rate**. Plant cells are relatively impermeable but always let a certain amount of water escape **in the form of vapor**. **If the air is dry, vegetables can lose water quickly, soften, shrivel and become unmarketable.** Maintaining a high relative humidity during storage helps to keep transpiration to a minimum.

<sup>3</sup> When humid air cools, the *dew point temperature* corresponds to the appearance of water in a liquid phase. When the dew point is reached, water in the air condenses: drops form and settle on surfaces, which appear to be wet. The dew point can be measured with a condensing hygrometer (dew-point hygrometer).

Storage at close to 100% humidity nevertheless requires **perfect temperature uniformity** inside the warehouse. If colder areas exist, water will condense and settle on vegetables, contributing to the development of diseases.

**Example of optimal storage conditions:**

For optimal preservation of green beans:

- Maintain a temperature of between 5.0 and 7.5 °C.
- Ensure the highest possible rate of humidity (at least 95 % relative humidity within the building).
- Store the green beans in the dark, protected from moulds and attack by insects and/or rodents.

The closer the storage conditions can be kept to these optimal values, the better/longer the preservation.

**❑ Importance of ventilation**

Ventilation plays a major role because it helps to ensure uniform temperature and same relative humidity inside the warehouse. As stored volume increases, ventilation becomes more essential. **Air must circulate** not only around but also within the stacks of vegetables, whether they are stored in bulk or in boxes.

Good ventilation is needed throughout the storage period, both at the start when the temperature of the harvested products is lowered, and subsequently when the temperature has been stabilized. It should be kept in mind that, even at a low temperature, vegetables continue the respiration process and produce heat. This heat has to be removed. Proper circulation of air is also essential in conditions of high relative humidity to **avoid condensation problems**.

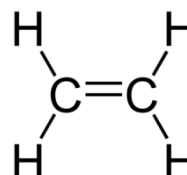
**❑ Physiological compatibility of stored products**

Products stored together must be able to tolerate the same temperature, same relative humidity and the **same level of ethylene in the storage environment**.

Products that emit a lot of ethylene (such as ripe bananas, apples and cantaloupes) **can stimulate physiological changes** in products that are sensitive to ethylene (such as lettuce, cucumbers, carrots, potatoes and sweet potatoes) and cause undesirable changes in color, taste and texture (see in an annex to this chapter the '*Compatibility groups for storage of fruit and vegetables*').



***What role does ethylene play in the maturation and conservation of fruit and vegetables?***



Ethylene ( $\text{CH}_2 = \text{CH}_2$ ) affects virtually every aspect of plant growth and development.



*Maturation and alteration in tomatoes, three weeks after the start of ripening. Left, ethylene inhibition – Right, absence of inhibition*



*Without ethylene*

*With ethylene*

Ethylene stimulates the lengthening of plant stems, leafstalks, roots and flower structures. As a general rule, ethylene delays or prevents flowering. For pineapple, however, it stimulates flowering. Producers therefore apply a treatment using products that produce ethylene for a uniform flowering of pineapples in fields.

A direct proportional relationship has been established between the rate of inhibition of ethylene production and the length of delayed fruit maturation. To avoid overly rapid maturation and withering of fruit during storage and/or transport, **it is vital to avoid an accumulation of this gas in cold storage rooms or containers!**

#### 4.1.4. Conditions for alteration by micro-organisms

##### ❑ Conditions that contribute to the development of micro-organisms

There are three types of micro-organisms **that cause products to spoil: bacteria, moulds and yeast.**

- **Bacteria:** bacteria develop on almost all types of fresh food that are not too acid: meat, fish, milk and vegetables.<sup>4</sup>
- **Moulds:** moulds are often quite visible because they form fine filaments or a solid mass that can be easily distinguished. **They cause a pronounced change in the taste of products.** Moulds develop best at low temperatures and in an acid environment.

<sup>4</sup> Sometimes the negative effects of bacteria are very clear (e.g.: sticky meat, formation of gas, rotten smell). However, food deterioration is not always obvious and the presence of certain bacteria does not necessarily result in a change in taste or appearance. Spoiled food should never be eaten in any case because there is always a risk of contamination or food poisoning (toxic waste secreted by bacteria).



*Certain moulds produce toxic substances (mycotoxins), especially in damp grains such as groundnuts, maize and soy, or on vegetables.*

➤ **Yeast:** yeast also causes food to spoil. It prefers low temperatures and acid products.

Development of these micro-organisms requires certain conditions. They cannot survive without the following elements:

1. **water** in sufficient amounts (this point will be developed below);
2. **oxygen** (except for certain 'anaerobic' micro-organisms that develop without oxygen, such as bacteria of the *Clostridium* genus);
3. an appropriate **acidity** (pH: the higher a product's acidity, the lower its pH);
4. **nutritive substances** (e.g.: sugars, proteins, fats, minerals and vitamins): micro-organisms need but rarely lack nutritive substances since they are found in all foods;
5. an appropriate **temperature**. On average, the temperature should lie between 5 and 65 °C for micro-organisms to develop (the number of bacteria in a foodstuff can double every 15 to 20 minutes in temperature and humidity conditions close to those of the ambient air).

As we can see, there is a **connection between a product's characteristics and possible contamination by these micro-organisms**. For instance, micro-organisms cannot develop when there is very little, or no, water (this is the case for dried fruit and vegetables). Another example: the slightly higher acidity of damaged fruit contributes to the development of yeast and mould.

Most micro-organisms need oxygen. In the absence of sufficient oxygen, it is difficult for them to survive and even more difficult to reproduce. There are always a few that manage to survive, however, and as soon as the oxygen level increases, they start developing and reproducing again. Some types of micro-organisms proliferate even in an oxygen-poor environment.

#### ❑ **Influence of cold on the development of micro-organisms**

The development of micro-organisms is also significantly **slowed at temperatures of 0 to 5°C** (in a cold chamber, for example), making it possible to store food for several days. *Listeria*, the bacteria that cause listeriosis (a serious illness), multiply at temperatures of 3 to 8°C, resulting in problems for prolonged food storage.

**A contaminated product does not improve simply because it is refrigerated.**

At a temperature below 0 °C, **microbial development stops completely, but micro-organisms are still alive.**

**They resume their activity once the temperature goes back above 0 °C.**

Micro-organism multiplication is merely slowed or halted by cold. Therefore, a cold storage room must:

- be washed and disinfected regularly because a product carrying bacteria can contaminate the entire installation;
- not be filled too completely, to allow circulation of the chilled air;
- allow for a separation of products to avoid cross-contamination;
- be checked regularly to ensure that the internal temperature corresponds to product preservation recommendations;
- allow for each product to be stored at its ideal storage temperature.

As a general rule, fruit and vegetables must always be stored at cool temperatures (observing the temperatures recommended on the label or packaging).<sup>5</sup>

#### ❑ Influence of high temperatures on the development of micro-organisms

One of the most widely used and most effective methods of preserving fruit and vegetables is to prepare them and place them in airtight containers that are then heated. Under the effect of the heat, the micro-organisms are gradually eliminated, but **not all at the same time!**

A high temperature kills micro-organisms and neutralizes enzymes. At a temperature above 65 °C, most micro-organisms have difficulty surviving. *Salmonella*, a major cause of food poisoning, is destroyed at a temperature of 65 °C maintained for 15 minutes or at 80 °C for 10 minutes. Any remaining spores cannot develop into bacteria and the food will be protected from all external microbial contamination. Certain micro-organisms, however, are unfortunately more heat-resistant: *Clostridium* and *Staphylococcus* can continue to multiply and damage food by producing toxic substances. *Clostridium* sometimes causes botulism and can be fatal. This bacterium has a harder time developing in acid products like fruit (pH < 4.5).

It is thus hard to achieve absolute safety, but lengthening heating time and increasing temperature help bring us closer to the goal. Techniques used to eliminate infectious organisms through heating include **pasteurization** and **sterilization**:

- Micro-organisms **die at boiling temperature** provided it is maintained long enough, namely around 10 minutes. If the temperature remains below 100°C, it has to be maintained longer to bring about a significant reduction in the number of micro-organisms present (e.g.: '**pasteurization**'<sup>6</sup> process).

<sup>5</sup> A food must never be refrozen. Any food, even a vegetable, that has been thawed and then refrozen should never be eaten (freezing temperature is -18 °C).

<sup>6</sup> Pasteurization is a gentle treatment that only slightly alters the taste and nutritive value of food. It neutralizes enzymes and destroys most but not all bacteria, which is why pasteurized

- Certain bacteria (*Bacillus* and *Clostridium* genera) produce a type of 'seed' known as a **spore, which survives at a temperature of 100 °C, even after the death of the bacteria**. As soon as the temperature drops, new bacteria are formed from the spores. **To eliminate spores, they must be exposed to a temperature of at least 121 °C**: this process is known as '**sterilization**'.

#### ❑ Influence of the substratum on the development of micro-organisms

As a rule, the type of product stored does not have a significant impact on the capacity of micro-organisms to colonize the substratum (because they find the elements they need in sufficient quantities).



In the case of fruit and vegetables, however, there can be host **specificity for parasite species**: *Penicillium expansum* on apple (and other pome fruit species), *Penicillium digitatum* on lemon, *Phytophthora infestans* on potato, *Trachysphaera fructigena* on banana (photo), etc.

Fruit has natural defense mechanisms: a thick skin and natural antimicrobial substances (essential oils, anthocyanins, benzoic acid, benzaldehyde, etc.) and/or organic acids (such as malic, tartaric and citric acids) that contribute to the acidity of fruit and vegetables by maintaining pH at < 4.6. Some types of fruit, however, including bananas, melons, figs and papaya, have a high pH. A low pH and the nature of the organic acid in itself determine the development of certain micro-organisms that tolerate acidity (essentially moulds).

#### ❑ Influence of concentrations of oxygen and carbon dioxide on the development of micro-organisms

Moulds are **aerobic organisms**: they need oxygen to develop. However, a number of moulds tolerate low concentrations of oxygen and/or high concentrations of carbon dioxide to different extents. The association of these two factors that tend to restrict gaseous composition in O<sub>2</sub> and to increase the concentration of CO<sub>2</sub> can have a restricting and selective effect on the development of mycotoxins.

A few species **tolerate the total absence of oxygen**. Examples include the mould *Byssoschlamys nivea*, whose sporulating lesions are relatively resistant to the thermal shock of pasteurization (leading to real risks for the preservation of fruit juices), and

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products spoil more quickly than sterilized products. To prevent spore-producing micro-organisms from multiplying, products must be stored at temperatures below 20 °C. Often a large amount of sugar is added to extend the shelf life of fruit. They can then be consumed for months. The greater the amount of acid or sugar in a pasteurized product, the longer its shelf life, because the remaining micro-organisms will not be able to develop. Fruit juices must be pasteurized at temperatures of 60 to 95 °C.

bacteria of the *Clostridium* (risk of botulism in case of contamination by *C. botulinum*) genus.

#### 4.1.5. Importance of water for product preservation

Vegetables, and fruit even more so, generally have high water content (up to 85 or even 90% water). This 'moisture' encourages the development of moulds. Their spores can germinate from a given degree of relative humidity of the ambient air resulting from evaporation of water from stored products. The mycelium then has to find 'available water' to continue its growth.

Water in a product is **more or less available**, and specialists use terms such as 'free water' and 'bound water' to express this concept. The use of drying processes is determined by these different types of water.

##### ☐ Free water

Free water is found in the product but is not bound to the components of the fruit/vegetable (sugars, proteins and vitamins). This water behaves like pure water and consequently **evaporates easily**. This water makes the product highly perishable because it is **accessible to micro-organisms** and it contributes to the biochemical and physico-chemical reactions that are the source of physiological ageing.

##### ☐ Bound water

Unlike free water, bound water is relatively fixed to product components through adsorption. It therefore **does not evaporate as readily**. It is also **less accessible to micro-organisms** and to biochemical and physico-chemical reactions.

##### ☐ Water activity ( $A_w$ )

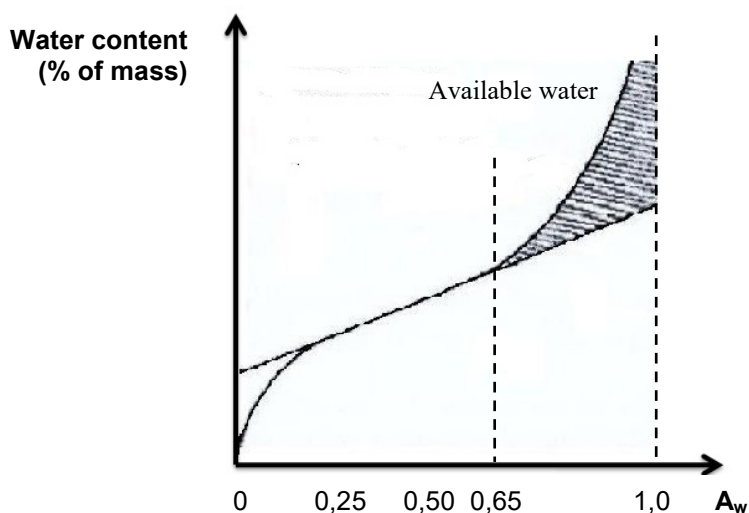
The availability of water therefore varies in terms of the water content (%) of fruit and vegetables and their biochemical composition. It is quantified in terms of so-called '*water activity*', abbreviated as  $A_w$ .

In very hydrated foods, such as fruit and most fresh vegetables, a very large part of water is in the form of free water (at surface level or in pockets), and another part is weakly absorbed, retained by capillary action in the fruit tissues.

'Available water' is measured by establishing a **sorption curve** for the product in question: this curve describes the relation between water activity ( $A_w$ ) and the product's water content.



Example of sorption curve for a given product:



Water activity is defined in relation to a reference state, which is that of **pure water, for which water activity is equal to 1**. It corresponds to the ratio of vapor pressure of the food compared to vapor pressure of pure water at the same temperature. The value of **Aw ranges from 0** (dry product in which all water is bound to the food and thus lacks reaction qualities) to **1** (all the water is free).

<b><math>A_w &lt; 0.25</math></b>	Tightly bound water, also called 'constitution' water. This water is practically not available as a solvent or reagent. It corresponds to a mono-molecular layer of water on the dry material.
<b><math>0.25 &lt; A_w &lt; 0.65</math></b>	Loosely bound water, but not very available.
<b><math>A_w &gt; 0.65</math></b>	Corresponds to 'free' water or 'liquid water'. It is held only weakly on the surface of the dry substratum and is available as a solvent or reactant. This is the only form in which can water be used by micro-organisms and can allow enzymatic reactions.

It has been observed that the behavior of fungi that infest food and can produce mycotoxins varies depending on water availability: some species have a preference for very moist environments (e.g.: *Aspergillus restrictus*), others prefer water but not to excess (e.g.: *Aspergillus flavus*, *A. nidulans* etc.) and still others prefer a barely moist or even dry medium (e.g.: *Fusarium* spp., *Mucorales*, etc.).

**At an  $A_w$  value of  $< 0.60 - 0.65$ , moulds no longer develop!**

Every type of food has its own sorption curve, which explains why there are **different water content levels corresponding to maximum  $A_w$  (0.65) required for proper preservation**: for example, water content for proper preservation is around 14 g of water for 100 g of dried mango.

#### 4.1.6. Other factors to be considered

Several other factors have to be taken into consideration in connection with product shelf life.

A food's keeping quality also depends on:

- **appropriate agronomy**, and in particular irrigation and fertilization arrangements, which play a role in maturity and physiological state at harvest;
- the **variety of the produce**: there are large differences in the shelf life of certain varieties of vegetables (ex.: onions). Shelf life is often tied to the cultivar used and long-term keeping quality for some species can vary widely from one cultivar to the next. Some cultivars are adapted to longer-term storage, allowing transport by boat rather than by air.
- **atmospheric conditions at the time of harvest** or prior to harvest (products can absorb large quantities of water very quickly if it rains);
- the physiological state of the fruit or vegetables at harvest. **Immature vegetables** have a higher respiration rate than mature vegetables, making it important to keep only vegetables that have matured in the field for longer-term storage. The species best suited to long storage periods, such as onions and potatoes, have a low respiration rate.

The use-by date for food must be scrupulously respected. The use-by date is the date on which a product must no longer be used for reasons of safety or effectiveness<sup>7</sup>. For packaged products, if the package is damaged or if the product has come out of the package, the use-by date is brought forward considerably. In all cases, the storage conditions indicated on the package must be observed. In the absence of information on storage conditions for a perishable product, it is preferable to recommend its storage at low humidity, at a sufficiently low temperature and protected from light.

<sup>7</sup> The risk of consumption after the use-by date is variable. A risk has been clearly established for meat, poultry and eggs. In other cases, it can affect the product's taste without presenting a health hazard. However, it seems wiser to adopt a firm position and to recommend scrupulous respect for these dates, even for products like fresh fruit and vegetables which in theory present less risk in case of consumption after the use-by date.

## 4.2. Use of cooling to preserve certain products

### 4.2.1. The usefulness of cooling and of temperature limits

Fruit and vegetable respiration **releases energy** in the form of heat. The quantity or respiratory intensity of this energy varies depending on the product type and variety, its degree of ripening, extent of injuries and temperature. Furthermore, most products deteriorate quickly if '**field heat**' is not eliminated before they are loaded for transport.

**The temperature of the fruit or vegetable has the greatest impact on respiratory activity.** Prompt, quick and uniform cooling upon harvest, in other words elimination of field heat, is crucial to reduce respiratory intensity. Cooling slows the deterioration process and gives the product a longer shelf life. The empirical rule is that, for every hour of delayed cooling, product shelf life is reduced by one day. This rule is not valid for all crops, but it applies mainly to highly perishable crops harvested in high heat.

Lowering the temperature of the fruit or vegetable also reduces the rate of ethylene production, dehydration, the multiplication of micro-organisms and deterioration from injuries.

Longer shelf life for fruit and vegetables is basically associated with the temperature levels within which they can be stored satisfactorily:

- The **lowest temperature limit** possible is the product freezing point (not always 0 °C), below which the plant cells are destroyed (and enzymes released). Since most products are vulnerable to damage caused by refrigeration, care should be taken **not to pre-cool or to store products below the recommended temperature**. Often the effects of such accidents do not appear until the retail sale stage. These include the failure to ripen normally, rot, shriveling and discoloration of fruit and vegetables.
- The **upper limit** is less well defined and corresponds to each product's specific sensitivity to the increase in temperature, relative to the shelf-life target.

### 4.2.2. Why pre-cool products?

In a cold chamber, products are stored in cold premises and **cool slowly but not uniformly**, mainly under the effect of conduction and also by natural convective contact with the cooled air. Most products deteriorate quickly if field heat is not eliminated rapidly. In most cold chambers, the **temperature rises every time a new lot of warm fruit and vegetables is added**. If this warming is significant due to insufficient capacity of the refrigerating unit, the other fruit and vegetables stored in the chamber become warmer and transpire.

**Pre-cooling to remove the heat is meant to bring the product as quickly as possible to recommended storage temperature and relative humidity.**

Pre-cooling must take place **as soon as possible** after harvest and transport of the products to the packaging station. This operation is crucial to maintain the quality of fruit and vegetables.

Pre-cooling lengthens the product's shelf life by reducing:

- field heat;
- respiration rate (heat released by the product);
- ripening speed;
- loss of humidity (the product shrivels and wilts);
- production of ethylene (maturation gas emitted by the product);
- the spread of decomposition.

### Important considerations

1. To reduce 'field heat' as far as possible, and consequently the demand for cold production to be met by the pre-cooling equipment, harvesting should take place early in the morning. Harvested products should be protected from the sun until they can be placed in refrigerated installations.
2. Refrigerating equipment is designed **to maintain the desired temperature** and should not be used to remove field heat from products packaged for shipping. Furthermore, **without a dehumidifier relative humidity cannot be raised or controlled by refrigerating equipment.**

Pre-cooling requires the use of a 'pre-cooling tunnel', but in the absence of such equipment, part of the cold chamber can be fitted out for this purpose.

➤ The pre-cooling tunnel:

- Forced-air cooling is one of the methods used to extract field heat from freshly harvested products. It can be used with most fruit and vegetables. This method involves the use of **powerful fans** that suck up the refrigerated air and force it through the stacks of products to be cooled. Rapid and uniform convective-type cooling results from active circulation of the cooled air, at high speed around the warm fruit and vegetables. This process results in quick cooling to very low temperatures.
- The installation must have **strong cooling power** and allow **intense ventilation**.
- It is preferable for the air to be **sucked rather than blown through** the products because it is easier to prevent or limit 'short circuits' of the cooled air, in other words, to prevent it from flowing directly to the fan without going through the stored products. Air will not flow as uniformly if blown as it will if sucked through the products. With proper container design and orientation, products can be cooled quickly and uniformly whether they are contained in baskets, crates, bins or sacks.
- A forced-air cooling tunnel uses cooled air much more efficiently than a cold chamber. Despite the additional cost involved, it is best to fit out a cold chamber reserved for forced-air cooling and to transport the cooled products to refrigerated premises where they can be stored over a longer period.
- **With this method, however, it is hard to avoid a significant loss in product weight.**



*Pre-cooling in a pre-cooling tunnel of oranges and clementines, packaged in crates, labelled and placed on disinfected pallets, before being moved to the cold storage room where they will remain until being shipped.*

- Fitting out a section of the cold chamber:
  - A compromise is to **set up a forced-air cooling area** by partitioning a corner of the cold chamber using a **tarpaulin suspended from the ceiling**. This is an adaptation that consists of guiding the ambient air through the stacks of products by covering them with a detachable tarpaulin. This method helps to reduce temperature fluctuations but it should only be used as a stopgap measure.
  - The pallets are placed in such a way as to provide a central air recovery channel to imitate the effect of a pre-cooling tunnel.
  - This moveable system makes it possible to use cold chambers for rapid cooling.

More information can be found in an annex to this chapter on the cooling rate of produce by means of forced air and factors that influence this operation.

### 4.2.3. Role of packaging in the cold chain

Packaging also has an impact on product shelf life: it fills a large number of functions for fruit and vegetables, especially once they reach the consumer. In addition to protecting against shocks and ensuring market appeal, packaging is **a constraint for preservation but can also be a factor for improvement**.

Between harvest and packaging produce is generally placed in temporary containers such as crates, cardboard boxes and so on. In practice, **the size of these containers should be limited to take account of the release of respiratory heat**: a difference of at most 0.5 °C between the different parts of these containers (e.g.: bottom and walls) is tolerable.

During distribution, packaging plays an **important role in the cold chain**. It acts as a division between lots and serves as a barrier to heat exchange, warming and cooling.

It is therefore important to provide the most stable temperature possible during transport. Changes of temperature can cause serious damage to products through **condensation** that occurs on cold packaging walls. If fruit and vegetables become wet, they are easily attacked at these temperatures by moulds and bacteria, especially in small packaging units, trays, plastic pouches, etc.



#### 4.2.4. Transport

Many products are shipped in non-refrigerated containers or in pallets for air transport. This requires good coordination at the airports of departure and destination to protect the products, particularly when flights are delayed.

Airports must have temperature-controlled storage installations to ensure product quality. Refrigerator containers exist and should be used as often as possible. Tarpaulins can also be used to provide thermal insulation.

The **design of vehicles** for the transport of plant products must take account of the same constraints as those for premises. In practice, short-distance transport rarely has special means. At best, it assures a temperature close to that of loading temperature, which is usually sufficient.

The problem is complex for longer transport because equipment is rarely used for just one purpose and the operating scheme must be adapted case by case depending on the requirements of the lot being transported.

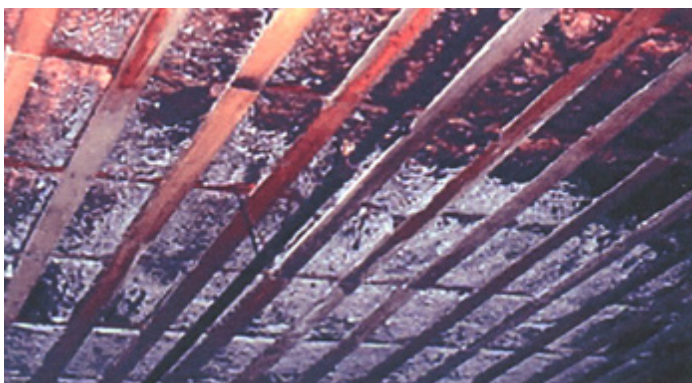
Constraints need to be analyzed to ensure the best possible compromise and **surveillance is required during transport**.

## 4.3. Hygiene and maintenance of cold chambers

### 4.3.1. Cleaning and disinfecting of cold chambers

#### ☐ Cleaning of cold chambers

**General hygiene rules** to be observed in the production chain, in fields and at the packaging station (see chapter 2) are also valid for cold chambers.



*Ceiling of a refrigerator warehouse contaminated due to the accumulation of dust and condensation.*

**Cleaning is the first hygiene measure.** It reduces the risk of development of micro-organisms that can contaminate products directly or indirectly.

**Cold chambers have to be cleaned regularly (floor, gutter, walls, doors and ceiling)** and be kept clean and free of all visible dirt, plant remains, filth on the floor, etc.

Waste and debris on the floor must be removed regularly during the work process. Simple **sweeping** may be enough, but vigorous scrubbing is sometimes necessary when debris attaches to the surface of walls, the floor, doors or the ceiling, or to drains and grating.

**Water from condensation or from the thawing of refrigeration systems must not drip onto fruit and vegetables!**

#### ☐ Disinfecting cold chambers

A sanitation plan for installations is needed to **supplement daily cleaning** and to eliminate micro-organisms that can lead to rot or mould on fresh fruit and vegetables during storage or even after shipment.

Cold chambers must be disinfected **at least once a year at the start of the season**, if they are closed and the refrigeration unit has been switched off.

A **disinfectant** destroys micro-organisms present on surfaces in the cold chamber. **It is a 'biocide': it can present a risk of contamination for the food in storage. Only biocides authorised for food use are recommended.**

For effective disinfecting, **the application conditions and contact time necessary** must be followed. **It is important to read labels thoroughly** before using disinfectants.

**Disinfection must always be performed with the area free of fresh products!**

It is important to **cover electrical and metallic installations**, especially if corrosive substances are used. Special care should be taken if there is excessive contamination.

Special attention should be paid to **observing time limits** between the use of disinfectants, the ventilation of cold chambers after disinfection and the storage of new products. To ensure proper ventilation of cold chambers, doors must be opened to let outside air into the premises.

#### ☐ **Rinsing**

**Certain disinfectants produce smells that can give an unpleasant taste** to fruit and vegetables. Furthermore, certain products can have the prolonged effect of **corroding** the materials that make up the cold chamber's structure.

To rinse, flush all surfaces treated during the disinfection abundantly with water, starting with the highest, so that residues are washed off. All standing water must be removed.

It is essential to use **potable water** to keep from recontaminating the installations.

Once the cold chambers have been cleaned, it is important to make sure that the **installations are not recontaminated** by soiled protective clothing, safety shoes, material coming directly from fields, crates, pallets, etc.

### **4.3.2. Maintenance and checks of cold chambers**

A malfunction in the refrigeration installations can have very serious consequences on the quality of the stored products: a break in the cold chain, risk of contamination, etc.

A **maintenance and check-up programme** must be set up (see also chapter 2 on PRP programmes).

The following must be checked:

- The cleanliness of the premises and installations: walls, floor, doors, ceilings etc. A product lot can be contaminated by **residues of chemicals** from products used to clean and disinfect the premises, odors from products stored previously or insects nesting in the fabric of the building.

- The impermeability of installations:
  - Check that **doors are kept closed at all times** and that entering and exits are kept to a minimum and are as brief as possible.
  - Check that **doors close completely and are totally impenetrable**: damage to walls or the ceiling can allow heat, humidity, dirt and insects to enter from the outside. To check: close the doors and have a person inside the cold chamber make sure that no light enters.
  - The impermeability of pipes in which refrigerating liquids circulate must be checked regularly. **Leaks** in these pipes can contaminate the premises and the food products.
- The temperature control system:

Temperature probes used to check the temperature in the cold chamber must be regularly **calibrated** (check of the temperature indicated by the probe using another thermometer whose accuracy has been confirmed). The probe should be adjusted or replaced as necessary.

**Reminder: mercury thermometers are prohibited!**

- Air circulation:

**If air circulation is insufficient, the lot will deteriorate.**

It is essential to **leave sufficient space between the upper row of boxes and the ceiling** to allow for sufficient air circulation underneath, around and through the stack to protect the product against problems arising from:

- **heat from product respiration**;
- accumulation of ethylene during to product maturation.



## 4.4. Techniques for preparing and preserving products

### 4.4.1. Preparation techniques

Fruit and vegetables to be preserved must be prepared **as soon as possible after harvest**, within 4 to 48 hours at most. The longer the delay, the greater the chance that the products will deteriorate.

#### ❑ Cleaning and washing

It is permitted<sup>8</sup> and even recommended to sort and clean fruit and vegetables before packing and storage in order to remove sand, attached soil and traces of dirt.

Cleaning generally consists of washing products under running water or in a basin of clean water that is changed regularly. In the absence of potable water, clean water can be used for the first washing (to remove sand/soil).

Certain types of fruit such as cherries, strawberries and mushrooms, lettuce, green beans, cucumbers and so on should never be washed because this would contribute to the spread of micro-organisms and shorten their shelf life.

For some products like head lettuce, instead of washing, the lower leaves are removed. These leaves have been in contact with the ground and are consequently the dirtiest and the most contaminated with residues (e.g.: fungicides) because they are the oldest and already formed at the time of treatments. Removing them eliminates a large part of the residues of plant protection products.

#### ❑ Peeling and cutting operations

Many types of fruit and vegetables are peeled prior to preservation. Peeling is easy using a stainless steel knife; this detail is very important because it prevents the discoloration of the product's flesh.

It is important to cut up products because more or less equal size pieces are needed for cooking, drying and packaging. Fruit and vegetables are generally cut up into cubes, fine slices or rings, or they can be grated. **The instruments must be sharp and clean to prevent micro-organisms from coming into contact with the food.** As soon as they have been cut up, the products lose quality due to the release of enzymes and substances that are nutritious for micro-organisms.

The loss of quality also results from the fact that the product's flesh is injured by cutting. This is why the time between peeling/cutting and the preservation process should be as short as possible.

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<sup>8</sup> Within the regulatory meaning, these operations that do not change the product's intended use do not differ from 'primary production' and do not change requirements related to the HACCP obligation, for example.



*Peeling and packaging of mini-vegetables in Kenya.*

*Due to extensive handling of the product, great importance has to be attached to staff hygiene and clean equipment.*

*The health risks presented by this type of operation are not comparable with those involved in produce washing. The organization of HACCP to identify appropriate control measures is essential.*



*Knives are cleaned and disinfected during the work process by soaking them in a disinfectant solution.*

*(Photos B. Schiffers)*

#### ☐ Blanching operations

Blanching or 'pre-cooking' is performed by immersing the fruit or vegetables in water at 90-95°C. Products can also be exposed to steam, which softens them and eliminates enzymes, but keeps vitamins intact. Leaf vegetables lose volume and **micro-organism levels are reduced**.



Vegetables are blanched before being dried to prevent changes in color or smell and to avoid the loss of too many vitamins. In theory, it is not necessary to blanch fruit, which does not discolor. Onions and leeks do not respond well to blanching.

#### 4.4.2. Preservation techniques

To preserve foods, sometimes it is necessary to drastically change the environment of micro-organisms. This can involve **removing water** (drying), **increasing acidity** or **heating the products** (to kill bacteria) before storing them in airtight containers to keep oxygen from entering (preserved/tinned foods).

##### ❑ Drying

Drying is one of the oldest preservation methods. The moisture content of agricultural products decreases to **10 to 15%**, which **prevents micro-organisms from multiplying and neutralizes enzymes**. Dehydration is generally not taken further because it would make the products crumbly. To prevent damage to dried foods, they should be stored in a dry place.

Drying is theoretically very simple. With the loss of water, products become lighter, which makes transport easier. There are two disadvantages, however: foods lose vitamins and their appearance changes.

The drying method used most widely consists of **exposing products to the air**. The air absorbs the water, and the warmer the air the more water is absorbed. For the best results, the air should be warm, dry and in movement. In a closed environment, the air must be changed regularly to keep it from becoming saturated with the moisture absorbed from the products. So it is very important to ventilate the premises well.

**Relative humidity (RH) must be less than 65%.** If this is not the case, the fruit and vegetables will end up drying, but not completely. When the sun is shining, RH is generally less than 65%, but when it is cloudy and especially when it rains, the RH is usually higher. The presence of sunshine is therefore very important! This is why products cannot be dried in this way in all seasons.

Before processing the fruit and vegetables, they are washed and possibly cut up into pieces. Sometimes they have to be prepared to protect their color and to keep the loss of nutritive substances to a minimum. Fruit and vegetables that are to be dried must be of good quality. Rotting or damaged fruit must not be mixed in with healthy fruit. Products have to be dried as quickly as possible after harvest to keep them from losing quality.

##### ❑ Sulphuring

Fruit is sometimes treated by **burning sulphur** and exposing it to the 'smoke' (sulphur dioxide gas) or dipping it in a sodium sulphite or bisulphite solution to prevent browning. This process is used for lychees.

These treatments protect color, taste and vitamin C, but the sulphite residues in the product can be dangerous (at high concentrations sulphites are allergens) and can alter the product's taste.

#### ❑ Preservation of vegetables in salt and/or vinegar

Salting is one of the oldest methods of food preservation, especially in areas where inexpensive salt is available. However, it is not used for fruit.

Salt **absorbs a large quantity of water** from food, making it hard for micro-organisms to survive. Use of a large quantity of salt is detrimental to the flavor of foods. To avoid this problem, the foods can be rinsed or soaked in water before being eaten. This reduces their nutritional value, however, which is why this technique should be reserved for cases where there is a surplus of fresh vegetables and no other method is possible.

The use of salt in small quantities is not sufficient in itself to prevent bacterial growth, but it encourages the development of certain bacteria that produce acid and limit the growth of other bacteria. Sauerkraut, for example, is made in this way. It has high nutritive value.

Another method for preserving vegetables is to add vinegar or acetic acid. This method is used for vegetables like cabbage, beets, onions and cucumbers and for fruit, including lemons and olives. The product must be salted and heated before being immersed in vinegar for storage. The vinegar must have a minimum concentration of 4 % (its pH must be less than 3.5 and should be checked with litmus paper).

# Appendices

## A.1. Recommended temperature and relative humidity for certain fruit and vegetables

Sources: Cited on the FAO site.

- McGregor, B.M., *Tropical Products Transport Handbook*, USDA Office of Transportation. Agricultural Handbook, 1989, p. 668.
- Kader, A.A., "Postharvest Handling", *The Biology of Horticulture – An Introductory Textbook* (J.E. Preece et P.E. Rend dir.), New York, John Wiley & Sons, 1993, pp. 353-377.

Product	Temperature (°C)	RH (%)	Approximate storage life
apricots	0	90-95	1-3 weeks
garlic	0	65-70	6-7 months
pineapples	7-13	85-90	2-4 weeks
artichokes, globe	0	95-100	2-3 weeks
asparagus	0-2	95-100	2-3 weeks
eggplants	12	90-95	1 week
avocados	4.5-13	85-90	2-8 weeks
bananas (green)	13-14	90-95	1-4 weeks
chard	0	95-100	10-14 days
boniato (sweet potato)	13-14	85-90	4-5 months
broccoli	0	95-100	10-14 days
cantaloupes (¾-slip)	2-5	95	15 days
cantaloupes (full-slip)	0-2	95	5-14 days
carambola	9-10	85-90	3-4 weeks
carrots, bunched	0	95-100	2 weeks
carrots, mature	0	98-100	7-9 months
carrots, immature	0	98-100	4-6 weeks
celery	0	98-100	2-3 months
celeriac	0	97-99	6-8 months
cherries, sour	0	90-95	3-7 days
cherries, sweet	-1	90-95	2-3 weeks
mushrooms	0	95	3-4 days
cabbage (early maturing)	0	98-100	3-6 weeks
cabbage (late)	0	98-100	5-6 weeks
cauliflower	0	95-98	3-4 weeks
lemons	10-13	85-90	1-6 months
pumpkins (winter squash)	10-13	50-70	2-3 months
clementines	4	90-95	2-4 weeks
cucumbers	10-13	95	10-14 days
taro root/dasheen	7-10	85-90	4-5 months

dates	0	75	6-12 months
endive	2-3	95-98	2-4 weeks
spinach	0	95-100	10-14 days
figs, fresh	0	85-90	7-10 days
strawberries	0	90-95	5-7 days
winged bean	10	90	4 weeks
ginger	13	65	6 months
pomegranates	5	90-95	2-3 months
green beans	4-7	95	7-10 days
yams	16	70-80	6-7 months
jicama	13-16	65-70	1-2 months
lettuce	0	95-100	2-3 weeks
greens, leafy	0	95-100	10-14 days
limes	9-10	85-90	6-8 weeks
lychees	1.5	90-95	3-5 weeks
corn, sweet	0	95-98	5-8 days
mandarins	4	90-95	2-4 weeks
mangoes	13	85-90	2-3 weeks
Yucca root	0-5	85-90	1-2 months
melons (Casaba, Crenshaw, Honeydew, Persian)	7	90-95	2-3 weeks
turnips	0	95	4-5 months
nectarines	0	90-95	2-4 weeks
coconut	0-1.5	80-85	1-2 months
olives, fresh	5-10	85-90	4-6 weeks
onions, dry	0	65-70	1-8 months
onions, green	0	95-100	3-4 weeks
blood oranges	4-7	90-95	3-8 weeks
oranges (CA, AZ)	3-9	85-90	3-8 weeks
oranges (TX, FL)	0	85-90	8-12 weeks
oranges Jaffa	8-10	85-90	8-12 weeks
grapefruit	15	85-90	6-8 weeks
papayas	7	85-90	1-3 weeks
watermelons	10-15	90	2-3 weeks
squash, summer	5-10	95	1-2 weeks
sweet potatoes	13-15	85-90	4-7 months
parsley	0	95-100	2 months
peaches	0	90-95	2-4 weeks
pepinos (cucumbers)	4	85-90	1 months
peppers, dry	10	60-70	6 months
leeks	0	95-100	2-3 months
pears	-1.5-0.5	90-95	2-7 months
peppers, sweet	7-13	90-95	2-3 weeks
apples	-1-4	90-95	1-12 months
potatoes, early crop	15	90-95	10-14 days
potatoes, late crop	13	90-95	5-10 months
pumpkins	10	50-70	2-3 months
plums and prunes	0	90-95	2-5 weeks
radishes/daikon	0	95-100	1-4 months

horseradish	- 1-0	98-100	10-12 months
grapes, vinifera	- 1	90-95	1-6 months
rhubarb	0	95-100	2-4 weeks
tomatoes, mature-green	8-22	90-95	1-3 weeks
tomatoes, firm-ripe	3-15	90-95	4-7 days

## A.2. Compatibility groups for storage of fruit and vegetables

Source: cited on the FAO site.

- McGregor, B.M.. *Tropical Products Transport Handbook*, USDA Office of Transportation, Agricultural Handbook, 1989, p. 668.

### Group 1: Low temperature (0 to 2 °C), high RH (90-95%), can produce ethylene

apricots cherries mushrooms figs (not with apples) strawberries raspberries pomegranates persimmons lychees turnips nectarines	coconuts oranges (Florida, Texas) peaches apples leeks pears plums radishes horseradish grapes (without sulphur dioxide)
--	---

### Group 2: low temperature (0 to 2 °C), high RH (90-95%), can be sensitive to ethylene

artichokes asparagus bok choy broccoli carrots mushrooms celery cauliflower endive/escarole spinach kiwifruit	lettuce leafy greens sweet corn turnips (without leaves) parsley peas leeks (not with figs or grapes) onions, green (not with figs, grapes, rhubarb or corn) radishes rhubarb
---	--

### Group 3: Low temperature (0 to 2 °C), lower RH (65-70%), humidity damages these products

garlic  
onions, dry

**Group 4: 5 °C, 90-95% RH**

cantaloupes lemons clementines lychees mandarin	yucca root oranges (California, Arizona) pepino tangelos
---	---

**Group 5: 10°C, 85-90 %, sensitive to chilling injury, can be sensitive to ethylene**

eggplant cucumber squash, summer okra beans green beans kiwano malanga	olives paprika peppers, hot peppers, sweet potatoes, storage taro root/dasheen
---	---

**Group 6: 13-15°C, 85-90 % RH, sensitive to chilling injury, can produce ethylene**

pineapples avocadoes bananas boniato carambola squash, winter feijoa ginger limes	mangosteen mangoes melons grapefruit papayas plantain potatoes, new tomatoes, ripe
---	---

**Group 7: 18-21 °C, 85-90% RH, sensitive to chilling injury, produce ethylene**

tomatoes, mature green  
pears (for ripening)

**Group 8: 18-21°C, 85-90 % RH, sensitive to chilling injury, sensitive to ethylene**

yams  
jicama  
watermelon  
sweet potatoes

### A.3. Product 'cooling times'

Source:

Fraser, H.W., "Tunnel Forced-Air Coolers for Fresh Fruits & Vegetables", Factsheet, Ministry of Agriculture, Food and Rural Affairs Ontario, Guelph, 1998, [www.omafra.gov.on.ca/english/engineer/facts/98-031.htm](http://www.omafra.gov.on.ca/english/engineer/facts/98-031.htm).



All fruit and vegetables cool quickly at first, then more slowly. The rate of cooling by means of forced air depends on several factors:

- density of produce in the container (the less dense the produce pile, the faster the cooling);
- container type, orientation and venting characteristics (if air passes uniformly and evenly around the produce, cooling is faster);
- volume to surface area of produce; the lower the ratio, the faster the cooling (cherries cool more quickly than melons);
- travel distance of the cooling air (the shorter the distance, the faster the cooling of the overall pile);
- airflow capacity (the higher the airflow, the faster the cooling).

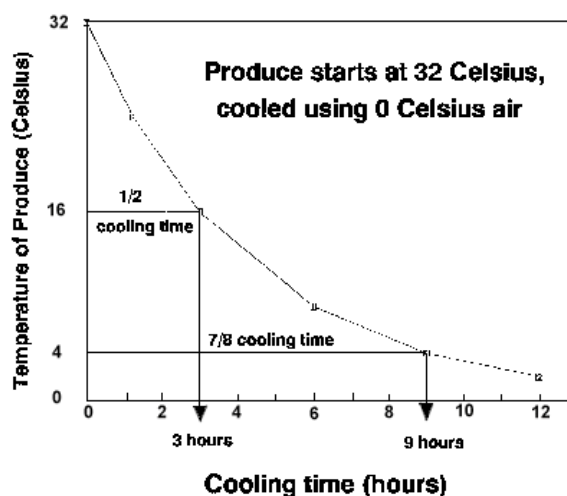
The relative humidity of the cooling air has little impact on moisture loss if it is above 85% and if the cooling period is less than one to two hours.

Regardless of the temperature of the cooling air or the starting temperature of the produce, the shape of the cooling curve remains the same, provided that all the other factors listed above are kept constant. Only the rate of cooling changes.

The expression '*7/8 cooling time*' is a standard industry term that describes the time needed to remove seven-eighths (87.5%) of the temperature difference between the starting produce temperature and the temperature of the cooling medium (refrigerated air, in the case of forced-air cooling).

**This is a convenient method for indicating when produce has come as close as possible in practical terms to the temperature of the cooling medium.**

The 7/8 cooling time is measured from the time the produce is first placed in the cooling tunnel. For example, with the air at 0 °C, if it takes nine hours to lower the temperature of a peach from 32 °C on its arrival to 4 °C, 7/8 cooling time is nine hours. In other words, the temperature difference between the produce and the cooling air, which was 32 °C, has been reduced by 28 °C. The 7/8 cooling time is theoretically three times as long as the 1/2 cooling time. As a result, the same peach that took nine hours to cool to 4 °C would take only three hours to cool to 16 °C, the temperature at 1/2 cooling time, all other things remaining equal. In practice, 7/8 cooling time does not often correspond to three times the 1/2 cooling time because conditions rarely remain exactly the same over the forced-air cooling period.



Sometimes the time a product will take to reach 7/8 cooling can be estimated if other cooling times are known. The table below lists cooling time relationships.

Factors used to calculate 7/8 cooling time	
If you know ...	... multiply by the following to estimate 7/8 cooling time
1/4 cooling time	7.5
3/8 cooling time	4.5
1/2 cooling time	3.0
3/4 cooling time	1.5

For some crops, it might not be necessary to operate the forced-air cooler at temperatures as low as the optimum holding temperature for the products. For example, some produce can be cooled with forced air to 5° C, then slowly room-cooled in an adjacent cold chamber. This compromise could eliminate the need for a refrigeration defrosting system in the forced-air cooling room.

Most fruit and vegetables can be forced-air cooled but the 7/8 cooling time should be shorter for some products with the following characteristics :

- have high respiration rates at harvest;
- lose moisture easily (berries, leaf vegetables);
- are quite ripe, such as tree-ripened peaches;
- are to be shipped to distant markets.

#### A.4. Drying methods source

Drying in the open air is called natural drying. We speak of artificial drying when the air is first heated to decrease the relative humidity to a desired level. Both methods are described below.

#### ❑ Natural drying

Drying in the open air is a simple and inexpensive process. It does not require any costly energy, just sunlight and wind. The product to be dried is placed in thin layers on trays (see Figure 6) or black plastic and exposed to direct sunlight. The trays are usually made of wood, and lined with plastic or galvanized nets. The trays should be placed one meter above the ground on stands set on a flat surface. This way no dirt can come in contact with the food from below and the food can receive maximum sun exposure. If necessary, the trays can be covered to protect the food from rain, dust, birds, insects and other pests. Mosquito netting probably offers the best protection from pests. To ensure that the fruits or vegetables dry uniformly, it is best to turn them regularly or at least to shake the trays. This does not apply to tomatoes, peaches or apricots, which are cut in half and arranged in a single layer on the trays.

Fruit dries very well in the sun, but some products are damaged by exposure to direct sunlight and are therefore dried preferably in a shady spot. Beans and (red) peppers, for example, are bunched and hung up under some type of shelter. Of course, drying these products takes more time.

In areas with a high chance of rain, it is advisable to have an artificial dryer that can be used when it is raining or when the RH is too high. This will prevent interruption in the drying process and thus also a loss of food quality. In the event of rain, the (moveable) trays should be covered with plastic or placed under a shelter. Afterwards, they should be returned as soon as possible to the drying spot. It takes about two to four days to dry tropical vegetables.

#### ❑ Artificial drying

The temperature of outside air often needs to be increased by just a few degrees to make drying possible. The product releases water faster at higher temperatures.

The air can be heated with solar energy or by burning natural or fossil fuels. The **maximum drying temperature** is important because above this temperature the quality of the dried product decreases quickly. Another reason for not drying at very high temperatures is that the product then dries quickly on the outside, but remains moist on the inside.

# Chapter 5

## The HACCP system

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## 5.1. Scope and significance of the HACCP method

### 5.1.1. Origin, definition and strategy of the method



For many years, methods such as '*Hazard and Operability*', or '**HAZOP**' studies, based on the idea that 'prevention is better than cure', were used in the chemical, nuclear and aerospace industry.

**It is on these basic principles that the 'HACCP system' was established.**

The agri-food sector soon adopted this system, particularly for managing the hazards of food supply contamination in the NASA space programmes. HACCP was first used by the Pillsbury Company and NASA to ensure food safety in the first manned space missions.

**HACCP** stands for:

**H** hazard  
**A** analysis  
**C** critical  
**C** control  
**P** points



**Hazard Analysis and Critical Control Point.**

**HACCP is a systematic and rational strategy** for controlling hazards in order to ensure the safety of a product. It is based on a simple principle: '**Prevention is better than cure**'.

**HACCP introduced a new approach** to managing food safety and quality, with an emphasis on **inspection and improvement during production**, rather than on **finished product inspection**.

The strength of the system lies in the fact that HACCP:

- **identifies and analyses the hazards** associated with different stages of food production and processing;
- **specifies the resources required to control them**;
- **ensures that these resources are implemented efficiently and effectively.**

As such, HACCP uses a logical scientific approach to identify specific hazards and indicate the measures to be taken to manage and guarantee food safety. HACCP is a tool that assesses hazards and implements management systems focused more on prevention than on analysis of the finished product.

### 5.1.2. HACCP in regulations and standardization

The HACCP strategy<sup>1</sup> is currently recognized by many international bodies as the most reliable tool for guaranteeing food safety.

The **Codex Alimentarius (FAO/WHO) Commission**, an international body responsible for harmonizing food safety regulations, decided to use the **HACCP system as a reference standard**.<sup>2</sup> **European regulations** on food hygiene therefore apply the HACCP system as the **reference standard for food safety management**.

The European Economic Community (EEC), following the recommendations of the *Codex Alimentarius*, introduced the HACCP method in Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. More recently, Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs, which supersedes Directive 93/43 EEC and which entered into force on 1 January 2006, requires food business operators to develop, implement and maintain a permanent procedure based on HACCP principles.

Regulation (EC) No. 852/2004 states that the HACCP system is an appropriate tool for controlling hazards in food industry companies, particularly those engaged in operations that may pose a hazard if they are not performed properly.

In the United States, the Food and Drug Administration (**FDA**) introduced a series of legal and technical measures which made application of **HACCP** mandatory at all food-processing establishments.

**However, it is important to note that HACCP is not a ‘standard’ as such, in the strict sense of the term!**

It is a method or approach for implementing a system which, in the case of food, aims to produce safe food by controlling hazards that are unacceptable and which may damage consumer health.

This has since inspired several countries to establish standards.

For example:

- the Danish standard DS 3027 (*Management of Food Safety based on HACCP*)
- the Moroccan standard NM 08.0.002 (*HACCP management system – requirements*)

Internationally, ISO published **ISO 15161:2000** (based on ISO 9001), a standard concerning management of the quality, rather than the safety, of food. Given the growing number of standards incorporating HACCP principles and given a real need to harmonize

<sup>1</sup> The terms ‘approach’, ‘strategy’, ‘system’ and ‘method’ are used interchangeably in literature on HACCP.

<sup>2</sup> In 1993 the *Codex Alimentarius* proposed the first ‘*Guidelines for the application of the HACCP system*’.



practices in a global marketplace, in 2005 the ISO published a further standard, **ISO 22000, which integrates HACCP into ISO 9001.**

Thus, a company may have its food safety management **system** (FSMS) **certified** based on HACCP principles. However, it should be noted that certification of a HACCP system is a voluntary procedure (e.g. for commercial reasons or due to a customer requirement), rather than a regulatory requirement.

### 5.1.3. The advantages of the HACCP method

Application of HACCP offers many advantages:

- HACCP can be applied throughout the food chain, from primary production all the way to the consumption stage.
- HACCP offers a **systematic approach** that addresses all aspects of food safety, based on scientific evidence.
- It **identifies hazards and focusses** on those for which management is essential for food safety (risk assessment: severity of damage and likelihood of occurrence).
- HACCP enables compliance with legal requirements for ensuring and managing the safety and quality of products sold (principle of due diligence).
- HACCP helps businesses meet customer requirements. Large retailers are increasingly sensitive to hazards and their control and request this type of strategy.
- Having a HACCP system boosts the confidence of trading partners, thus making international trade more straightforward.
- HACCP can be easily integrated into existing quality management systems; it provides a clear methodology for developing a specific food safety plan.
- Through its prevention-based approach at all stages of the production process, HACCP helps reduce the risks of non-conformity that may arise during inspections of the finished product.

## 5.2. Description of the HACCP method

### 5.2.1. HACCP basic principles

HACCP is based on 7 basic principles:

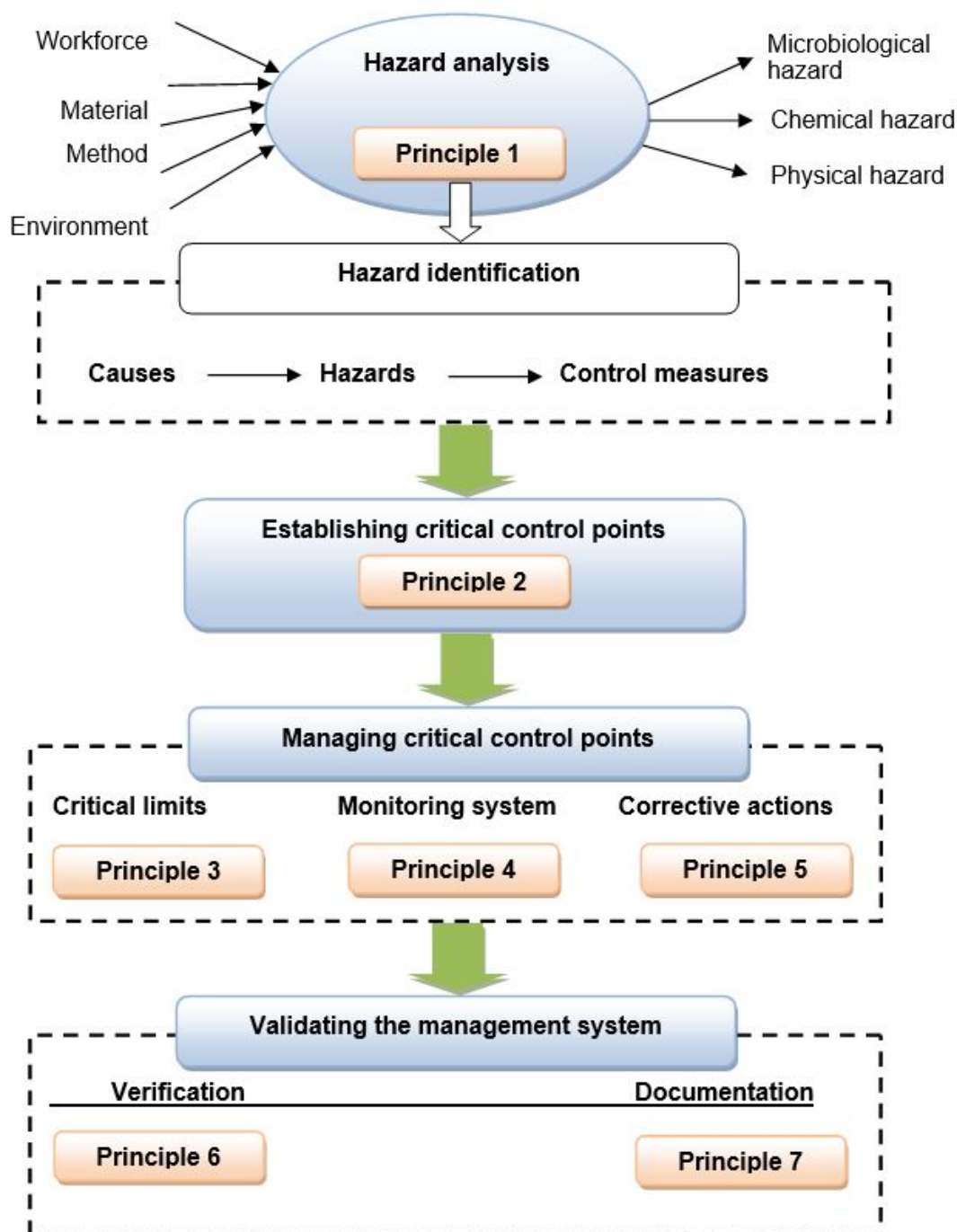


- |                     |   |
|---------------------|---|
| <b>Principle 1:</b> | Conduct a hazard analysis   |
| <b>Principle 2:</b> | Identify <b>Critical Control Points (CCP)</b>   |
| <b>Principle 3:</b> | Establish <b>critical limit(s)</b>  |
| <b>Principle 4:</b> | Establish a CCP <b>monitoring system</b>  |
| <b>Principle 5:</b> | <b>Establish corrective actions</b> to be taken when monitoring indicates that a CCP is not under control |
| <b>Principle 6:</b> | Establish <b>verification</b> procedures for ensuring that the HACCP system is working as intended        |
| <b>Principle 7:</b> | Establish <b>files</b> and maintain <b>records</b>  |

### 5.2.2. Flowchart for the HACCP method

On a practical level, the HACCP method is implemented in a logical sequence based on four points:

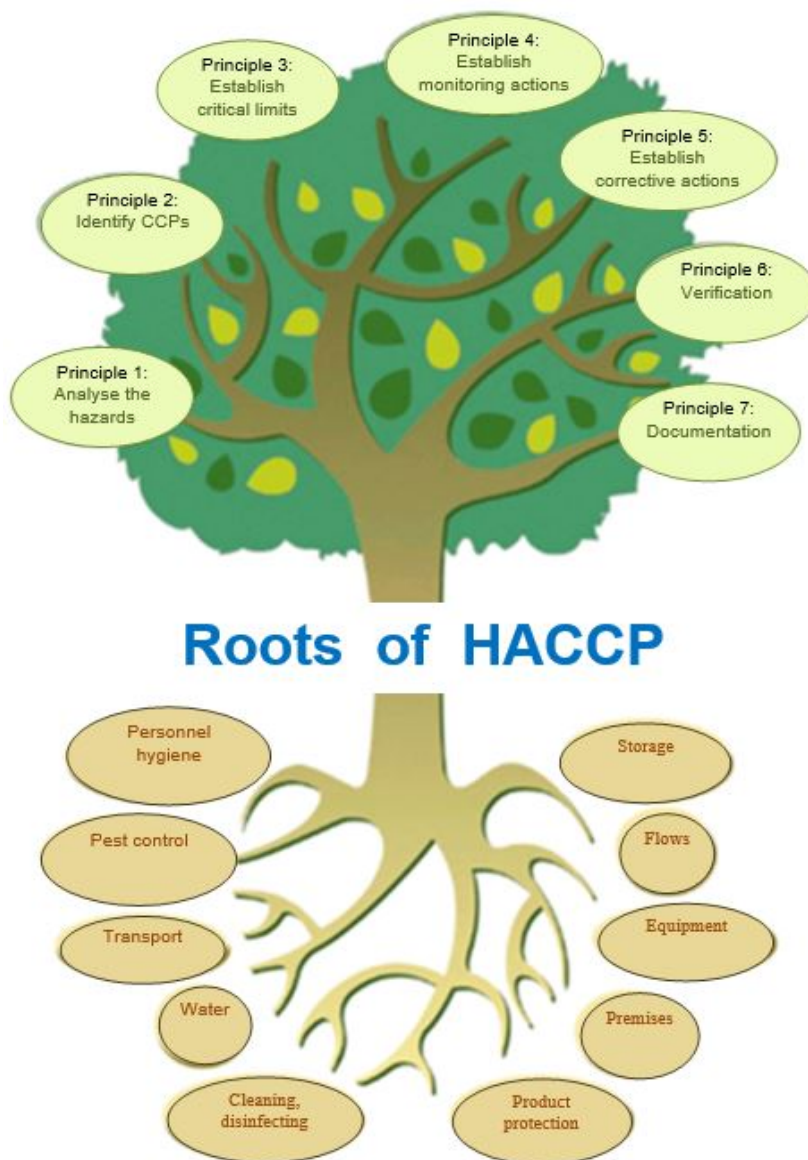
- **Hazard analysis**
- Identifying **critical control points**
- **Managing critical control points**
- **Validating** the management system



### 5.2.3. Implementing the HACCP method

#### ❑ Prerequisite programmes (PRP)

Before a HACCP plan is implemented, prerequisite programmes (PRP) must already be in place.

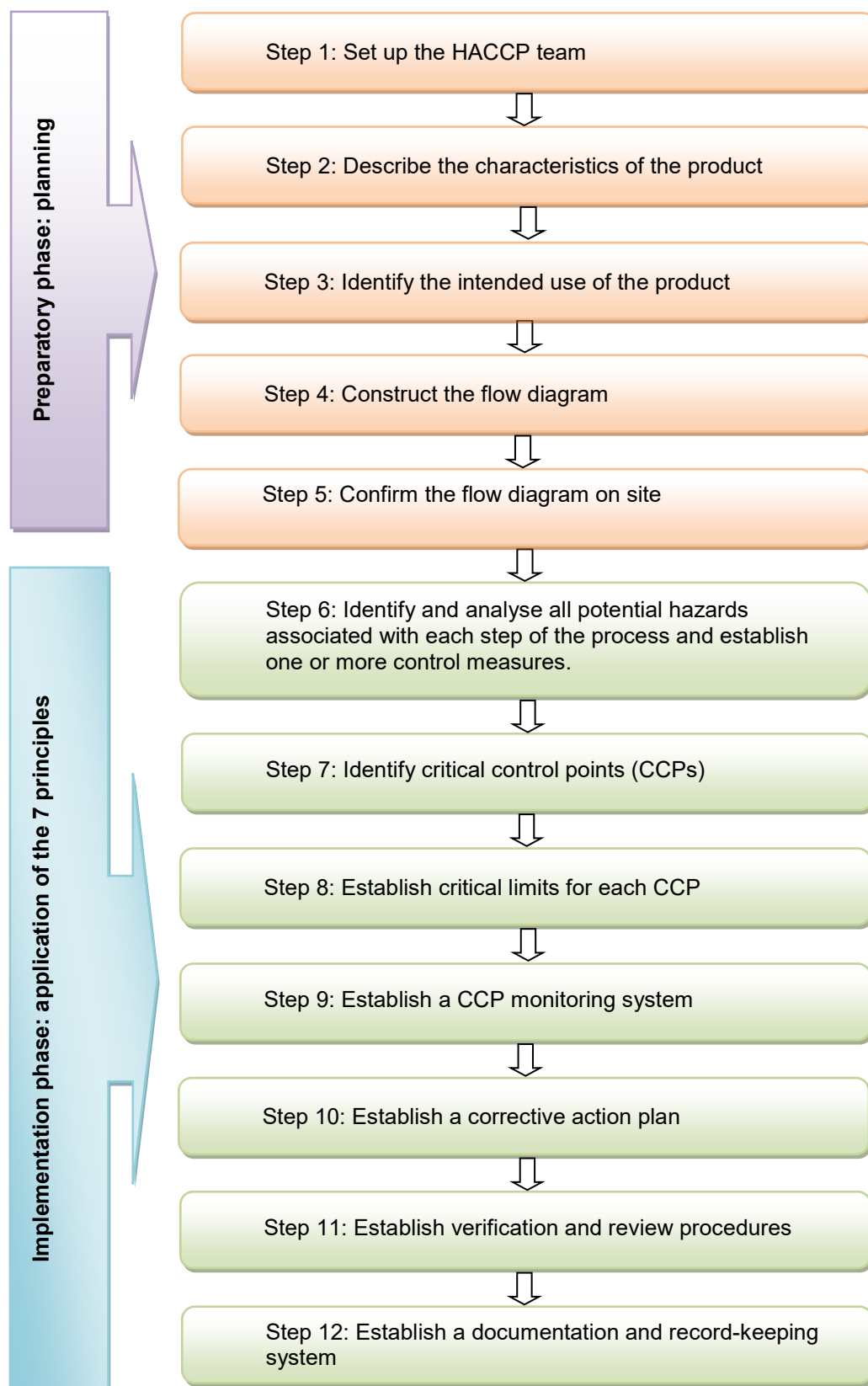


As such, implementing a HACCP system assumes that appropriate Good Practices have **already been established** for building and developing the tools and working methods that enable staff to implement the food safety system.

To verify application of the PRPs, it is recommended to use checklists to review the relevant Good Practices and implement corrective actions in the event of any non-conformity.

#### ❑ Applying the HACCP method

According to the *Codex Alimentarius* guidelines, HACCP principles are applied using a **12-step strategy** consisting of two phases: a *preparatory phase* and an *implementation phase*.



### ➤ *The preparatory phase*

- **Step 1: Setting up the HACCP team**

Implementing HACCP requires **a multidisciplinary team** to develop, establish, maintain and review the system. The HACCP team should have experience and knowledge of the products, processes and hazards within the scope of the study. A HACCP team leader should be appointed. External experts may be used, in which case the expert's responsibility and authority in the HACCP system must be defined.

In a small company, one person may have the skills required to carry out the HACCP study, but it is recommended that an external expert validates the system.

- **Step 2: Describing the product characteristics**

A full description of the product under study must be given, in order to identify the factors that may influence its safety and quality.

Information on the following aspects must be included, where these relate to hazards inherent to the product:

- Description of the raw materials
- Product data sheet (botanical variety, category, grade etc.)
- Chemical, physical and biological characteristics
- Origin
- Delivery method, type of packaging, storage conditions etc. This is where all available documentation about the product should be collated.

- **Step 3: Identifying the intended use of the product**

The potential users and/or consumers of the product should be identified, and any groups recognized as vulnerable should be indicated. Foreseeable deviations from normal usage should also be taken into account.

- **Step 4: Constructing the flow diagram**

This involves creating a **detailed schematic representation of all steps or operations** to be followed during the production process. It summarizes the main stages of the production process, from receipt of the raw materials to shipping the finished product. The chart should be accompanied by a diagram illustrating the movements of materials, ingredients, packaging etc. This diagram should help to highlight any areas of potential cross-contamination at the premises (cloakrooms, toilets, waste collection area etc.).

There are no formatting obligations for this diagram. The aim is to provide a comprehensive yet concise description of the different stages of the process.

- **Step 5: On-site verification/confirmation of the flow diagram**

On-site verification serves to ensure that the flow diagram to be used to perform hazard analysis does indeed correspond to the production process concerned.

### ➤ *Implementation phase*

The **implementation phase** is when the **7 principles of HACCP** are applied.



- **Step 6: Conduct a hazard analysis (Principle 1)**

This involves identifying hazards (chemical, biological or physical) at the different stages of the process, assessing the likelihood of them occurring, and identifying control measures to be implemented to manage food quality and safety.

- **Step 7: Identify Critical Control Points (CCP) (Principle 2)**

A **CCP** is an operation which, **in the event of loss of control, no other operation would control the hazard** and this would **result in an unacceptable risk**. Of the hazards listed in the previous step, those whose control is critical to safeguarding the hygiene and safety of the product must be identified. Tools such as the *Codex Alimentarius* decision tree can be used.

- **Step 8: Establish critical limit(s) (Principle 3)**

Critical limits must be specified for each CCP so as to ensure their control. These limits can be numerical values, sensory parameters or measurements. A single CCP can have several critical limits (for example, the application rate and pre-harvest interval for the use of plant protection products).

- **Step 9: Establish a system to monitor control of the CCPs (Principle 4)**

This involves conducting analyses or taking measurements, recording observations or saving data to ensure that the CCPs are being controlled. The procedures followed must be able to detect any loss of control.

- **Step 10: Establish corrective actions to be taken when monitoring indicates that a CCP is not under control (Principle 5)**

Corrective actions should be developed for each CCP in order to rectify any deviations. This involves immediate actions that the operator responsible for the step in the process must implement in order to meet the control requirements of their process. These actions must ensure that the CCP has been brought under control and provide for management of the affected product: destruction, downgrading or recycling, identification and traceability.

- **Step 11: Apply verification procedures to confirm that the HACCP system is working effectively (Principle 6)**

This step involves verifying the effectiveness of the system but also its effective implementation. Verification and auditing methods, procedures and tests may be used, including random sampling and analysis to determine whether the system is working correctly. It must also ensure that any amendments to crop protocols or processes have been fully taken into account, and that the HACCP plan is up to date. For example, it should be verified that plant protection products used have been approved under relevant legislation.

This could involve **auditing procedures combined with continual improvement** considerations.

- **Step 12: Establish documentation (procedures and records) (Principle 7)**

Establish a documentation system which takes into account the various documents, procedures, operating modes and records. This is the last principle, but by no means the least, since these are documents that can be presented to authorities and to customers if necessary.



## 5.3. Example application of the HACCP method: production and packaging of fresh mangoes

Although its application in primary production **is not mandatory**, HACCP identifies hazards and designs a food safety and quality management system that can be adapted to specific types of production and packaging of fresh fruit and vegetables.

**This case study will illustrate how a 'HACCP Plan' is established for the production and packaging of fresh mangoes.**



The production and packaging process for fresh mango as described in the case study may not reflect the specific processes used in all companies. It merely serves as a practical example to illustrate how the HACCP method can be implemented. The potential hazards identified in the study may not be the only hazards associated with mango production and packaging in particular companies.

### 5.3.1. Prerequisite programmes (PRP)

The first step when mangoes are produced and packaged is to ensure that the prerequisite programmes are in place. The main PRPs to implement include:

- Staff training/education
- Good Agricultural Practices
- Good Hygiene Practices
- Good Production and Packaging Practices
- Good Storage and Transport Practices
- Product traceability and recall

#### ☐ List of prerequisite programmes (not exhaustive)

- Staff training, information and/or education programme
- Plant protection strategy
- Register of plant protection treatments
- Procedure for cleaning and maintaining the premises, facilities and equipment
- Hygiene procedure for staff (employees and visitors)
- Water quality control programme (production and packaging station)

- Data sheets and/or labels for chemicals (detergents,
- Calibration procedure for pesticide application equipment
- Pest control procedure
- Register for monitoring the temperature of cold storage rooms
- Procedure for recall and withdrawal of non-compliant products

See attached example of an operating procedure for rodent control.



#### ❑ Verification and control of PRP implementation

The implementation of PRPs should be permanent, and the procedures to control and verify their implementation must be available and applied.

See attached checklist for the verification and control of PRPs.

### 5.3.2. Implementing the HACCP method

#### ❑ Step 1: Setting up the team

In order to have skilled human resources able to provide the necessary information at the different stages of the production and packaging process, the HACCP team may be composed of:

- a site manager
- a quality assurance manager (team coordinator)
- a packaging station manager

The quality assurance manager will need to have been trained in HACCP and have sufficient knowledge about the principles and steps involved in its implementation.

#### ❑ Step 2: Key characteristics of fresh mango

Appearance: according to the data sheet standard (class, grade etc.)

Storage and shipping conditions:

- removal from the fields to the station by truck;
- temperature: 10-12 °C;
- shipping by air or boat.

Packaging: 4 kg and 6 kg boxes.

#### ❑ Step 3: Identifying the intended use of the product

The mango is sold on the fresh fruit and vegetables market.

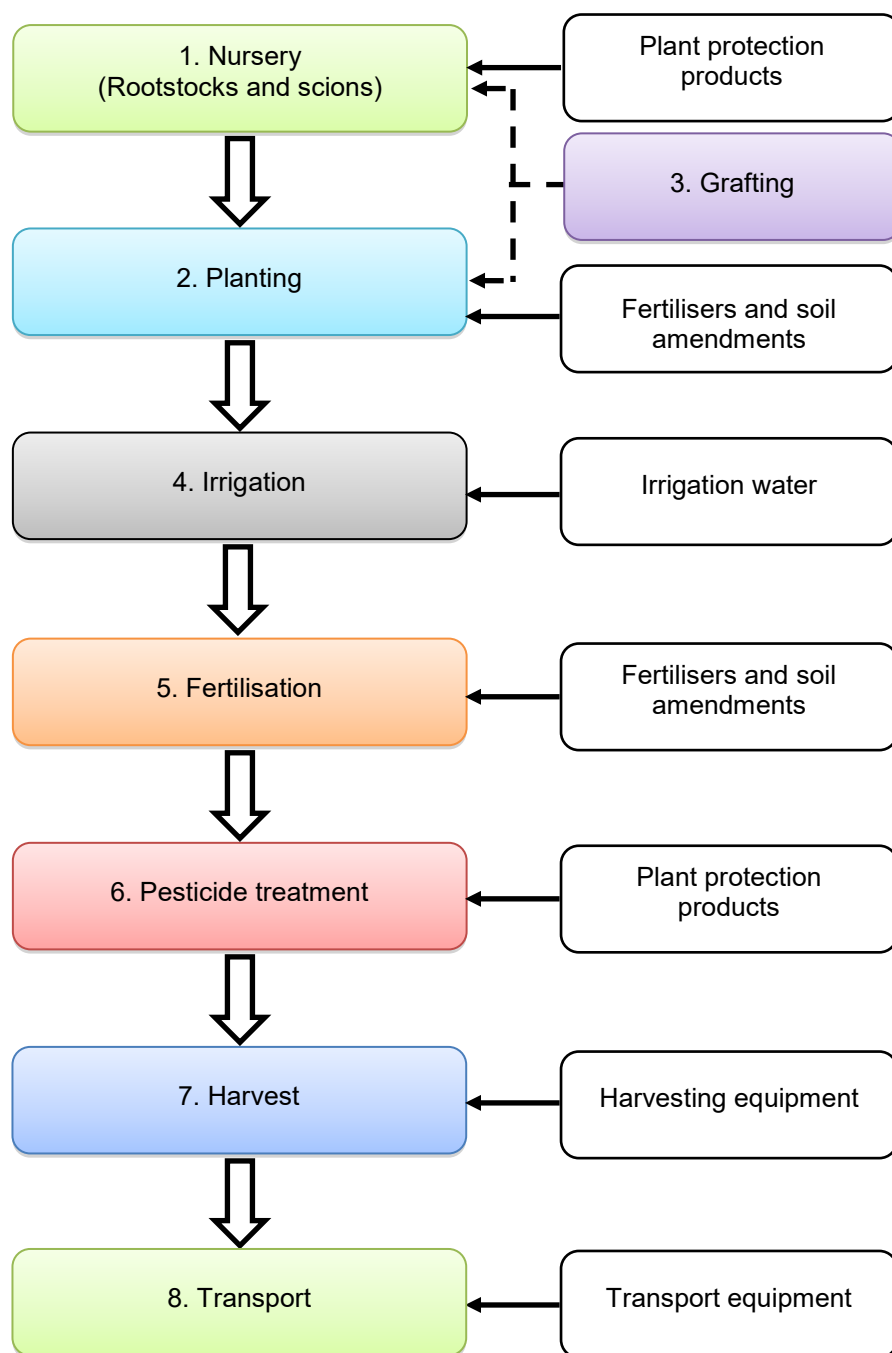
#### ❑ Steps 4 and 5: Construction and on-site verification of the flow diagram

The flow diagram shows the stages of field production and packaging of the mango at a packing station. The shipping process does not fall within the scope of the study.

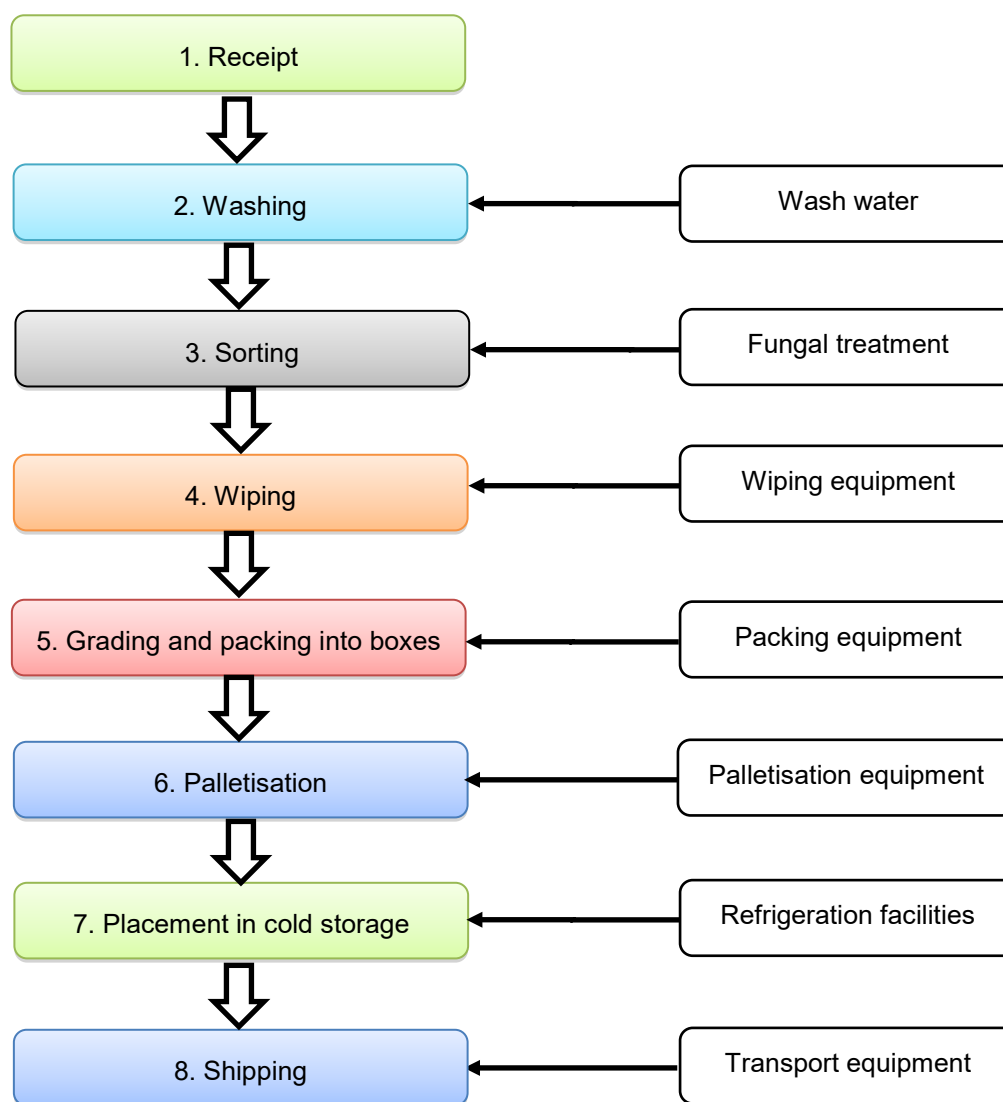
The production and packaging process flow diagrams are described below:



➤ **Fresh mango production process**



➤ **Fresh mango packing process**



❑ **Steps 6 and 7: Hazard analysis and identifying Critical Control Points (CCP)**  
(Principles 1 and 2)

Using the production and packaging flow diagrams, the potential hazards (chemical, microbiological and physical) have been identified at each stage of the process and the control measures to be implemented have been specified.

The results are shown in **Table 1** below.



Table 1: Hazard analysis and CCPs (Principles 1 and 2)

1. Production process						
Step in the process	Potential hazards introduced, controlled or increased at this step		Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column) <sup>3</sup>	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan? <sup>4</sup>	Is this step a Critical Control Point (CCP)?
1.1. Nursery	Biological	No	No	No risk because of the long crop cycle before production	-	-
	Chemical	No	No	No risk because of the long crop cycle before production	-	-
	Physical	No	No	-	-	-
	Biological	No	No	-	-	-
1.2. Planting	Chemical	Yes	Yes	Soil contamination by heavy metals	Keep production sites away from sources of chemical pollution (industrial sites) Follow Good Agricultural Practices (choice of soil, depressed areas etc.)	No (PRP)
	Physical	No	No	No risk	-	-

<sup>3</sup> Justification based on the severity and likelihood of the hazard occurring.

<sup>4</sup> List of control measures to be implemented at this stage or at a later stage.

Step in the process	Potential hazards introduced, controlled or increased at this step	Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?
1.3. Grafting	Biological	No	No risk because of the long crop cycle	-	-
	Chemical	No	No risk because of the long crop cycle	-	-
	Physical	No	No risk	-	-
1.4. Irrigation	Biological	Yes	Possible contamination by pathogenic micro-organisms	Avoid using waste water and sludge Perform a microbiological analysis to ensure that the water quality is suitable	No (PRP)
	Chemical	Yes	Possible contamination by heavy metals	Avoid using waste water Perform a chemical analysis to ensure that the water quality is suitable	No (PRP)
	Physical	No	-	-	-

Step in the process	Potential hazards introduced, controlled or increased at this step		Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?
1.5. Fertilization	Biological	No	No	Negligible risk because of the long crop cycle before production	Avoid using human manure Follow Good Agricultural Practices	No (PRP)
	Chemical	Yes	Yes	Possibility of introduction of heavy metals due to poor quality or non-compliance with fertilizer usage requirements	Verify the fertilizer composition Follow the prescribed doses and modes of application	No (PRP)
	Physical	No	No	-	-	-
	Biological	No	No	-	-	-
1.6. Plant health protection	Chemical	Yes	Yes	Application of non-approved products Contamination by residues on the fruit that exceed the Maximum Residue Level (MRL)	Use only approved products Use suitable application equipment (grading, maintenance etc.) Observe the dosages of active ingredients Observe Pre-Harvest Intervals (PHI)	Yes <b>CCP 1</b>
	Physical	No	No	-	-	-

Step in the process	Potential hazards introduced, controlled or increased at this step		Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?
<b>1.7. Harvest</b>	<b>Biological</b>	Yes	Yes	Contamination by pathogenic micro-organisms	Observe Good Hygiene Practices: clean harvesting equipment and accessories. Staff observance of hygiene rules	No (PRP)
	<b>Chemical</b>	Yes	Yes	Contamination by chemicals	Observe Good Hygiene Practices	No (PRP)
	<b>Physical</b>	Yes	Yes	Possible introduction of foreign particles (grass, sand, insects, etc.).	Observe Good Hygiene Practices	No (PRP)
<b>1.8. Transport</b>	<b>Biological</b>	Yes	Yes	Contamination by pathogenic micro-organisms	Observe Good Transport Practices and Good Hygiene Practices: cleaning and maintenance of vehicles, staff hygiene	No (PRP)
	<b>Chemical</b>	Yes	Yes	Contamination by chemicals	Observe Good Hygiene Practices: no chemicals in the vehicle, cleaning and maintenance of vehicles	No (PRP)
	<b>Physical</b>	Yes	Yes	Possible introduction of foreign particles (grass, sand, insects, etc.).	Observe Good Hygiene and Handling Practices: covered vehicles, careful handling of products	No (PRP)

2. Packing process						
Step in the process	Potential hazards introduced, controlled or increased at this step	Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?	
2.1. Receipt	Biological	Yes	Product contamination due to poor staff hygiene and/or poor hygiene in the receiving area	Observe Good Hygiene Practices: cleaning and maintenance of the premises where the goods are received and observance of the hygiene procedures by staff. Educate staff about compliance with hygiene and safety procedures.	No (PRP)	
	Chemical	Yes	Contamination through failure to observe Good Hygiene and Packaging Practices	Observe Good Practices for storing chemicals (pesticides, detergents etc.) and packaging. Educate staff about compliance with hygiene and safety procedures.	No (PRP)	
	Physical	Yes	Possible introduction of foreign particles (grass, sand, insects, etc.).	Observe Good Hygiene and Product Handling Practices	No (PRP)	

Step in the process	Potential hazards introduced, controlled or increased at this step	Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?
<b>2.2. Washing</b>	<b>Biological</b>	Yes	Contamination through use of unsafe water	Use drinking water Perform microbiological analyses of water.	Yes <b>CCP 2</b>
		Yes	Contamination of fruit due to non-observance of the wash water replacement frequency	Establish a procedure to change wash water.	No (PRP)
		Yes	Contamination of fruit by to washing equipment (bowls, brushes, sinks etc.)	Establish a cleaning plan incorporating materials and equipment.	No (PRP)
		Yes	Fruit damaged by scratches (fingernails, cutting rings etc.)	Educate staff about observing basic hygiene rules	No (PRP)
	<b>Chemical</b>	Yes	Chemical contamination by cleaning products (for example, soaps used to wash latex).	Establish a procedure to verify the types of products authorized for foodstuffs	No (PRP)
			Chemical contamination of fruit during fungal treatments	Establish a procedure for post-harvest processing (use of approved and/or authorized products, correct dosages of the active ingredient)	Yes <b>CCP 3</b>
	<b>Physical</b>	No	-	-	-



Step in the process	Potential hazards introduced, controlled or increased at this step		Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?
2.3. Sorting	Biological	Yes	Yes	Contamination of fruit due to poorly cleaned sorting tables	Use smooth-surfaced tables that are easy to clean Clean and maintain sorting tables regularly	No (PRP)
	Chemical	No	-	-	-	-
	Physical	Yes	Yes	Presence of broken glass or light bulbs in fruit	All lights at the station must have protective shields Prohibit the use of glass at the packaging station	No (PRP)
2.4. Wiping	Biological	Yes	Yes	Contamination of fruit due to the use of dirty cloths (towels)	Use cloths/towels that are clean or new Regularly change cloths/towels to reduce the growth of microorganisms due to humidity.	No (PRP)
	Chemical	No	-	-	-	-
	Physical	Yes	Yes	Presence of debris from wiping materials (cloths, brushes etc.)	Check and maintain wiping materials	No (PRP)

Step in the process	Potential hazards introduced, controlled or increased at this step		Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?
2.5. Grading and packing in boxes	Biological	Yes	Yes	Poor hygiene of staff and/or materials (grading, packaging etc.)	Educate staff about observing basic hygiene rules Observe the cleaning procedure Use suitable packaging that is not a source of fruit contamination.	No (PRP)
	Chemical	No	-	-	-	-
	Physical	Yes	Yes	Introduction of foreign bodies (personal belongings etc.)	Educate staff about observing basic hygiene rules and Good Packaging Practices	No (PRP)
2.6. Palletization	Biological	No	-	-	-	-
	Chemical	No	-	-	-	-
	Physical	Yes	Yes	Presence of metal parts in the fruit boxes (nails, staples etc.) inside the pallets.	Educate staff about observing basic hygiene rules (observing prohibitions)	No (PRP)



Step in the process	Potential hazards introduced, controlled or increased at this step	Is the hazard likely to occur?	Why (rationale for the decision taken in the previous column)	What measures should be taken to prevent, eliminate or reduce the hazards addressed in the HACCP plan?	Is this step a Critical Control Point (CCP)?
<b>2.7. Placement in cold storage</b>			Contamination of the pallets in dirty cold storage rooms	Implement the cleaning plan, including regular cleaning of cold storage rooms	No (PRP)
	<b>Biological</b>	Yes	Refrigeration defects (rotting due to non-observance of temperature procedures and/or interruption to the cold chain and/or damaged temperature sensors)	Display temperature guidelines at the entrance to the cold storage rooms Maintain the cold chain Perform calibration, maintenance and control of the temperature sensors	No (PRP)
	<b>Chemical</b>	Yes	Chemical contamination of fruit due to disinfectants for the cold storage rooms	Use authorized disinfectants suitable for foodstuffs	No (PRP)
	<b>Physical</b>	No	-	-	-
<b>2.8. Shipping</b>	<b>Biological</b>	Yes	Dirty or poorly cleaned containers.	Implement the cleaning plan, including regular cleaning of the transport containers	No (PRP)

❑ **Steps 8 and 10: Establishing critical limits and CCP monitoring procedures**  
(Principles 3, 4 and 5)

For each CCP identified, critical limits, monitoring procedures and corrective actions to be implemented in the event of deviation have been established

The results are shown as an Annex in **Table 2**.



Table 2: Critical limits (Principle 3), monitoring measures (Principle 4) and corrective actions (Principle 5)

Step in the process / CCP	Nature of the hazard	Critical limits	Monitoring procedures			Corrective actions
			What	How	Frequency	
1. Production process						
1.6. Plant health protection CCP 1	Chemical	Maximum residue levels (MRL) for pesticides exceeded	Approval of the product Observing usage instructions (application techniques and dosage, PHI etc.)	List of approved products Observing the chosen application technique/application rate/PHI	At each application	Plant health protection manager  Implement the procedure in the event a MRL is exceeded Train staff in Good Plant Protection Practices
2. Packing process						
2.2. Washing CCP 2	Biological	WHO standards: undetectable <i>E. coli</i> in a 100 ml sample. Total Coliforms	Color and cleanliness of the water Frequency of refreshing the basin water	Visual appearance Packaging planning	Each lot of mangoes	Refreshing the basin water Second wash of the affected lot

Step in the process /CCP	Nature of the hazard	Critical limits	Monitoring procedures				Corrective actions
			What	How	Frequency	Who	
2.2. Washing (continued) <b>CCP 3</b>	Chemical	Maximum residue levels (MRL) exceeded for pesticides	Approval of the product Observing usage instructions (application techniques and dosage etc.)	List of approved products Observing the chosen application technique/dose	On each lot	Station manager	Implement the procedure in the event the MRL is exceeded Train staff in Good Plant Protection Practices



❑ **Steps 11 and 12: Verifying and documenting the management system**  
(Principles 6 and 7)

➤ **Verification**

The following verification procedures have been established. Internal audits of the HACCP system, including:

- Customer feedback in order to measure their satisfaction or any complaints.
- Pesticide residue analysis against MRLs on the mango at least once early in the season.
- Bacteriological analysis of wash water at the station early in the season.

➤ **Review of the HACCP system**

- At least once early in the season.
- In the event of a change to the production crop protocol and/or packaging process (pesticide approval, new facilities, new practices etc.).

❑ **Step 12: Documentation and records**

➤ **The following documents are kept in the archives:**

- List and data sheets of the plant protection products and detergents used
- Water analysis certificates
- Certificates for pesticide residue analysis on the mango

➤ **The following records are kept on file or in the archives:**

- Orchard monitoring register
- Register of plant protection treatments
- Register of fertilizer applications
- Register of calibration of pesticide sprayer
- Corrective actions undertaken
- Wash basin monitoring register
- Premises and facilities cleaning register

The results are shown as an annex in **table 3**.



Table 3: Verifications and records (Principles 6 and 7)

Step in the process (CCP)	Nature of the hazard	Verification of the activities	Records – Procedures
<b>1. Production process</b>			
1.6. Plant health protection <b>CCP 1</b>	Chemical	Verification of the list of approved products Verification of the register of fertilizer applications	Staff training file Register of sprayer calibration List of approved products Register of plant protection applications
<b>2. Packing process</b>			
2.2. Washing <b>CCP 2</b>	Biological	Microbiological analysis conducted in accordance with sanitary risk assessment Observance of the procedure to refresh wash water	Microbiological analysis results Washing basin monitoring register
<b>CCP 3</b>	Chemical	Verification of the list of approved products Verification of the register of fungal treatments	Action plan in the event of exceeding MRL Pesticide residue analysis results

## Appendices

### A.1. Example procedure for rodent control

#### 1. Purpose

The aim of this procedure is to describe the rodent control measures implemented.

#### 2. Scope

This procedure applies:

- To the packing station
- To the storage premises for the finished products, raw materials and packaging.

#### 3. Description

Rodent control consists of the following steps:

- Install rat traps according to the map of the premises (receiving, sorting, grading and packing areas, packaging storage area etc.)
- Identify the different traps using serial numbers on a map and lay the bait
- Ensure that the rat traps are well protected to avoid contamination of the products or staff
- Check the traps daily and ensure the bait is replenished as needed
- Enter the results of the captures in the table below:

Date	Trap number	Results	Comments	Inspector's signature

If using bait, ensure it is appropriate and is not a source of contamination for products or staff.

Quality assurance manager

Station manager

## A.2. Checklist for control and verification of PRP implementation

Training/education	Yes	No	N/A	Corrective actions
A staff training, information and/or awareness programme on food safety must be available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Each staff member must be trained in the good practices applicable to their role (Good Agricultural Practices, Good Hygiene Practices, etc.).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
At least one member of the supervisory staff must be trained in the HACCP principles and method	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Transport staff are educated about observing hygiene and safety procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Good Agricultural Practices	Yes	No	N/A	Corrective actions
The origin and nature of the grafts of the seedlings are known	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
The applications (pesticides and irrigation) carried out at the nurseries are known	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Pesticide applications at production plots are justified (based on plant health observations)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Pesticide applications are carried out in accordance with the requirements for operator protection, , the environmental requirements and based on the information provided on the label	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Chemical control	Yes	No	N/A	Corrective actions
All chemicals are kept separate from food products (either at separate storage premises or at a store away from the food)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
There are practical arrangements for ensuring chemicals are kept separate from the food.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
The material safety data sheets (MSDS) can be accessed for each chemical stored	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Disinfectants used are approved and suitable for food products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....

Good Hygiene Practices				
Cleaning and decontamination	Yes	No	N/A	Corrective actions
A cleaning plan involving regular cleaning of the cold storage rooms is available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
The cleaning and disinfection procedures for the equipment and facilities are available and documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
The cleaning and disinfection procedures are followed (implemented)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
A cleaning and decontamination schedule is available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
A schedule for cleaning the harvest crates is available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
A schedule for cleaning the vehicles transporting the harvested crops is available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Clean and/or new cloths (towels) are used and changed frequently	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Staff hygiene	Yes	No	N/A	Corrective actions
Written hygiene policies and procedures for staff, employees and all visitors are available and documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
The staff hygiene policies and procedures are observed by every person who enters the production or work area	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Hand washing facilities are available and accessible to employees	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Mandatory hygiene and safety warnings are displayed at appropriate places	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....

Water	Yes	No	N/A	Corrective actions
Written procedures for water purification are available and implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Microbiological and chemical analyses of the water are performed to test the potability of the water used at the packaging station	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....

A procedure for changing the sink water for washing the post-harvest mango is available and implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
<b>Waste management</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Corrective actions</b>
Written waste management procedures are available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
The waste has been classified and a collection, storage, recycling or disposal system exists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
<b>Pest control</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Corrective actions</b>
A pest control programme is available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Pest control is carried out by a qualified operator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Documentation of the pest control procedures is available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....

<b>Good production and packaging practices</b>				
<b>Supplies, facilities and maintenance</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Corrective actions</b>
The facilities are correctly installed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Maintenance schedules for the facilities are available and documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Schedules for calibrating production apparatus (pesticide application, irrigation etc.) are available and documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
A calibration, maintenance and inspection programme exists for temperature sensors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Smooth-surfaced, easy-clean tables are used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
All light bulbs at the station have protective shields.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Suitable packaging that is not a source of contamination for food products is used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
<b>Chilling and temperature control</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Corrective actions</b>
The temperatures of the mangoes in the cold storage rooms are maintained and monitored	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....



Good storage and transport practices				
Storage	Yes	No	N/A	Corrective actions
All products are stored in sanitary conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
All products are stored in areas with suitable temperature and humidity conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
FIFO-based stock rotation is observed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Transport	Yes	No	N/A	Corrective actions
The products are transported in customized refrigerated trucks/vehicles/containers, in compliance with hygiene and safety conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
Traceability and recall	Yes	No	N/A	Corrective actions
A traceability system in order to identify and trace the origin of the products is available and implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....
A documented recall procedure to manage the withdrawal of products if necessary is available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	..... .....



# Chapter 6

## **Establishing a FSMS (Food Safety Management System) in a company**

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## 6.1. Usefulness and evolution of 'quality approach' concepts

### 6.1.1. Quality and non-quality

Quality is defined as *"all the characteristics of a product that fulfil customer requirements"* and cited the terms used to refer to quality in international standard ISO 9000:2000.



The concept of quality has evolved over time and the meaning given to this word generally depends on the context in which it is used. We have seen that, for food, there are multiple components of quality, that they have increased considerably and that they depend on the product or service concerned. Food quality requirements do not relate solely to the 'food safety and plant health' aspects of a product, but also to its mode of production, appearance, taste, packaging, and to related services (e.g. delivery times, product information or product history).

Practice has also given a common-sense meaning to 'quality', which is the opposite of a product 'defect', namely as regards non-observance of regulatory or commercial requirements (e.g. exceeding an MRL). What matters are the gaps in expectations: this is what we refer to as 'non-quality'.

The greater the demand for quality, the less the defect will be tolerated.

#### 'Quality' depends on our individual perceptions!

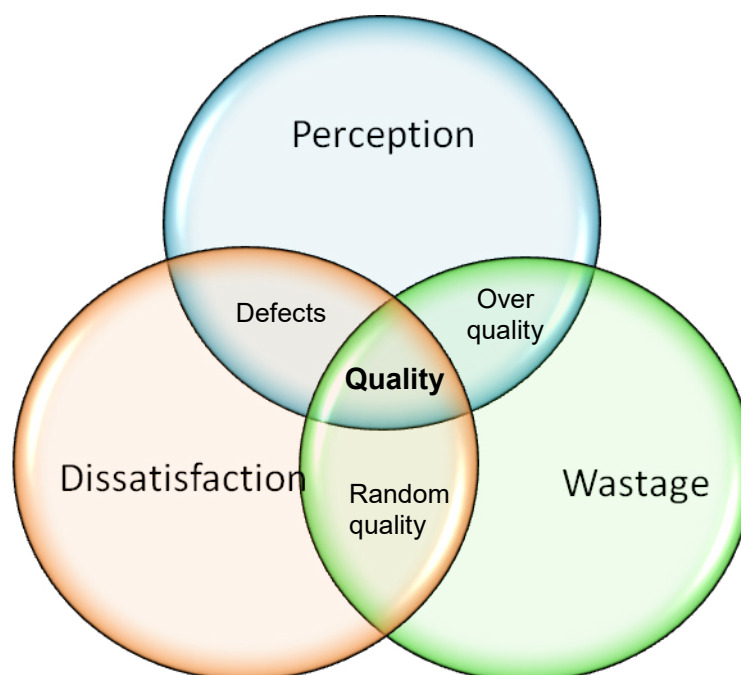
We can identify **several perceptions of quality**, both from the customer's perspective and from the supplier's perspective (Doucet, 2005):

- The quality the customer (implicitly or explicitly) desires.
- The quality specified by the conditions, contract, commercial specifications etc.
- The **objective characteristics** of the product, defined by its performance measured against the specifications (e.g. residue levels < MRLs).
- The **quality perceived by the customer**, which takes into account the customer's subjective assessments. This 'perceived quality' is a decisive for customer loyalty and image.
- **Quality defined by the manufacturer, which often differs significantly from the above definition of quality**, since it is very difficult for the manufacturer to put itself in the customer's shoes. Aspects considered details by the producer may be of particular importance to the customer.

In fact, the most important criterion is **'value for money'**. For producers, quality becomes a relative achievement: in order to sell, they must fulfil customers' expectations, and if possible do so better than their competitors, at the same price or less. We cannot

therefore separate the notion of quality from its commercial context. The opening up of borders has created ruthless competition between suppliers; customers often have huge freedom of choice and their choices will dictate the survival or failure of some suppliers.

**Quality comes at a cost.** To return to the Euler diagram introduced in chapter 1, we can say that for a company, 'quality' will only be found where all three circles intersect: this is **controlled quality**.



Food quality requirements have increased with the **growing complexity of sector and market organization**. The expectations of wholesalers who supply supermarket chains bear little resemblance to expectations in eras when the producer would sell their products themselves at a weekly market stall.

The greater the number of players in the food chain, the greater the risk of 'defect'. In the event of a crisis, this has multiple consequences which can lead to legal action and compensation. There is less and less tolerance of incidents and companies must now control a multitude of risks. This demands ever more advanced management of each of their basic activities.

Controlling quality and reducing non-quality therefore requires the **use of increasingly sophisticated and effective methods**, since the goal for a company is now as much to provide a 'quality' product (meeting expectations) as to do so at the lowest cost and while effectively managing all identified risks.

The **company must therefore adopt a strategy and implement a 'quality approach'** in order to prevent and reduce non-quality and ensure all requirements are **continuously** being fulfilled. This also implies that a **'continual improvement strategy'** is adopted by the company.

In order to achieve this goal, the company's **activities must be organized** as a **coherent whole**, a quality management '**system**': **food safety and plant health management** will need to be addressed by measuring the performance of the system in place, and by assessing the suitability and effectiveness of the control measures adopted as regards the 'quality level' desired by the producer and the 'risk level' tolerated by its customers.

**This is the aim of any Food Safety Management System (FSMS).<sup>1</sup>**

**The outcome of the FSMS will be 'quality assurance':** obtaining the desired level of quality safely in line with the accepted risks. In simple terms, this is about giving the consumer a guarantee that the product will be 'safe to consume'.

### 6.1.2. Definition and evolution of quality control concepts

There have been many discussions about the concept of quality since the industry's inception. Numerous approaches and methods<sup>2</sup> for managing product quality have therefore gradually been developed. These include:

- quality control (1940-1955);
- quality management (1955-1970);
- quality assurance (1970-2000);
- quality management (since 2000).

#### ❑ Managing quality through quality control

As its name suggests, this is about 'controlling' the quality of products at the end of the process (e.g. after harvest, after packaging) to be able to 'sort' the lots of products that are compliant or non-compliant. According to this concept, 'quality control' consists of:

- **measuring** one or more characteristics of the product,
- then **comparing** the result against a reference standard (criteria) to
- **decide** whether the product is **compliant**.

This (historical) strategy is costly (and increasingly expensive, as requirements for total absence of defects increase) and it has proven very unreliable: it includes a significant risk of error. The basic origin of these errors is twofold:

1. **Sampling limitations:** since it is impossible with large production volumes to inspect all products, inspection is only carried out on **a sample**. Sampling has two major limitations:

<sup>1</sup> Referring to ISO standard 9001:2000, we prefer to talk about QMS – Quality Management System – to describe the system governing the company's activity.

<sup>2</sup> A range of methods is used to manage quality problems. Many of these are seldom applied in the field of fruit and vegetable production, even in the agri-food sector (e.g. 'Kaizen' quality circles or small steps, benchmarking, re-engineering, management by objectives, the EFQM model, the Six Sigma, etc.). Other tools, meanwhile, are used regularly, such as: the Deming wheel, the Ishikawa diagram or the Pareto chart.



- the less one wants to run the risk of error (clearing a non-compliant product), the larger the sample must be;<sup>3</sup>
- inspection of a sample will only be representative if the batches inspected are relatively uniform, which is not necessarily obvious with fruit and vegetable products whose production conditions can vary greatly and rapidly over time.

2. **Measuring tools:** inspections involve the purchase, maintenance and regular checking of measuring devices.<sup>4</sup> It should be noted that, given the cost of the facilities and of maintaining them, very few companies are able to measure parameters as important for compliance as heavy metal content or nitrate or pesticide residue levels. The vast majority of in-company inspections are documentary and visual inspections, which are important but insufficient for guaranteeing quality. Many other measures are in fact only 'verification'; inspections have not been performed against certified standards or under sufficiently meticulous conditions (e.g. 'inspection' of pH, often done without taking into account the temperature at the time of measurement or verifying the electrode).

A number of techniques are associated with this approach and there have been a number of developments: metrology, Statistical Production Control (SPC), control charts etc.

While the approach itself is obsolete, the inspection of facilities and of production remains essential but must be seen as one means for testing the performance of the FSMS.

#### □ The 'quality control' approach

This approach involves 'building' quality at the required level, ensuring that the various basic conditions are met. These conditions, grouped into **five key categories**, are essential for obtaining quality (if one fails, quality will be variable):

- competent and trained **manpower** (staff) implementing the relevant procedures;
- appropriate **methods of work** described in detail in accurate, verified and up-to-date documents available at the place of performance;
- **materials** selected to fulfil the intended use;
- suitable **machinery** (equipment) that is verified and maintained;
- a suitable **milieu** (working environment and conditions).

This approach is based on the Ishikawa diagram, or causal diagrams.

<sup>3</sup> The producer is obliged to use a calculation to verify that the sampling rate (the number of samples to take) will not interfere with the method of taking the sample (where there are low numbers of products), and also to use sampling techniques whose effectiveness has been demonstrated for products whose size, density and shape may vary (melons, pineapples, lychees and cashews cannot be sampled, for example). We shall return to the risk of error during inspections in Chapter 7.

<sup>4</sup> 'Metrology' aims to ensure the reliability of measurements. Aspects to bear in mind are the accuracy of the measurement, the allowed tolerance, the measurement range, the accuracy of the device used, the maintenance over time of the device's accuracy and calibration.



### ❑ The 'quality assurance' approach (ISO 9000:1994)

Quality assurance is a systematic approach in which provisions are made in order to meet the following five essential requirements:

1. protecting operators' health;
2. consumer protection and information;
3. fair trading;
4. environmental protection;
5. inspection by the public sector (which ensures compliance with the above four requirements).

Each product has specific requirements under different regulations. The system in place aims to:

- satisfy the customer, getting it right first time;
- manage non-compliant products;
- propose actions to eliminate the causes of non-conformity;
- give customers confidence.

To achieve its aim, the system will review all the quality requirements for each phase of the production (and delivery) process, and will undertake to identify:

- the people who can accomplish this task, and their training;
- the person responsible for each task, as precisely as necessary;
- the different phases of each task, as precisely as necessary;
- the method and equipment used to complete each task;
- the interactions between the various stakeholders;
- verifications specific to the different phases.

This will also require verification of various documents.

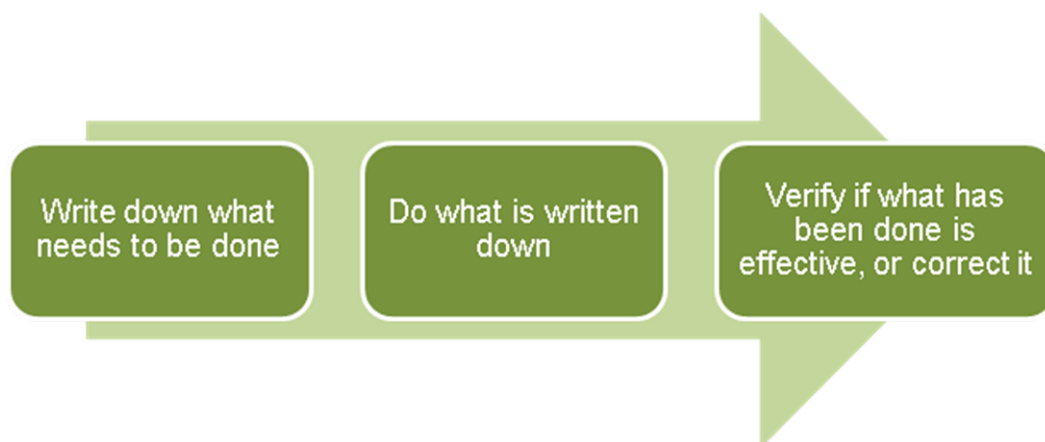
**Furthermore, the system in place must include its own monitoring system (self-evaluation) to ensure that everyone strictly adheres to the system requirements.**

The **three fundamental principles** of any quality assurance approach are as follows:

1. Record in writing what needs to be done to achieve quality
2. Carry out what is written down
3. Verify that this has been done and that it is effective.

These principles are combined with the principle of **continual improvement by correction** (in the event of non-conformity or non-effectiveness) and **by prevention** (taking action before non-compliance happens).

**Basic quality assurance diagram:**



In fact, no system can be an absolute guarantee of quality. Variable elements can be foreseen and neutralized through appropriate verification, but human error is still possible. It is therefore also essential to combine technical skill and knowledge of the objectives through a training, information and quality-focused policy.

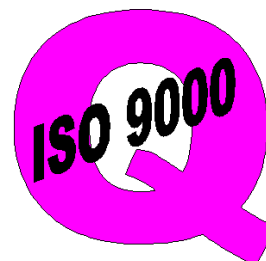
The provisions described above provide the company with **a means of achieving the required quality level with a certain degree of probability. They are specific to the company and cannot be transferred**, since they are tailored to its particular size, structure, production type, etc.

However, the basic conditions for achieving quality remain the same and correspond to the requirements of the ISO 9001 standard.

❑ **The ‘quality management’ approach (ISO 9000:2000)**

In this approach, **quality management is seen as one facet of overall company management**, which incorporates many aspects and areas of management.

Food safety management is just one of these areas and follows the same principles.



Based on the quality of the products and services provided, the quality management approach aims to increase the company’s earnings through a high degree of customer and stakeholder satisfaction. It is **based on the existence of three ISO standards on quality management**:

- **ISO 9000:** Quality management systems – Key principles and terminology.
- **ISO 9001:** Quality management systems – Requirements. This is the standard used as the basis for certification. It also serves as a reference for all management standards which all gradually lead back to it.
- **ISO 9004:** Quality management systems – Guidelines for improving performance. It provides guidance on the company’s internal organization.

In the ISO 9000:2000 standards, **eight principles** are identified to help companies to improve their performance and to fulfil their customers’ needs:

1. **Customer focus**  
*Organizations depend on their customers. They therefore need to understand their present and future needs, meet their requirements and strive to surpass their expectations.*
2. **Leadership**  
*Leaders give purpose and direction to the organization.  
They should create and maintain an internal environment in which people can become fully involved in achieving the organization's objectives.*
3. **Involvement of people**  
*Staff at all levels are the essence of an organization and their full involvement means their skills can be used to the organization's advantage.*
4. **Process approach**  
*A desired result is achieved more efficiently when resources and related activities are managed as part of a process.*
5. **System approach to management**  
*Identifying, understanding and managing processes together as a system improves the effectiveness and efficiency of the organization in achieving its objectives: this is the system approach to management*
6. **Continual improvement**  
*The continual improvement of the overall performance of an organization should be a permanent objective of the organization.*
7. **Factual approach to decision-making**  
*Effective decisions are based on analysis of data and information.*
8. **Mutually beneficial supplier relationships**  
*An organization and its suppliers depend on each other and mutually beneficial relationships enhance the abilities of both organizations to create value.*

The management approach of the ISO 9000:2000 standard includes requirements to be met and evidenced. These requirements are management tools to serve the company and its customers, rather than vice versa.

To establish a Quality Management System (QMS) designed according to these principles, the company will implement an approach which includes:

- identifying the **needs and expectations** of customers and other interested parties;
- establishing the **quality policy** and **quality objectives** of the organisation;
- identifying and analyzing the **processes** and **responsibilities** necessary for achieving the quality objectives;
- identifying and providing the appropriate **means/resources** necessary for achieving the quality objectives;
- defining and implementing methods for **measuring the effectiveness** of each process;
- identifying ways to manage and **prevent occurrences of non-conformity** in order eliminate their causes;

- establishing and applying a **continual improvement process** for the quality management system.

*This approach can be seen as being part of Food Safety Management and represented as follows:*



**This is the approach that we recommend for establishing an FSMS at a horticultural company** (despite its drawbacks outlined below), **and we will explain the steps to be followed.**

This 'ISO-based' approach to the FSMS has **advantages**, such as reference to a management method considered to be the most widely used and most internationally recognized,<sup>5</sup> the fact that this approach enables the company's activities to be better formalized, and particularly the fact that it leads to the possibility of system certification. This is a good method for defining the company's objectives and organisation.

But there are also **significant drawbacks** that should be kept in mind and avoided when implementing the FSMS. The most significant drawback is that **it requires a certain 'formality' which is not in fact always absolutely necessary**: a quality policy, quality manual, management reviews. If poorly conceived, misunderstood or

<sup>5</sup> In practice, however, the number of companies, particularly SMEs and micro-businesses, with ISO 9000 certification is very low, even in Europe (just a few per cent of all companies, but these are large organisations which due to their size are able to impose their modes of operation on the markets).

misused, this formality may create a rigid system **that is too cumbersome** to manage, ill-suited to the size of the company and sometimes not fully accepted by staff.

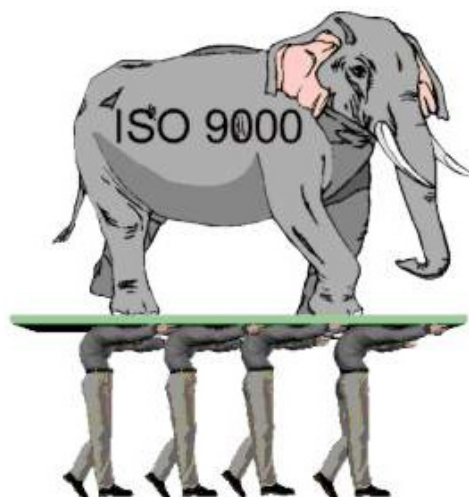
**Such a management approach must therefore always be implemented as part of overall 'quality approach' objectives, avoiding unnecessary bureaucracy!**

*Remember that most of the 'elephants' in this approach have disappeared: a system that is too cumbersome will eventually die of its own accord, due to time constraints, lack of resources and lack of motivation!*

*It has also been found (Doucet, 2005) that in industrialized countries:*

- *the number of ISO certifications decreases over time;*
- *it is the most poorly organized companies and those which have a strong need to formalize their operations that most often apply the ISO 9000 standards.*

*Certification is neither an end in itself, nor an obligation!*



## 6.2. Principles of establishing an FSMS in a company

### 6.2.1. Why set up an extensive FSMS?

Quality approaches are **initially voluntary** and allow suppliers to differentiate their services and inspire confidence in their customers.

However, some customers now require producers to follow a '**quality standard**' and obtain '**certification**' of their quality management system: **the assessment must now verify 'conformity' with the standard**, rather than the company's ability to provide quality products and services!

**The quality approach enables in-depth improvements to be made in order to meet the requirements of a standard. Certification also allows them to enhance their commercial standing.**

The requirements of buyers, importers and distributors are many and varied (see also Chapter 8):

- **market access requirements:** marketing standards, compliance with food safety standards, pesticide use and compliance with MRLs, crop protection and control of pesticides, use of GMOs etc.
- **food safety requirements:** food and crop safety, hygiene, product traceability etc.
- **specific requirements of buyers/importers/distributors** for organoleptic quality (taste, smell, color, etc.), product presentation and labelling, environment and conservation of animal species, health, workplace safety, workers' social welfare, ethical values and company management.

These requirements are defined and described in the various quality standards. For example:

➤ **Specific safety standards:**

- GLOBALG.A.P.
- BRC
- IFS

➤ **International standards:**

- ISO 9000
- ISO 22000
- ISO 14001

➤ **Private standards or standards based on social and ethical criteria:**

- SA 8000



- ETI
- Fair Trade (e.g.: Max Havelaar)

➤ **Product standards for official signs of quality:**

- Organic farming

**Compliance with these standards** means, in the majority of cases, that a (private) inspection or certification organisation that is duly accredited and approved by the standards-setting bodies conducts **audits, inspections and/or controls** to certify the conformity of practices with the requirements of these standards.<sup>6</sup>

This is why it is often necessary for the company to implement a Quality Management System (QMS) whose '**scope**' is **broad**er than that normally required for managing food safety and plant health problems.

It is therefore normal for the company to include in its control measures those necessary to ensure compliance with the other quality 'dimensions', and to have provision for grouped audits/inspections!

The scope and complexity of the QMS will depend on the target markets, the size and complexity of the supply chain (including the nature of the company's links with producers), the number of identified risks, the type and form of the exported product.

A quality approach can certainly exist without being certified, just as certification can be obtained without having conducted a real in-depth improvement strategy, since certification is sometimes limited to verifying formal compliance. In these circumstances, certification often appears quite rapidly to be of little commercial value and to fuel customer distrust.

### 6.2.2. Advantages of an FSMS in a company

Adopting a 'management system' offers several advantages for the company, including:

1. Improving the **safety** of products:
  - meeting regulatory requirements for market access, controlled by the public authorities;
  - establishing a quality policy and setting quality objectives;
  - identifying sources of hazards and the factors that explain them, in order to decide which poses a threat (= risk) to food suitability;
  - having the means to prevent or eliminate these risks;
  - having the ability, in the event of a problem, to trace the history, destination or origin of the product.

<sup>6</sup> Since the market often requires a combination of standards (e.g.: Fair Trade and Organic), the number of audits is rising and costs are increasing, although combined audits are possible.

2. To improve the production of products of **consistent quality**:
  - to continually improve the effectiveness of the management system;
  - to meet the requirements and objectives of the company;
  - to reduce the number of defective products.
3. To provide customers with **quality assurance**:
  - to meet market requirements;
  - to improve customer satisfaction.
4. To give the company's staff members **more confidence and pride** in performing their tasks:
  - to better define the tasks and responsibilities of each staff member;
  - to enhance their skills;
  - to promote compliance with good practices;
  - to involve staff in the continual improvement process;
  - to guarantee employment through the good economic health of the company;
  - to reduce staff turnover.

### 6.2.3. Defining a food safety policy linked to the company's corporate strategy

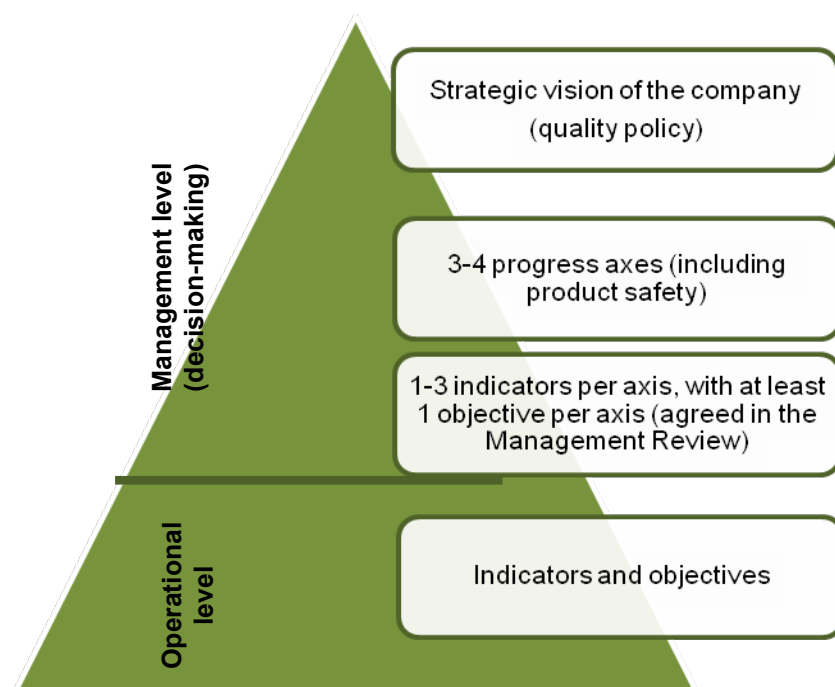
The food 'safety policy' for the company's products must include a definition:

- of the **goals** to be achieved;
- of **commitments** regarding the human, material and financial resources needed to achieve them.

It may be **integrated into a wider policy such** as the company's 'quality policy'. Any 'policy' **must be validated by the company's senior management** and shared throughout the organisation.

It should never be a decision taken only at 'middle management' level (for example: the quality manager, the station manager, the head of production etc.), who may not have a good understanding of the markets and/or ability to mobilize the necessary resources. This would eventually doom the project to failure. Conversely, the company's senior management must be involved in setting the quality policy, by incorporating it into its strategic vision. The senior management's 'quality policy' will often result in **seeking certification**, which often has the positive effect of mobilizing staff, overcoming resistance to change and providing a deadline to aim for, and which also enhances the commercial value of its efforts. The policy adopted should follow a pyramid scheme to facilitate its internal communication and understanding by everyone in the company:



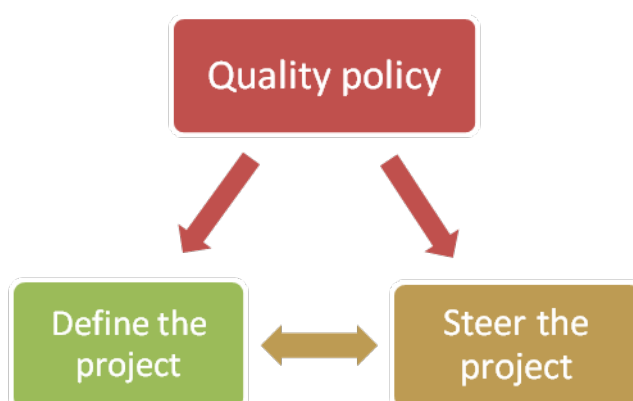


#### 6.2.4. Working with a 'Project Approach'

##### ❑ What are the benefits of the project approach?

This involves using a **work method** that can produce new, comprehensive and lasting solutions by developing the **partnership and involvement of the various stakeholders concerned** and in particular by clearly defining the **role of each**.

This includes two aspects: devising the project and steering the project.



- **Devising the project** is a strategic task and is the responsibility of senior management (assisted, for example, by the quality and traceability manager).

- **Steering** the project includes the following:
- clarifying the framework in which the project will be carried out (project parameters, steps, deadlines, indicators etc.);
  - **defining each staff member's role in the project** (hierarchies, steering group, project group, project manager);
  - clarifying the project's mission;
  - **choosing a method.**

From the outset, the responsibilities of each person involved in the project, and the operating rules between each 'group' and its mission, must be defined. They can be summarized as follows:

1. **'Hierarchies'** (e.g.: board of directors, senior management, chief financial officer), who will:
  - appoint/assign members of the company involved in the project;
  - clarify the level of resources available/allocated to the project;
  - ensure compatibility between the project's priorities and those of the company;
  - resolve any problems related to the project's development;
  - translate the project's achievements into the company's daily practices (validate, consolidate).
2. **The steering group** (e.g.: quality manager and director), who will be responsible for:
  - starting and closing the project;
  - validating the project's results at every step;
  - continuing actions, rolling back or stopping the project;
  - allocating resources to the project;
  - possibly reporting to senior staff.
3. **The project group:** everyone in the company included in the scope of the project should:
  - bring their professional experience to the project;
  - suggest/develop solutions (e.g.: control measures, improvements to the process, inspections, training, record-keeping, procedures to be put in writing, changes to practices, inputs to prevent, etc.);
  - be positive and participatory, championing the project to subordinates and external parties (e.g. small-scale producer partners);
  - manage and control use of resources.
4. **The project manager** (e.g. head of production) is the person who should:
  - lead and coordinate the project group;
  - manage conflicts within the project group;
  - report to the steering group.

### 6.2.5. The three essential 'players'

The company should **define and document the duties**, responsibilities and hierarchical relationships of all employees whose activities affect product safety and, more broadly, quality. It is advisable that a 'team' with multidisciplinary expertise be set up to manage the FSMS. The three key players of the FSMS are: senior management, the quality and traceability manager and the FSMS team. A number of aspects addressed during implementation of the HACCP also come into play here.

#### ❑ Organisation and responsibilities of management

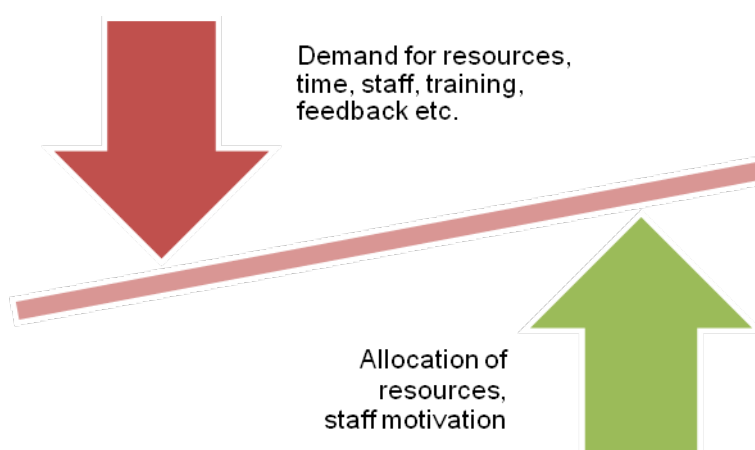
The company's senior management has responsibility for the product safety policy and the food safety management system, including its monitoring and record-keeping methods.

Senior management also undertakes:

- **to review** the FSMS to ensure its effectiveness, suitability and adequacy (also referred to as 'management review' under ISO 9000);
- **to allocate the necessary resources** for applying the control measures, reviewing and improving the quality management system. This point is crucial. It sometimes involves the allocation of significant resources that are not directly 'productive' (e.g. additional staff assigned to inspection), which is often perceived as too large a burden by senior management. It is the level of allocation of resources that offers the best measurement of senior management's commitment to meeting its own obligations (its quality policy).



**Senior management should provide on-going proof of its genuine commitment to developing and improving the FSMS:**



## □ Appointment of a 'Quality and Traceability Manager' (QTM)

A 'food safety' or quality and traceability manager will be appointed. This person should **report directly to senior management** or, as a minimum, report directly for aspects relating to food safety.

Given his duties, **this manager should not be placed under the authority of the staff he will be tasked with monitoring.**

He will therefore have a 'separate' place in the organisation chart. It is not normal for this person to combine the 'quality manager' role with a production role (e.g. packhouse manager or head of production).

It is the QTM who will handle the implementation and daily monitoring of the FSMS, ensuring that all actors in the production process correctly assume their roles and responsibilities as intended.

The QTM ensures that:

- the FSMS procedures are applied throughout the company;
- all pre-defined aspects are systematically verified and recorded;
- communication is effective in an emergency situation that would require immediate intervention;
- a traceability system is in place within the company and for supply;
- regulatory and commercial monitoring is organized to anticipate changing requirements.

This manager plays a key role within the company, ensuring that its food safety policy is well implemented through control procedures and records, but also by continually analyzing the risks throughout the supply chain and by communicating with customers, importers and producers.

**His skills should be commensurate with this key role.**

*The quality and traceability manager: a superhero!*

- *He reports directly to senior management*
- *He knows all regulations*
- *He understands customers' requirements*
- *He can anticipate market requirements*
- *He is highly skilled*
- *He is a good communicator*
- *He is persistent yet diplomatic*
- *He is highly motivated!*

**But...** senior management must allocate the necessary time and give the quality and traceability manager direct access to information and training!





## ❑ The team responsible for setting up and managing the FSMS

Alongside the quality and traceability manager (QTM), establishing a true 'team' that will be responsible for product safety and for the FSMS on a daily basis is strongly recommended.



*The team will ideally include senior managers, middle managers, and others who manage and supervise staff and whose roles have an impact on product safety. Typically, such a team will consist of two or three people, and up to six or eight depending on the size and complexity of the company. For example, for a small horticultural company: QTM, packhouse manager, head of production.*

All people who have knowledge and expertise of the processes and products should be included, in order to develop, apply and continually improve FSMS. Additional training is desirable.

The team which manages food safety as part of its routine tasks must:

- have clear objectives;
- have team management procedures;
- know the procedures to be followed;
- know which records should be made;
- know the frequency of record collections;
- have clearly defined responsibilities for each team member;
- provide feedback on the company's food safety policy in order to facilitate continual improvement.

This phase of setting up a team and the team's operating procedures is essential to the success of the approach. It is essential to take time to reflect on this in full consultation with senior management.

**It is often at this point that senior management truly realizes the scale of the FSMS project,** and the importance of their commitment to the success of the policy.

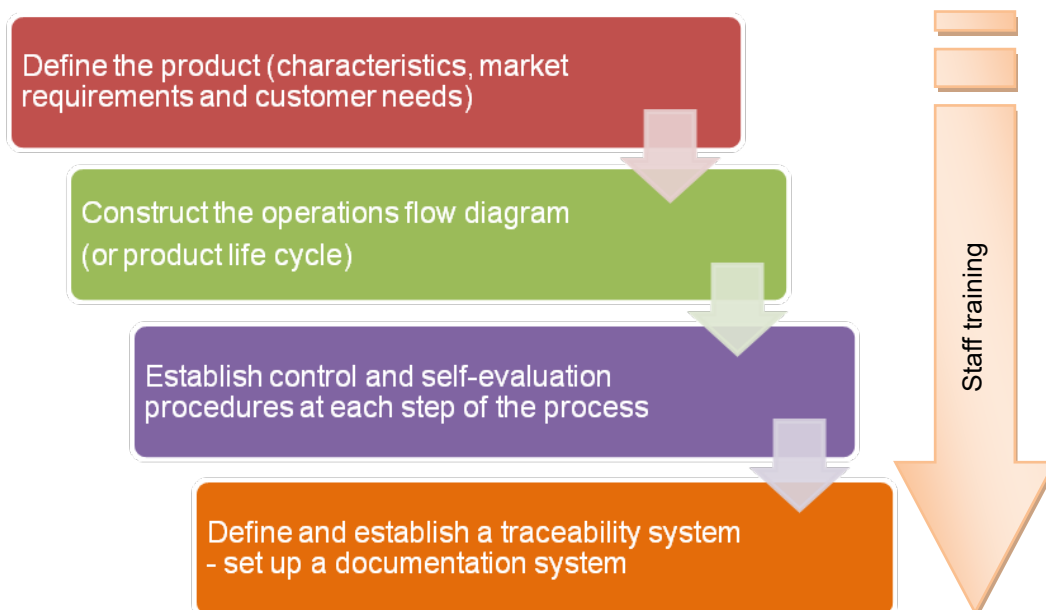
To help the quality and traceability manager to convince their senior management, **an external consultant can be very helpful at this stage.** However, everyone needs to be aware that:

- this external resource will only intervene during the FSMS implementation phase (e.g. leading the company until the time of certification). This mission has a limited duration;
- a consultant asked to act within a company can never be held responsible. Their role is that of '**facilitator**'. He is not part of the company's organizational structure (and is referred to more as a 'coach'), does not play a hierarchical role and **does not make decisions but simply proposes solutions.**

## 6.3. The key steps

### 6.3.1. Steps for setting up an FSMS in a company

Setting up an FSMS in a company requires a **four-step strategy**:



Gradually, as the project takes shape, **the need for complementary skills will become apparent**. A capacity building programme for operators at all levels in the company is therefore usually necessary and is one of the essential requirements. The alternative is to attract skills from outside the company by creating jobs.

We will return to each of these steps below.

### 6.3.2. Defining the product

To 'define the product', it is necessary to:

- Provide a full description of the product, specifying its **characteristics** (perishability, storage conditions, protective treatments, packaging, maturity at harvest, preservation conditions at the point of sale, etc.), **how it is used by the consumer** (peeled or unpeeled, raw or cooked etc.).
- Meet customers' needs, by answering each of the following questions:
  - Who are these customers?
  - What do consumers and buyers importing products expect? What do they want to know about the products?

- What key information do they expect to see?
- What are the product characteristics and elements to be highlighted?

**Examples of information sought by customers:**

- 1) *Plant protection products: product name/quantity/date and usage conditions*
- 2) *Fertiliser: product name/quantity/date and usage conditions/origin of organic fertilisers*
- 3) *Seeds or seedlings: supplier name/presence or absence of GMOs*
- 4) *Planting: type of soil disinfection/previous crop/date of planting*
- 5) *Irrigation: origin and quality of the water/quantity provided*
- 6) *Harvest: maturity/harvest date/quantity harvested*

Customers' needs are also taken into account in private standards.

- Meet regulatory requirements: identify and analyze regulations for the specific production type.

**Examples of information on fruit required by French regulations:**

- 1) *Maturity: in degrees Brix (% of sugar in the juice) at harvest*
- 2) *Qualitative characteristics of the lots sold: variety, category, grade and weight*
- 3) *Identification and origin of the product: lot number*
- 4) *Register of product quality and pesticide residue inspections*
- 5) *Harvest: maturity/harvest date/quantity harvested*

- Meet the specific requirements of the company (organisation, responsiveness). The data used throughout the production line should be highlighted. The collection, archiving and use of this data is the company's responsibility, in order to improve its overall functioning and relationships with its producers.

**Examples of useful information for improving quality management in the company:**

- 1) *Raw material quality on receipt at the packhouse (initial conformity check)*
- 2) *Cold storage duration and conditions: temperature, humidity, controlled atmosphere.*
- 3) *Performance of the grading system.*
- 4) *Customer destination of the despatched product.*
- 5) *Identification of persons involved in the processes: who conducted the initial conformity check, inspection of the finished products etc.*
- 6) *Treatment and follow-up of customer complaints: type of non-conformity, frequency, volume etc.*

### 6.3.3. Devise a flow chart or life cycle chart

#### ❑ Analysis of the life cycle of the product

A detailed analysis of the product's life cycle is the **starting point** for all work to build a product safety system.



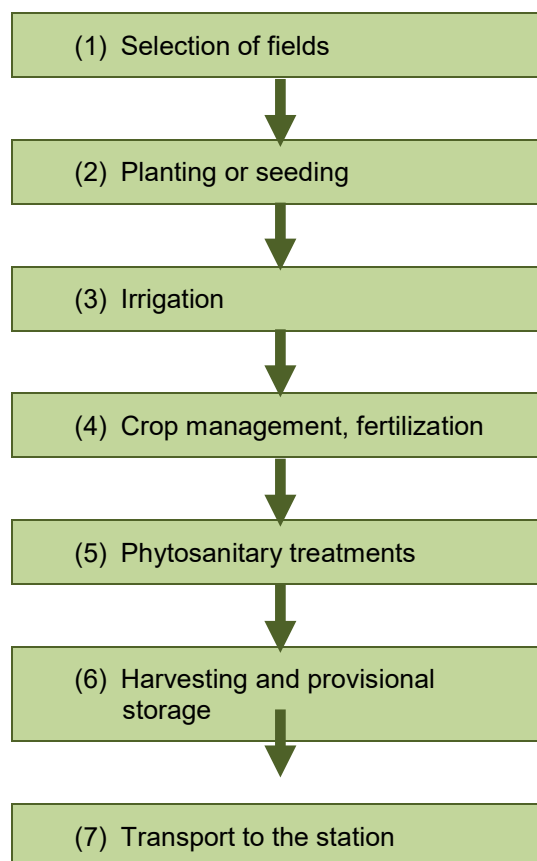
*The **life cycle of the product** describes the different 'stages' or 'operations' carried out from primary production to distribution.*

*It involves drafting a '**flow chart**' to represent the operations carried out in the company **in a logical sequence**.*

A product's life cycle is the central tool for food safety:

- for assessing the hazards, potential risks and identifying where control measures are needed, as well as the critical control points;
  - for establishing top-down and bottom-up traceability systems.
1. **Identify the main activities** carried out at the company.
  2. **Prepare a list** of all the different company activities and arrange them as a chart.
  3. **Number each activity** to help identify them and refer to them in the procedures and traceability protocols.
  4. **Identify coherent 'activity groups'**: field production (from field to packhouse), packing (from receipt at the packhouse to the cold store), storage and shipping. Each activity group may be regarded as a **process**.

**Sample flowchart of activities: group of activities involved in the primary production of fruit and vegetables**



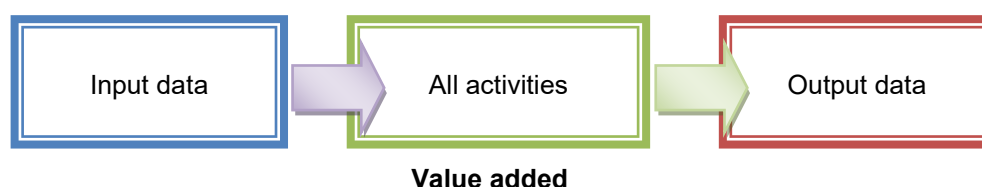
Each activity numbered 1-7 represents a **logical series** of self-contained operations, each with a **beginning and an end**. As a whole, they **give value to the product**. They are part of a **'process'**. This process can be called **'plant production'**

❑ **Processes and management using the systems approach**

The basic concept underpinning this approach is that of **'process'**, in line with ISO 9000.

➤ **What is a process?**

According to ISO 9000:2000, a process is a *'set of interrelated or interacting activities which transform inputs into output'*. It should be noted that a process aims to **add value to the product**.



*An important aspect of a process is its 'value added' or its 'target'. It is thus possible to measure this value added (indicator) and set a progress objective (target value).*

A process enables one or more activities to be carried out, in order to meet company objective(s), and to fulfil a customer's needs through the delivered product.<sup>7</sup> It must:

1. **Be repeatable:** the process can be repeated under the same conditions and in the same time. It can be followed and understood by all staff who operate or improve it.
2. **Be measurable:** it ensures that the product or service resulting from the process corresponds to the intended goal, and performance indicators are put in place to this end.
3. **Interact with other processes.** Thus, in the example cited above (the 'plant production' process), the production process requires several 'ancillary' processes (purchasing fertilizer, recruiting staff, maintaining the machines, etc.).

When establishing an FSMS it is important to **distinguish the processes that may impact on the safety of the other processes!**

➤ **Why describe the company's activities as a process?**

Processes provide a picture of the company's overall know-how. It is **essential to identify and describe them**, and to establish indicators so that they can be continually improved and any flaws corrected.

In the company, **different activities contribute to a single process.**

The description of a process includes the **following aspects**:

- giving a title to the process;
- defining its purpose and rationale;
- identifying the area(s) in which it is implemented;
- identifying the stakeholders or participants;
- identifying their roles;
- identifying the launch conditions;
- describing the actions chronologically: sequence;
- identifying information flows: data input, output;
- defining the conditions for ending the process;
- establishing potential interactions with other processes;
- identifying associated tools and documents.

The precise description of a process provides an '**identity card**' for the process. It is essential to steering the process. It makes it possible to determine the process outlines, interactions and particularly the operating procedures, in order to ensure control and draw up relevant performance indicators.

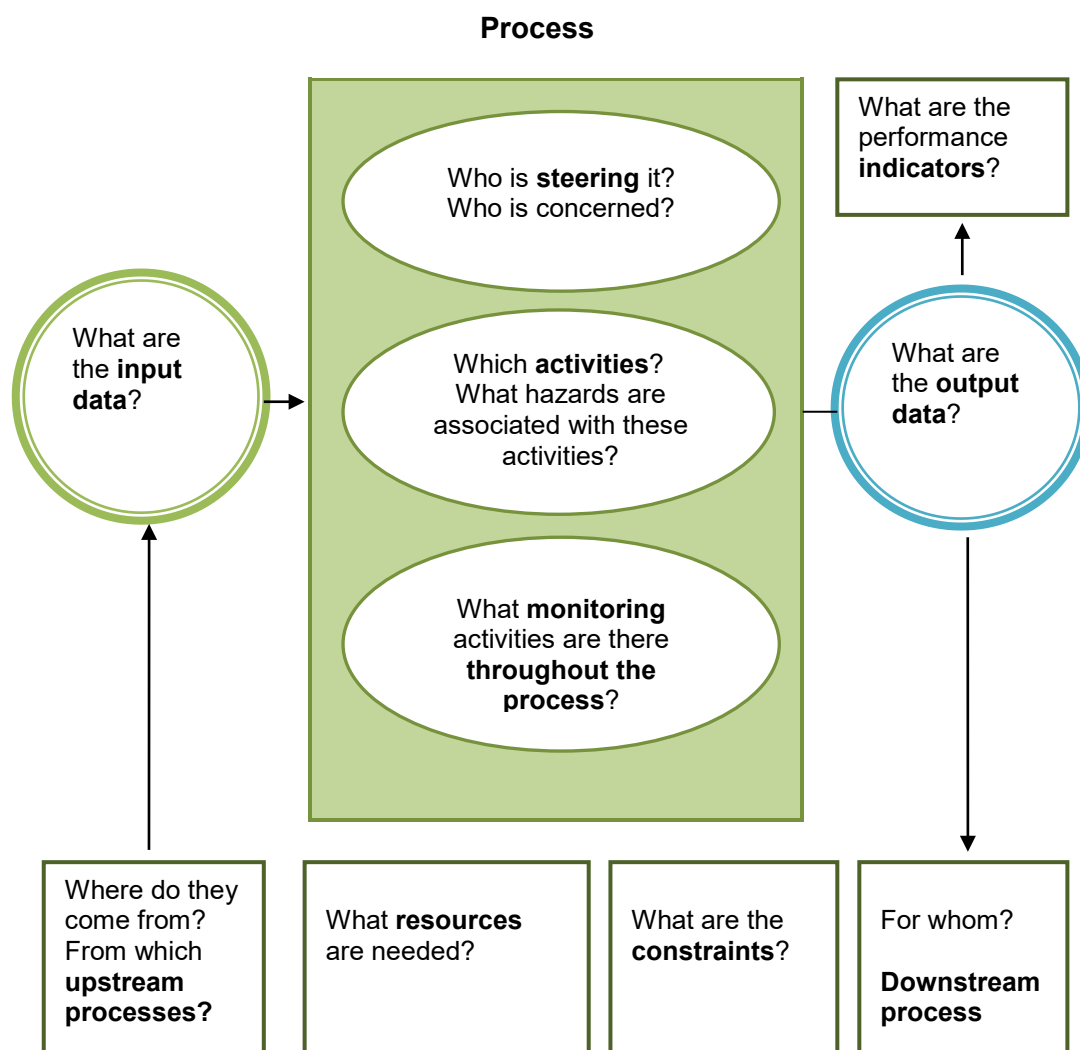
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<sup>7</sup> Processes (pre)exist in a company, whether or not there is a quality approach. If there is a quality approach, contrary to what some consultants might advise, the processes are not 'created' and, save for a major anomaly, are not changed at this point. It is inappropriate, even dangerous, to fundamentally change the processes at the same time as a certification. The quality approach is not that of '*re-engineering*', but a search for continual process improvement.





A number of questions must be answered in order to establish this 'card':



Based on the answers to all these questions, an identity card can be drawn up for each process. This will contain:

- the name of the activity manager;
- the activity (description);
- the type of document to use (e.g. manual, user guide, instructions);
- the type of records that will be kept during this activity.

This formalization will enable an '**Operating Procedure**' to be prepared on the basis of the process.

**Sample process flowchart (hypothetical):**

Who?...	... does what?	... how?/with what?
Crop manager	<pre> graph TD     A([Oval]) --&gt; B[Rectangle]     B --&gt; C[Rectangle]     C --&gt; D{Diamond}     D --&gt; C     D --&gt; E[Rectangle]           </pre>	Crop plan Market research Cost analysis
Greenhouse manager		Map of fields Instructions Field notebook
Supervisor, area manager		Instructions Field notebook
Quality assurance manager		Analysis procedure Data logging
Site manager		Registration of lots Instructions Stock movements register

Use the second part of the identity card to complete these tables. The flowcharts give a very simple description of the sequence of major steps in the process.

A company consists of a **series of interrelated processes**. The output data of a process 'A' becomes the input data of a process 'B'. **These interactions are very important**, as they form links between the different company processes, so they must be identified as fully as possible.

**It is in the interfaces, the 'border lines' between the processes, where hazards most often emerge.**

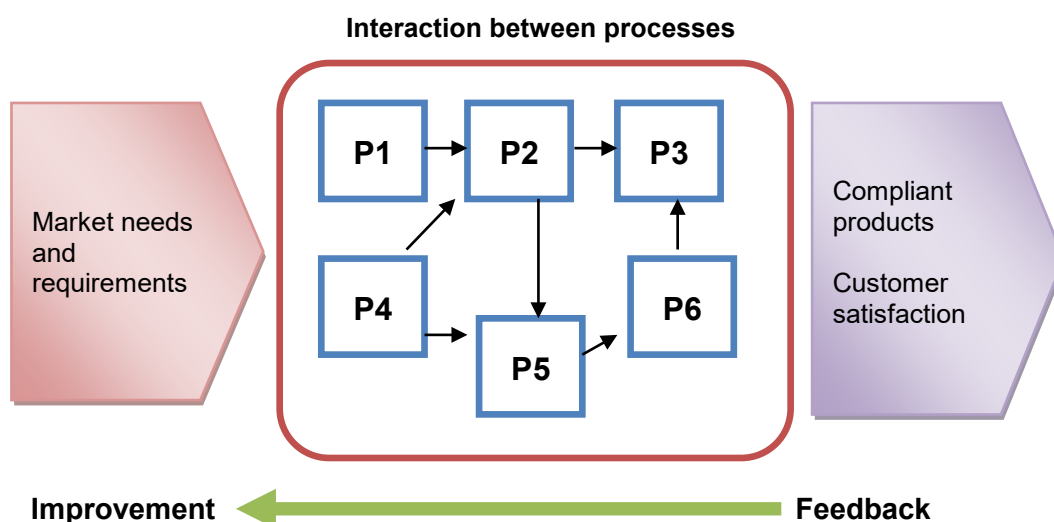
Control points must therefore be set at these interfaces.

➤ **A 'systems approach' to processes?**

For management of the food safety and quality control system to be effective, **the links between processes have to be organized and the different operations to be performed by a 'systems approach' organized**. The idea is to identify, understand and manage a set of interrelated processes that function as a 'system' and that help to achieve the goal (to produce enough products) and contribute to the effectiveness (produce compliant products) and efficiency (produce at a reasonable cost) of the organisation.

Processes in a company can be divided into several categories:

- **the organization's management processes**, including processes related to strategic planning, policy development, goal setting, communication, making the necessary resources available and management reviews;
- **resource management processes** (or '**support processes**'), including processes contributing to the provision of resources needed for the implementation processes;
- **implementation processes** (or '**operational processes**'), including all processes that can provide the expected results in the company;
- we also talk about **measurement, analysis and improvement processes** (or '**steering processes**') necessary for measuring and gathering data relevant to performance analysis and improving effectiveness and efficiency. These processes, which include measurement, monitoring and auditing processes, as well as corrective and preventive actions, **are an integral part of the management, resource management and implementation processes.**



*P1: plant production - P2: package - P3: export the products*

*P4: manage food safety and quality*

*P5: process (cutting) - P6: freeze and store the products*

Once all the processes have been mapped, it is helpful to identify the **company's key processes** which are essential to its smooth functioning. **When it comes to hazards, the major risks are generally found in these key processes.**

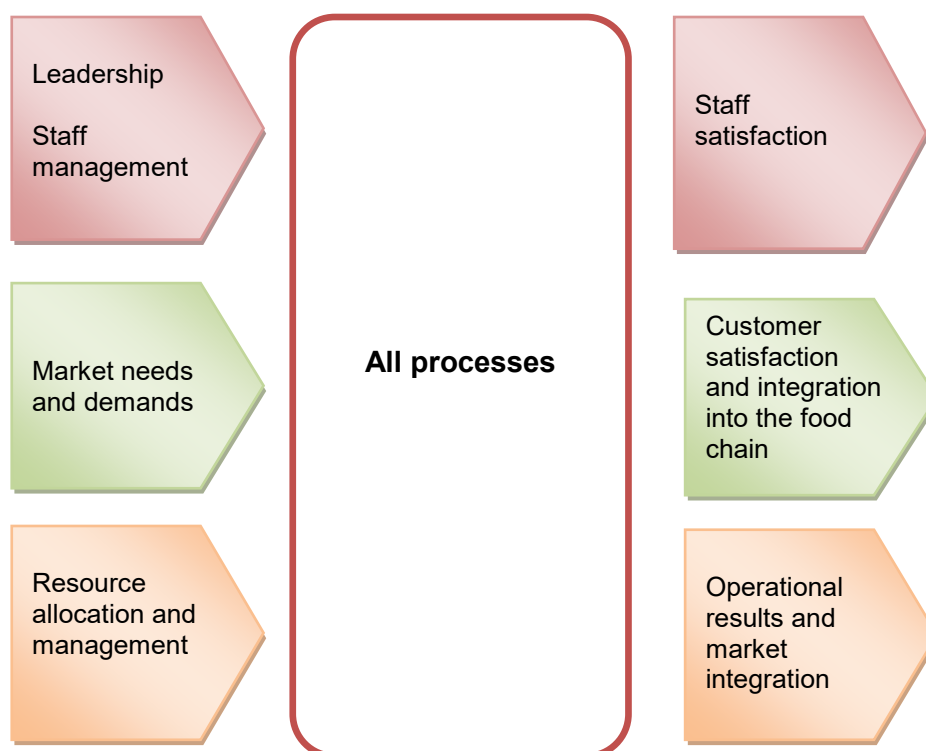
'Processes mapping' will require **group work**. It is advisable to describe the activities and processes with action verbs such as the verb 'package', rather than the word 'packaging': the latter would restrict the process solely to people working in the packaging area at the station, when this activity is part of the overall preparation for market involving several people working in other parts of the company, such as accounting, quality control, procurement, transport, etc. (support processes).

A manager will be assigned to describe each process, with support from the working group. They will report to the steering committee (or senior management).

Benefits of 'process mapping':

- the company is more apt to adopt a customer focus;
- it provides a shared vision of the key activities;
- it serves as a communication tool.

- **Processes are central to the company's overall organisation as part of an 'overall quality' approach**



**Examples of the types of processes required in a produce company applying a quality approach**

- **Management processes:**

- management review,
- controlling non-compliance, quality planning,
- documents and records management.

- **Support processes:**

- human resources management processes,
- facilities and equipment management processes.

- **Implementation process:**

- customer processes (listening to customers and customer satisfaction, dispute handling),

- production processes (risk management plan, product traceability, production monitoring and control, receipt of products),
- product purchase processes (selection, monitoring and evaluation of producers, receipt of products),
- processes for other purchases (selection and evaluation of suppliers, placing orders and receipt of supplies),
- grading and preparation for market,
- packaging processes,
- storing and shipping processes (cold chain management, monitoring product storage, preparing and shipping the products).

➤ **Steering and measurement processes:**

- data analysis and continual quality improvement,
- corrective and preventive actions,
- quality audits and internal inspections.

This list is given as an example and is not necessarily exhaustive.

#### 6.3.4. At each stage of a process, analyze(s) the hazard(s) and implement control measures

The **priority is to identify hazards** (biological, chemical and physical) **and to calculate the food safety hazards by using the HACCP system** (see chapter 5).

But **we must also consider all other risks of non-conformity** according to the objectives (environmental hazards, ethical hazards, etc.).

After identifying their causes, **control measures that are known to be effective and economically viable need to be put in place**. Traceability measures form part of such measures (see chapter 5).

#### 6.3.5. Setting up a documentation system

The 'documentation system' is the repository of all documents needed for managing the FSMS. It **formalizes expertise**, helps with **training new staff** and in particular with **controlling risks of non-quality**. It thus helps to clarify and structure the organisation, and more broadly the practices developed within the company.

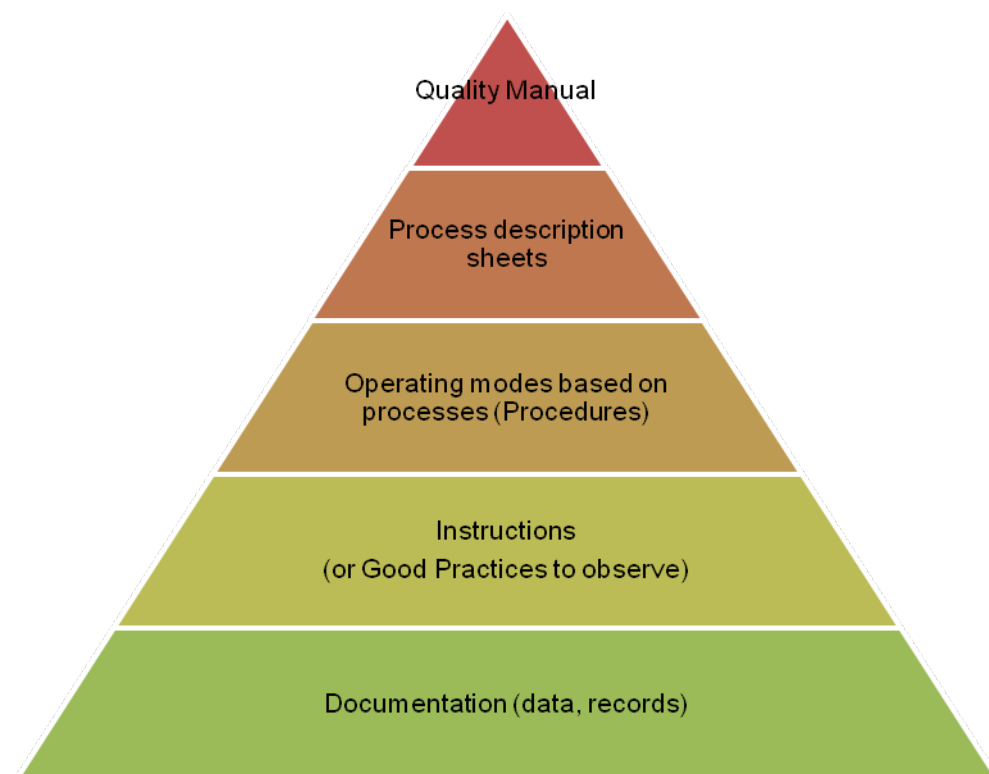
Each company must build its own quality documentation system, taking into account the complexity of its activities, its size and its staff's qualifications, including **their ability to handle written documents!** There is no sense in creating a written record if in the latter stages of the drafting process there is no dissemination or application of the written procedures and instructions.

##### ❑ The 'documentation pyramid'

**When starting to draft the documents, what is most difficult is to keep things simple to keep the company from drowning in a sea of documents. There is no**

**need to describe everything**, but simply to formalize the key elements of the quality management system in a way that is straightforward and suitable for its users.

The tendency is to represent the documentation system using a pyramid that moves from the **more general to the more precise**: the further down the pyramid we go, the more the number of documents increases and the more precise they are in their usage.



*For each document, it is necessary to clarify who validates the documents before they are disseminated, who manages and updates them, and how they are distributed.*

- The 'Quality Manual' is a document of some thirty pages describing the company's quality management system. It should be clear and concise, in order to reinforce the company's ability to meet its customers' expectations. It will contain the company's 'quality policy' declaration. **It is not always necessary to draft such a document**, but some certifications require it.
- The 'SE Guide', or self-evaluation guide, is a reference document that will be used by the company to establish its FSMS, including analyzing its processes and establishing its control procedures.

To establish the documentation system, proceed as follows:

- using the process mapping, describe the current status, verify it, correct as applicable and confirm. Write the identity card processes and their description;
- then select the procedures to formalize who describes the key activities of the process: who does what;



- finally, identify the operating procedures or detailed instructions to be formalized for describing certain tasks among the selected activities.

In an agribusiness company, a documentation system will ideally include:

- **Explanatory and descriptive documents:**<sup>8</sup>
  - the food safety management policy,
  - description of senior management's formal commitments,
  - system organisation: hierarchy and functional organisation charts,
  - internal regulations, if necessary,
  - life cycle charts and traceability charts,
  - a summary of procedures and instructions for risk control,
  - a summary of procedures, recording mechanisms and traceability instructions.
- **Procedures and instructions for risk control, and in particular the procedures for:**
  - non-conformity and how it is handled,
  - customer complaints,
  - product release,
  - tests on shelf life,
  - traceability procedures and instructions, particularly the product recall procedure,
  - verification procedures,
  - and so on.
- **Types of records such as:**
  - list of approved suppliers,
  - the actions taken during the operations,
  - list of the staff at work,
  - list of pesticides and other inputs authorized and used,
  - non-conformity and corrective action sheets,
  - customer complaint forms,
  - and so on.
- **A safety system documents management procedure.**

All documents in use must have been approved by senior management and/or the quality manager. They must include at least a title, a number, an issue date and a version number.

The documentation must also:

- be accessible by all those who need it, when and where they are working;
- be as simple as possible, tailored to the person using it, through its use of language, words, symbols etc.

<sup>8</sup> The 'Quality Manual' generally summarises the entire system.

- be accurate, and therefore updated as often as necessary;
- comply with current laws and regulations;
- maintain consistency between documents, without being verbose or contradictory;
- be known, used and assimilated by the people in charge of applying them, which entails:
  - **constant pressure** to utilize the current operating procedures, which are sometimes ignored in favor of personal knowledge ('*We know!*'), or even 'little notebooks' ('*I have my notes!*');
  - **periodic training and exercises** for operating procedures relating to rare situations, **particularly those relating to crisis management (withdrawal, recalls), since they will be used at stressful moments!**

### 6.3.6. Staff training

As recommended in the *Codex Alimentarius* and in European regulations, senior management must undertake to train and/or educate all their staff about direct and indirect contact with food products and about appropriate levels of food hygiene.

All company employees, **including seasonal and temporary workers**, must be made aware of the implications of poor food hygiene and the threat it poses to food safety.

**This also applies to other requirements, those which are not directly linked to food safety and quality but which must be met:** negligence by some staff members (e.g.: throwing away packaging, emptying dirty water tanks near a water source, working without suitable protection, etc.) may result in the loss of certification for all, not to mention the risks of pollution and poisoning!

Training needs should be identified **by analyzing staff skills and skill requirements**. The 'Training Plan' will be formalized and the training provided will be documented for use during the certification audits.

The **type and level of training** of the company's staff in product safety will depend largely on:

- vulnerability of the products to contamination (e.g. products posing a potential contamination risk, such as meat, fish and eggs, compared with plant products, whole products or peeled products, irrigated and non-irrigated products);
- the target market;
- the level of supervision in the company;
- the level of responsibility given (often depends on the previous point).

In analyzing and scheduling training, the following are distinguished (see also COLEACP Training Manual, *Techniques of training*):

1. **General skills: technical knowledge** that is particularly extensive and covers very diverse fields. These range from basic pre-requisites (e.g. literacy and numeracy) to technical know-how (educational background, boosted by continuous training during professional career, and/or experience, debates, quality circles, reading journals, websites, self-guided training, etc.). These can

be evaluated by a knowledge 'test' (oral questions, multiple choice questionnaire, set exercises, etc.).

2. **Operational skills:** this is more the 'ability to perform' an operation than knowledge as such. It means being able to carry out a technical operation effectively (e.g. harvesting, sorting, calculating doses, adjusting a device, etc.). These are assessed through on-site observation.
3. **Behavioral skills:** these are the ability to lead, to work in teams, to train others, to react in the event of problems, to suggest solutions, etc. **All too often neglected, these skills should be strongly reinforced for those in charge!**

The effectiveness of the training and awareness programmes should be measured periodically to ensure they are appropriate. Special attention needs to be paid to the time allowed for training and especially the methods used according to the type of skill concerned, and the training programme should be adjusted as necessary.

**Examples of training topics according to roles at the company:**

Role	Training topics
Senior management Company head	Strategic analysis Market research Implementing an FSMS to access European Union markets Project management Company change management
Quality and traceability manager	Basic principles of food hygiene Quality control and HACCP Product traceability, procedures and records Market and customer requirements Documentary review Group leadership, communication skills
Station inspectors	Basic principles of food hygiene Application of procedures and record keeping Handling and preservation of products
Packhouse staff	Training in basic hygiene Health protection Product sorting/grading technique Maintenance of premises and equipment Taking measures
Agricultural workers	Basic hygiene training Cultivation techniques Application of plant protection products Recording field data Harvesting

## Appendix: Aspects of the documentation system

### A.1. Procedures

Procedures are documents that describe the organizational rules and/or processes defined within the company, which formalize '*who does what*' in a simple way. In a general sense, **procedures can be defined as written and formal organizational rules**, compliance with which ensures that the system functions normally. The procedure offers a general description of how to conduct one or more of the activities of a process.

Under ISO 9000, the company has at least **6 mandatory procedures** focused on how the quality management system functions: *document management procedure, records management procedure, procedure for handling a non-compliant product, internal quality audit, procedures for corrective actions and preventive actions.*

#### ❑ How should a procedure be prepared?

##### ➤ Firstly **define**:

- What procedure model is chosen?
- Who drafts and verifies the documents' content and validates application of the procedures?
- Who disseminates the procedures and how?
- Who updates these documents and how?

##### ➤ Then, **write the procedures in 4 stages**:

- describe the current status;
- describe what should be;
- describe what will be;
- confirm.

##### ➤ **Clarify** the purpose of the procedure and its purpose before embarking on the '*who does what*' description.

##### ➤ In the content, **use only permanent information**, i.e. focusing on actions to be repeated and for which standardization of methods is needed.

##### ➤ **Adapt and review** the procedure according to changes in the system: this determines its credibility and effectiveness.

#### ❑ Which procedure?

##### ➤ **A procedure should be:**

- **compatible** with any other procedure or practice. A central coordination body is therefore required;

- **useful**;
- **written** with stakeholders: **the quality assurance manager should not write the procedures alone!**
- **adapted** to its users in its content and format;
- **known** and available;
- easy to **apply**.

➤ **Advantages**

- The procedure clarifies and formalizes the organizational rules.
- It complements the identity card processes. The content comprises the 'who does what', the documents, and may refer to the operating procedures or other procedures.

➤ **Precautions**

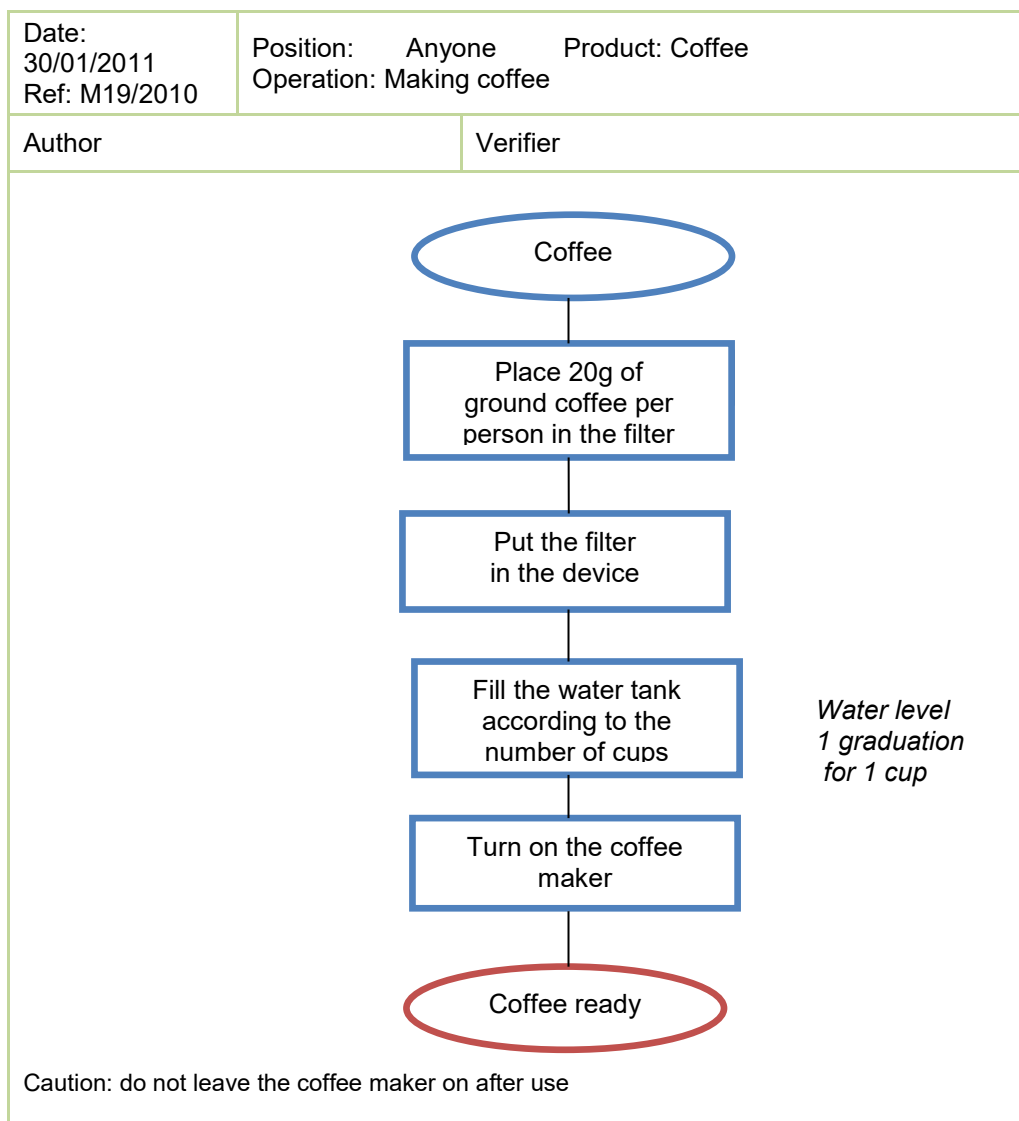
- Keep it simple. A procedure can be written as text or, if the process is simple, as a flowchart.
- Do not go into detail (purpose of the operating procedures or instructions).

**Example procedure: handling a complaint**

Steps	Manager	Documents/ Records
<div> <div>Verbal complaint</div> <div>Transmission</div> <div>Recording</div> </div>	Anyone	
<div>Written complaint</div> <div>Analysis of the complaint</div>	Quality assurance manager secretary	Records card
48 hours	Quality assurance manager	Report
<div>First response to the customer</div> <div>Processing the complaint</div>	Quality assurance manager secretary	Letter
<div>Final response to the customer</div> <div>Customer confirmation</div>	Quality assurance manager	Report
<div>Corrective action procedure</div>	Quality assurance manager with department concerned	Letter
	Customer	Confirmation of receipt
	Quality assurance manager with department concerned	E-mail sent to the department

## A.2. Work instructions

These are guidelines for completing an action.



In summary, the operating procedure details a 'how to do something'. **It is linked to a role, a function.** The operating mode or work instructions supplement the procedures by detailing how to carry out the tasks outlined in the procedure.

The work instructions facilitate the handover of a role to a new post holder. It is certainly not mandatory if the task is performed by an authorized or qualified person, as the level of instructional detail depends on the skills of the people likely to use the instructions (for example, instructions for carrying out electrical work is only necessary for authorized staff). This means the job profile needs to be defined first.



#### ❑ How should a set of work instructions be written?

- Create a working group of at least one or more operators and a technician, and/or supervisor in order to write instructions for several people. The group may also include a methods or maintenance representative.
- Assemble current know-how, share difficulties and risks encountered, propose improvements or simplifications to practices, writing in user friendly language so that the instructions can be fully understood.
- List all the operations carried out in the role in chronological order then group them if necessary into main sequences.
- Note for each operation the key points in the method and/or in the settings to be adjusted and/or the tools and equipment to be used. A 'key point' is what determines proper execution of the work (quality) in the easiest and/or quickest (efficiency) and safest conditions.
- List the necessary controls and supervision.

The wording should be kept simple, with the use of flowcharts, diagrams, photos and tables rather than lengthy narratives. Use language that is as accessible and precise as possible. Use short sentences.

Once drafted, the document **should be commented on and confirmed** by all operators required to use it. This ensures acceptance of the document and allows for criticism to be taken into account immediately where applicable. **Displaying a document at the place of work is not sufficient** to ensure acceptance and to expect consistent application.

In the above example, the operations are described in a flowchart in simple and precise language.

**The level of detail should be adapted to the levels of qualifications of the staff.**

**A document will never replace skills or staff training.**

### A.3. Records management table

This is an essential checklist for the quality and traceability manager.

**Example table to be kept up-to-date:**

Records	Place of storage over year n	Archive location	Who	Duration	Destruction
Internal audits report	Quality department	Quality department	Quality and traceability manager	3 years	Shredder

Inspection report	Inspection department	Inspection department	TH	1 year	Shredder
Customer order	Sales department	Sales department	YH	1 year	Shredder
Attendance sheet for quality awareness	Quality department	Quality department	Quality and traceability manager	3 years	Dustbin
Daily results of inspections	Production department office	Production department office	JF	3 years	Dustbin

The records table provides an overview in a single document of all records of the quality management system, as well as their archive location and period.

The records table aims to identify all quality management system records to include:

- the storage location for each document (over the calendar year);
- the archive location (beyond the calendar year) and the person in charge, as well as the conditions of access to these documents;
- the archive duration;
- the type of archiving;
- the mode of destruction.

Records management is an important aspect of the quality management system. Records serve to prove the application of the planned provisions: (inspection report, certificate of training, audit report, etc.). It is therefore important to keep them over a given period in order to present them to a customer, an auditor or regulatory body, and also to trace a document's location.

#### ❑ How should a table of records be prepared?

- List the records to keep, process by process or as chapters of the defined quality standard.
- Define the responsibilities and storage conditions.

The storage conditions should ensure that the documents are protected (electronic documents) both in terms of access and of the environment in which they will be stored. The conditions must ensure that the documents cannot be altered, stolen, or borrowed without permission.

The storage duration may be statutory. Otherwise, an archiving period is defined that is consistent with the shelf life of the manufactured product.

The conditions for the destruction of the documents depend above all on the document type (including those on crisis management).

**Procedures describe the rules to apply at the company. Records prove the application of the prescribed action.**

For more information, see F. Gillet-Goinard and B. Seno, *La boîte à outils du responsable qualité* ('The Quality Manager's Toolkit'), Paris, DUNOD, 2009.



# Chapter 7

## The internal control and FSMS certification process

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## 7.1. The continual improvement principle

### 7.1.1. The normal range of a process

**Hazard prevention** is the best way to minimize the likelihood of food hazards. Prevention continually seeks to keep a process effective, *i.e.* meeting the requirements of 'customers'. The process thus remains within the '*normal*' range (of operation) and its '*indicators*' give values in line with expectations.

**The normal range is easy to describe, but only if customer expectations have been properly and fully identified, and if the processes have been properly described.**

Remember that indicators chosen as 'relevant' to a company depend largely on what is regarded as a benchmark: regulations, market expectations (marketing), the requirements of the quality standards and private standards.

The performance indicators to be monitored and the frequency of the inspections should be defined and described in the process sheet, in the procedures and in the instructions.

'**Value ranges**' should have been fixed for each indicator. For example:

- for a pH value set to pH 6 – ranges: 5.5 to 6.5;<sup>1</sup>
- for the weight of a box set to 4.6 kg – ranges: 4.5 to 4.7 kg;
- for a residue value  $\leq$  MRL: no tolerance for exceeding the ranges.

It is also important to note that the operator in charge of verifying may or may not have responsibility for interpreting the recorded value. The value ranges are given as guidelines for this 'interpretation' and to facilitate decision making.

The **frequency of monitoring the indicators is clearly essential**: it is done month by month, day by day, hour by hour, even minute by minute, depending on the process in question (e.g. water analysis, residue analysis, pH control, visual inspection, temperature verification, inspecting the cleanliness of the harvest trays etc.).<sup>2</sup>

Once the performance indicators start to move away from the accepted value ranges, the range is no longer 'normal', which creates a **risk of non-conformity** of the product.

**The continual improvement principle is about detecting malfunctions in order to eradicate them as early on as possible.** The company may use a number of methods and tools to keep the process within the normal range, but also to further improve its performance.

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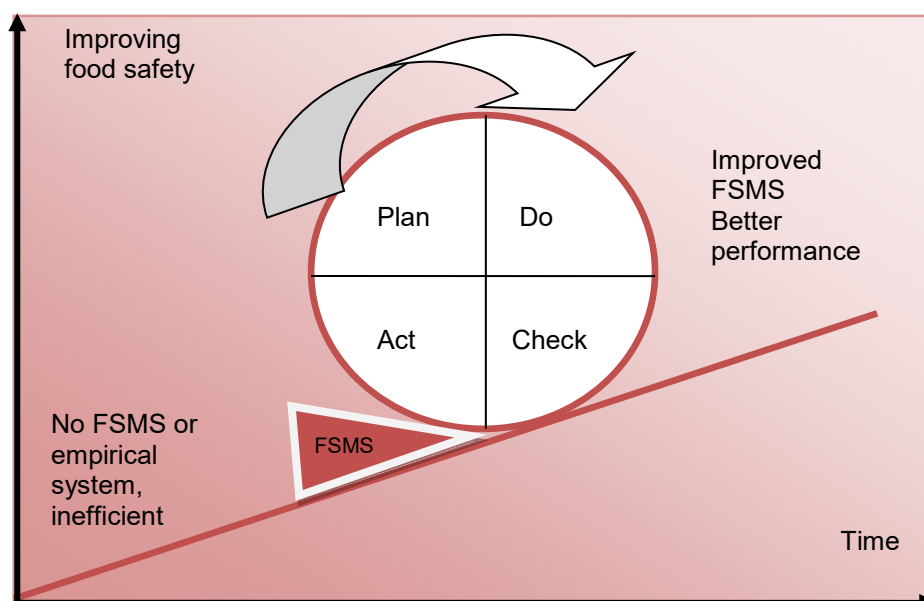
<sup>1</sup> Note that in this case, this means that the pH-meter is able to measure a pH half unit with sufficient reliability!

<sup>2</sup> For support processes that are not key processes affecting food quality and safety, some indicators may 'deviate', without normal operation being affected *per se*, but action should nevertheless be taken without delay (e.g.: delay in processing complaints).

The principle of continual improvement is symbolized by the '**virtuous circle of continual improvement**' (also called the '*Deming Wheel*'). It is typified by an iterative four-step successive cycle (PDCA):

- **Plan:** plan, prepare, predict. Identify goals, plan the list of actions.
- **Do:** do, carry out, implement. Carry out the planned actions.
- **Check:** verify, measure, evaluate, monitor. Measure or evaluate the effectiveness of the actions carried out and whether the goals have been met.
- **Act:** react, consolidate, take note, validate. Based on the analysis of the system's effectiveness, decide whether to react,<sup>3</sup> and what to react to.

**The image of the turning wheel rolling up the slope (which represents the effort of moving towards greater progress). It is the food safety management system (FSMS) that prevents the wheel from falling backwards:**



Continual improvement involves the creation of a 'zero point' against which progress will be measured. This 'zero point' is not always easy to define<sup>4</sup> but without this preliminary

<sup>3</sup> If we look at Deming's work, we see that he emphasises the importance of evaluating the process (its significance, its potential performance, its limitations). He also stresses that 'consolidating' is not inevitable: abandoning a process and envisaging how to do it differently is not forbidden, quite the opposite.

<sup>4</sup> Some quality approaches, such as ISO 14011 certification, expressly provide for carrying out an initial audit ('due diligence') in order to establish this zero point. This is a good way to proceed, particularly for anything related to the environment (e.g. CO<sub>2</sub> emissions, waste management), but this can also lead to abuse (exaggerating in order to have a baseline situation considered catastrophic and to be able to then inform customers about the great progress achieved!). For product safety conformity criteria, the zero point can be defined as strict compliance with the regulatory health and safety standards (otherwise the product is not saleable).



work, measurement will not be possible and therefore no evidence of the approach's effectiveness will be possible!

### 7.1.2. Evaluation and continual improvement of the FSMS



In order to make progress, the company must adopt **effective methods and tools** to assess performance and identify malfunctions in its management system ('Check').

Corrective actions must be taken to improve the functioning and effectiveness of the system ('Act'). The effectiveness of these actions must be verified.

**Any quality management system (QMS) must have an internal and/or external verification system.** This is to verify that the system is working well and ensures that the products sold meet the requirements of food safety as well as buyers' trading requirements.

Assessment of the FSMS should answer the following 3 questions:

1. *Does the FSMS meet the goals set by the company in its food safety and quality policy for its products?*
2. *Does the FSMS meet customers' requirements?*
3. *Does the FSMS allow for continual improvement of the safety and quality procedures implemented?*

Assessing the FSMS means ensuring that:

1. the procedures in place actually work and are effective;
2. the records made confirm and **provide evidence** of food safety management.



Verification of the FSMS ideally comprises four components:

1. continuous controls of the system's functioning (verifications, monitoring or supervision, using various methods);
2. internal audits;
3. periodic senior management reviews (this process, repeated at least once a year, places the system in a continual improvement loop);
4. external audits (conducted by a third party, with a view to certification).

The first three points are what is called self-evaluation.

The last two points are not mandatory under the regulations.

## 7.2. Self-evaluations and internal audits

### 7.2.1. The FSMS monitoring and verification system

The internal verification or self-evaluation system includes:

- **On-going controls:** visits and inspections carried out at a frequency established in an 'internal inspection plan', coupled with other announced inspections. They are carried out by the quality and traceability manager (and their team in larger organizations). They are **complemented by the measurements, sampling and analyses** targeted according to the risk analysis carried out on the basis of the processes.
- **Internal audits:** these are carried out by auditors especially trained in food safety, in order to ensure the FSMS is working effectively in all its components. It should be noted that even if they are 'internal' audits (i.e. whose results are not communicated externally in principle), the company may contract paid external auditors in order to supplement the lack of internal skills or in order to gather the opinion of an external expert. The internal audit is usually conducted **once or twice a year** or **when key processes change!**
- **Senior Management Reviews:** the results of the inspections and internal audits will be analyzed periodically as a team composed of the company managers, the quality assurance manager, and led by the senior management.

Verifications and analyses must be sufficiently frequent to confirm that hazard identification, risk assessments, controls and corrective actions are working properly.

Inspections, analyses and internal audits, and their content and frequency will be defined in a specific procedure on verification of the FSMS.

### 7.2.2. On-going controls

**The notion of 'controls' should be understood in the broadest sense.** Their aim is the voluntary and regular verification of the FSMS (application of the general hygiene principles, control measures, corrective actions, traceability). **Qualitative** controls (visual inspections, product defects) are distinguished from **quantitative** controls (measurements of parameters relating to product composition). The locations and frequencies of the on-going controls should be indicated in an internal verification procedure. In order to draft this procedure, the producer may refer to the 'Self-evaluation System Guide', if available.



## On-going controls lead to records.

Records continually provide elements and data which the quality and traceability manager and their team monitor in order to ensure that the limitations and thresholds for each risk are never exceeded. **When these thresholds are not observed, the quality and traceability manager and their team intervene to have corrective actions** implemented, and they perform additional controls to ensure these actions have had an effect.

The various measures to be implemented include:

- **Visual controls:** easy to perform, these are often effective with regards to **basic hygiene measures**, for example. They have the disadvantage of being dependent on the observer's experience and level of tolerance with level deviations. They are, however, the most common controls and are used constantly in the field. They are therefore not only carried out by the quality assurance manager, but also by a specialist worker or a supervisor.
- **Measurements:** an instrument or device is used to **measure a parameter** (for example: to measure the temperature in a cold storage room or measure pH). As the result is known immediately, corrective action can also be taken immediately. We have said that without well calibrated and/or well used devices, these 'measurements' are often 'verifications' giving indicative values. They are often performed by a specialist worker or a supervisor.
- **Inspections:** these are performed by the quality assurance manager who 'inspects' the operations carried out **while work is proceeding**. They verify compliance with the procedures and ensure that the necessary records have been made during the work (i.e. not from memory or retrospectively!). These inspections are either planned (most often) or unannounced. The large portion of the inspection consists in documentary verification.
- **Analyses:** these are microbiological analyses and analyses of extraneous matter, water quality, analyses of nitrate content, plant protection product residues, heavy metals, mycotoxins and other contaminants etc.

These analyses are **rarely done on site** (sometimes this is possible for certain microbiological or biological analyses, such as the search for quarantine pests). They require specialist equipment and environment, as well as methods applied by highly-trained staff.



## ❑ Pre-harvest controls to be conducted

These are **self-evaluations carried out before harvest by the operator**, or by a group of producers. This type of control involves:

- **documentation reviews:** verification of temperature records, readings records, verification of the list of products applied, of the measured dose, the date and the number of applications etc.;
- **controls by sampling and analysis:** inputs (fertilizer, compost, pesticides, biocides etc.); of irrigation water, washing water etc.; of soil or leaf analyses, in order to adjust the fertilizer;
- **visual hygiene controls:** of the nurseries and orchards; of the general hygiene of the facilities, of the storage areas, of the plots, of the staff, of the packaging stocks, of the stores, of the transport vehicles etc.

In the case of soil and water, the controls performed before or during production mainly aim to detect risks of contamination by heavy metals (soil) or by biological agents (water, compost). In the case of plant protection products, the pre-harvest controls are specifically designed to detect (potential) cases where maximum residue levels (MRLs) of one or more pesticides may be or are exceeded, in order to delay harvest, validate or correct the relevant crop protocol (and to adapt it according to Good Agricultural Practices).<sup>5</sup>

## ❑ Visual controls of the products' saleable quality

On **entry to the packhouse**, each operator should carry out a visual quality control of a representative sample of the fruits and/or vegetables (e.g.: on a minimum of 0.5% of the units), which must meet the quality criteria. The target quality is a basic quality. The data from these initial quality controls should be recorded.

On **shipment** there is another visual quality control (e.g. on a minimum of 3% of the units if the products are in the cold storage rooms for over 72 hours). The fruit and/or vegetables prepared for shipment must be inspected to ensure that they meet the quality criteria (class, sorting, tolerance requirements, uniformity, packaging requirements etc.) and to check there are no foreign particles. The data from these quality inspections should be recorded.

## ❑ Post-harvest controls and sampling

These are controls carried out by the operator, by a group of producers or by an approved body (or by the competent authority) **on the finished products**. These are:

- reviewing compliance with categories and grades;
- reviewing the labelling and documentation accompanying the product (e.g. plant health certificate);
- sampling per lot;
- plant health inspection per lot (if necessary by product and market);

<sup>5</sup> If the analysis of product samples to test for pesticide residues shows the authorised MRLs have been exceeded, the effectiveness of the control points regarding the application of pesticides should be re-assessed. This could include: calibration of the sprayer, the operator's competencies, the pesticide dosage and the number of applications or even control of the pre-harvest interval (PHI).

- analysis of samples in an (approved) laboratory in order to identify biological and/or chemical toxins.

#### Analyses conducted as part of self-evaluation

These are usually contracted out to external laboratories. These will preferably be **ISO 17025 'accredited'** to perform these analyses. This is the only real guarantee that the results will not be challenged (or are difficult to challenge) by the customer.

**Conducting analyses comes up against the same problem as that of sampling, which can be a real 'trap' if you aren't careful!** A reminder of some of the sampling principles is available as an annex.

The control will also verify that:

- packaging of the shipment (one or more lots) is secure so that neither its identity or its physical integrity is altered;
- if necessary, the shipment is accompanied by the original plant health certificate;
- the shipment is stocked separately or is marked so that it can always be identified and traced at the time of the physical inspection.

### 7.2.3. Internal audits

#### ❑ Significance of internal audits

The main purpose of internal audits (sometimes called 'first-party audits') is to assess the application and effectiveness of the quality management system implemented, or of a selected part of this system (for example: audit of a new activity or a critical process for the company), in order to **ensure that the system has not deviated from its goals**, to check it is regularly updated and identify **areas for possible progress**.

Internal auditing always gives indications of quality control, and it also helps to identify skills gaps and propose staff training actions.

It is often very useful and effective to carry out internal audits during the growing season and, once a year or every two years, for example, to conduct **a full internal audit contracted out to a supplier specializing in audits**.

#### ❑ Organizing internal audits

For this practice to be effective and above all accepted by staff members:

- **Audits must be planned:** define and have Senior Management validate the topics to be audited over the year or over several years, based on previous results. Inform staff members affected by the audit and plan this exercise with them so that they are available during the audit. Send out a schedule.
- **Prepare for each audit, identifying:** the reference documents to be consulted (field notebooks, invoices, delivery notes, records etc.) and the activities, processes, procedures to be audited, people to meet etc. (draft auditing guidelines).

- **Prepare for the audit visit:** refer to the objectives of the audit, establish a constructive relationship with the future auditees by obtaining their approval; explain how the results will be used by senior management and confirm the planned schedule.
- **Make audit (or self-evaluation) 'checklists'** available (see attached example).
- **Conduct audit interviews** with the auditees and identify evidence of good practice or areas for improvement (listen).
- **Validate the findings with the auditees** (if necessary help them understand their mistakes, faults etc., **by explaining why** they are harmful to the products' quality and safety!).
- **Formalize the audit report** (formal report with positive and negative points), describing the corrective actions to be taken and indicating the deadlines for each.
- **Involve the auditees in the progress action points** prompted by frank and open discussions. It is important to communicate in advance about how the audits should be handled, stressing that they represent constructive dialogue, rather than sterile checks and balances. Avoid the internal auditor being seen as senior management's 'cop'.

The internal audits should be carried out by **staff trained in auditing**, as well as in methodology and in management of the auditor-auditee relationship. It is preferable for auditors to be recognized for their **professional and 'educational' abilities**. It is useful to call on external auditors from time to time in order to benefit from a fresh look at the company's practices, including its internal audits!

Internal audits are essential for sustaining a quality approach. It is a chance for dialogue which makes each stakeholder in the project **accountable for their practices**. The internal auditor must work towards a goal of improving the system, rather than punishing people!

A summary of the internal audits will be presented during the *Management Review*: this must be an opportunity to highlight best practices identified, ensure they become widespread and capitalize on progress made audit after audit.

## 7.2.4 Management Reviews

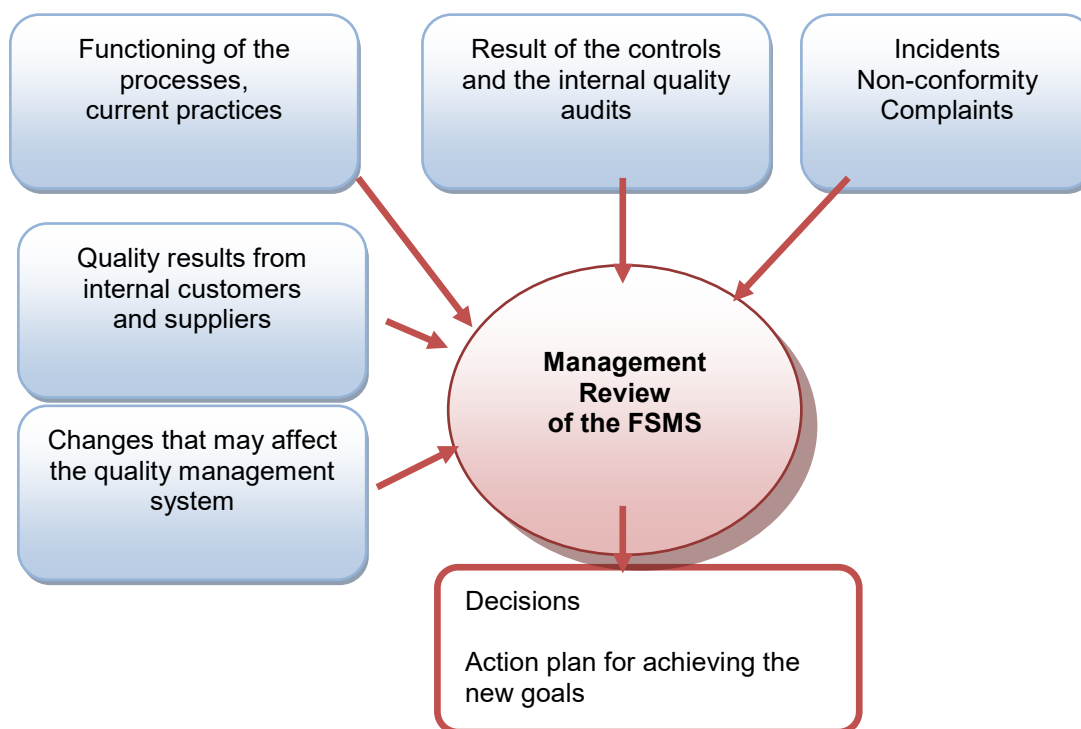
The 'Management Review' of the FSMS is simply a **review and decision-making meeting** organized in the presence of the company's senior management, the quality and traceability manager and all company executives (including those responsible for 'support processes' in this instance). It will take place at the initiative of the company's senior management and is preceded by one or more internal FSMS audits. Ideally, one of the seasonal internal audits will have been contracted out to an external auditor. It will take place once or twice a year, regularly or occasionally for specific reasons (e.g. starting new production, or a major incident after shipping).

The main objective of the Management Review is to share the company's progress in quality. This is the place and time to **put the 'customer' at the heart of the company's**



**concerns, anticipate market expectations**, look at the company's quality results and motivate the entire organisation towards new, even more ambitious goals.

***The Management Review is a place to take stock, but above all for clear, shared decision making!***



The internal audits and inspections, as well as the Management Review(s), should have been carried out before an external auditor becomes involved as part of the certification process.

It is essential to confirm the content of the Management Review with senior management. Focusing the review on a select number of results and topics will be more effective. This meeting can also be prepared beforehand and individually with the process owners.

A well prepared and well executed Management Review has a strong impact internally and greatly enhances the quality assurance manager's role. This allows them to continue their work based on decisions taken collectively at the meeting.

#### 7.2.5. Some additional tools and methods to be used for quality management

There are numerous methods for managing quality in a company. Each has its advantages and disadvantages, and good skills and experience are needed in order to implement and benefit from them. It is advisable to consult specialist literature before

launching them.<sup>6</sup> Another limitation of these methods is that they mostly offer a logic for identifying the causes of non-conformity, but do not offer a way to solve the problems! This is where the experience of the quality and traceability manager should come in, and grow over time, in order to provide cost effective solutions.

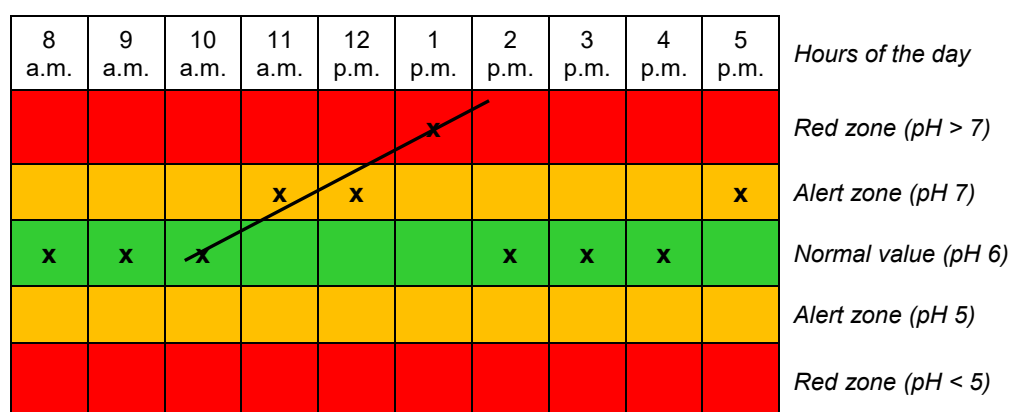
By way of example, we present, ranging from the simplest to the most complex, some additional techniques that are easy to implement, such as:

- control charts;
- the Pareto chart;
- the Ishikawa diagram method;
- risk analysis of the process;
- process review.

### □ Control charts

This is a method that tracks the evolution of a parameter/production characteristic over time (hours, days, weeks, months). This makes it easier to identify a deviation, a 'trend' that deviates from the expected specification, without requiring calculations or statistical methods. Once this trend has been identified, action can be taken to correct it. This is therefore a preventive method.

#### **Example control chart: changes in pH of a water-bath during the day:**



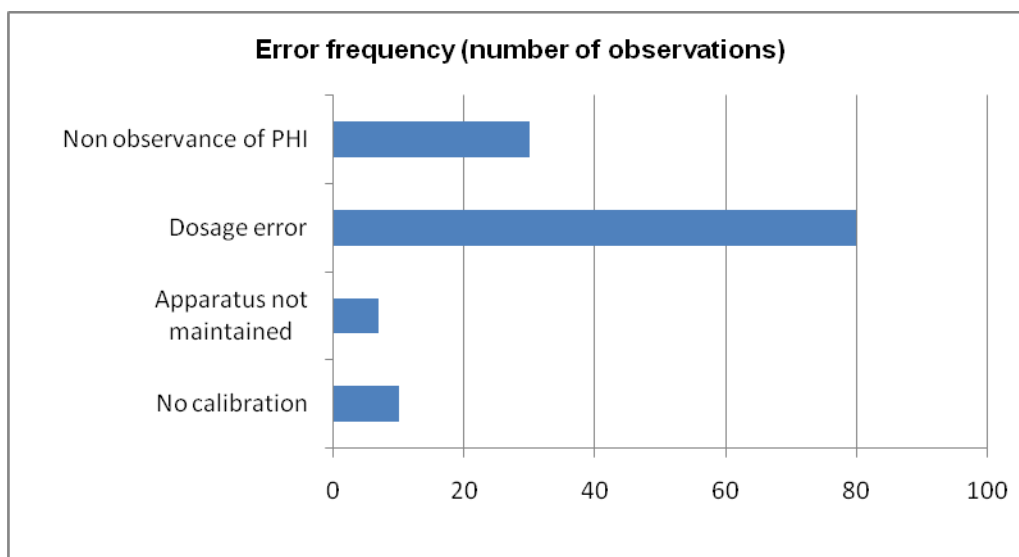
At 1 p.m., the pH is too high. The operator corrects the pH of the bath and returns it to a value close to that instructed. The work can continue. Note that as the procedure itself has not been changed, the same deviation will recur later on.

### □ The Pareto chart

The Pareto chart is a **graphical presentation** method that highlights the relative importance of the factors, such as incidents that have occurred or their cause. Either each type of incident is recorded over a specified period (e.g. the season), or the causes of these incidents are charted if they are known.

<sup>6</sup> For example, some of the elements discussed here were taken from F. Gillet-Goinard and B. Seno, *La boîte à outils du responsable qualité* ('The quality assurance manager's toolkit'), Paris, Dunod, 2009. See also the bibliographic references in this manual.

*Example Pareto chart: specific causes of errors found during the application of the plant protection products leading to a breach of the MRLs*



In this example, the dosage error represents around 65% of the total error sources identified. By correcting this error – for example through better staff training<sup>7</sup> – a large number of cases of exceeding MRLs will be eliminated, enabling significant progress in this area.

This way of viewing the sources of an error demonstrates that often just a few anomalies can play a major role. It therefore focuses on the essentials in the quality approach.

#### ❑ The Ishikawa method or cause-and-effect diagram

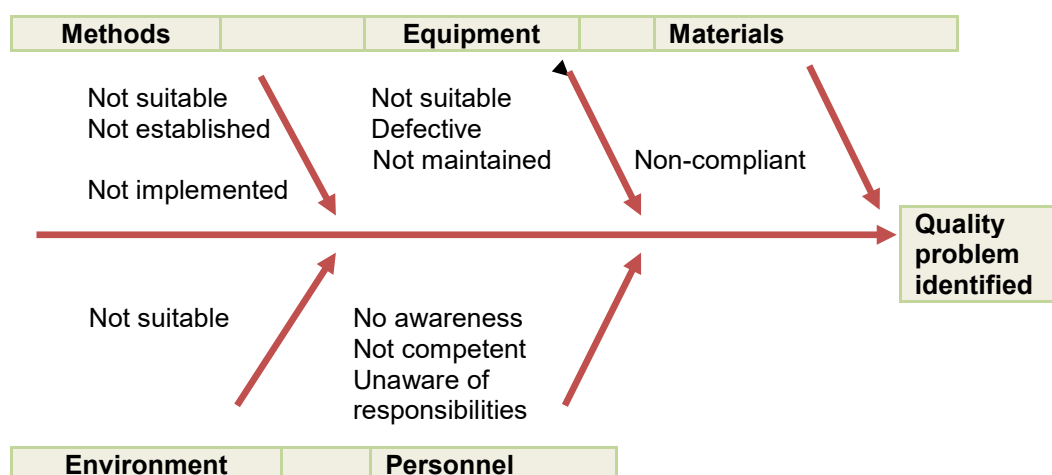
The Ishikawa diagram method (also called the **cause-and-effect diagram, fishbone diagram or Fishikawa**) is a **tool for classifying all causes** that may be at the source of a problem. This method has already been mentioned in previous chapters. The grouping of the causes of non-conformity is based on 5 categories: Personnel, Environment, Methods, Materials, Resources.

It is interesting that it is also a **communication tool for explaining a phenomenon**.

<sup>7</sup> Note that this requires a deeper analysis of the cause: *Lack of skills (e.g. reading and numeracy)? Is the operator in question able to carry out the calculations? Is a measuring scoop available?*

### Establishing the Ishikawa diagram:

- personnel: competencies, motivation, etc. of the person doing the work;
- materials (raw material): which material is provided for doing the work and is then processed, which comes from suppliers;
- resources: machinery, equipment, information system used to 'produce', to complete the task;
- methods: how to implement the process.



This method **does not give 'the' cause of a problem**, but it is used to find all possible causes, working without preconceptions and by thinking 'out of the box'.

Using this method effectively calls for group work where all ideas and all possible causes are considered, with a 'brainstorming' session. The ideas are then ranked according to the 5 categories cited above, and the cause(s) to be tested are identified (probable causes). This verifies, by testing, that they are indeed the origin of the problem. Using this confirmed cause, the working group then seeks to trace the root causes by asking the question 'why did this origin of the problem appear?'.

### ❑ Risk analysis of the process

Analysis of the risks associated with a process must be **part of a rationale of prevention** rather than reaction. Through the discussions, this evaluation method also allows the operators to be educated, to adjust the monitoring plan and to anticipate faults by implementing preventive actions.

The purpose of this tool is to enable the manager of the process to identify the **major risks** of their process. Once this analysis has been carried out, the most important thing is then to **establish a prevention plan** that will reduce the likelihood of a malfunction appearing and will limit criticality.

This analysis can be integrated into an overall approach to risk management used throughout the company. Depending on the company, risks associated with the process are seen in terms of the costs of non-quality, or financial and safety risks.

In order to implement this method:

- **An overall discussion** at process level must take place: what consequences will there be if the process malfunctions?
- **Answering this question** must take into account various impacts: financial, customer, environment, employees, other stakeholders and the media. Each risk is evaluated in terms of the severity of its impact (S) and its likelihood of occurring: (L).
- **Multiply the two scores** (ranging for example from 1 to 5) to obtain criticality ( $C = L \times S$ ); criticality is therefore a maximum of 25. If the criticality is deemed unacceptable, an attempt to reduce the likelihood of occurrence is made, by working primarily on the causes. If the risk is unacceptable, a control can be established in order to systematically eliminate any risk.
- **Seek to reduce** the criticality score once the analysis has been carried out. If only minor impacts can be made on the severity, **the likelihood of occurrence can be reduced by researching the causes of the faults** ('Why do we have this malfunction?').
- **In order to refine this analysis, study** each stage of the process by asking the following questions: *What malfunctions are possible? How serious are they? What is the likelihood? What is the overall criticality? How could the risks be reduced?*

**Example: quality risk analysis of the 'packaging' process:**  
where  $C$  (Criticality) =  $S$  (Severity)  $\times$   $L$  (Likelihood)

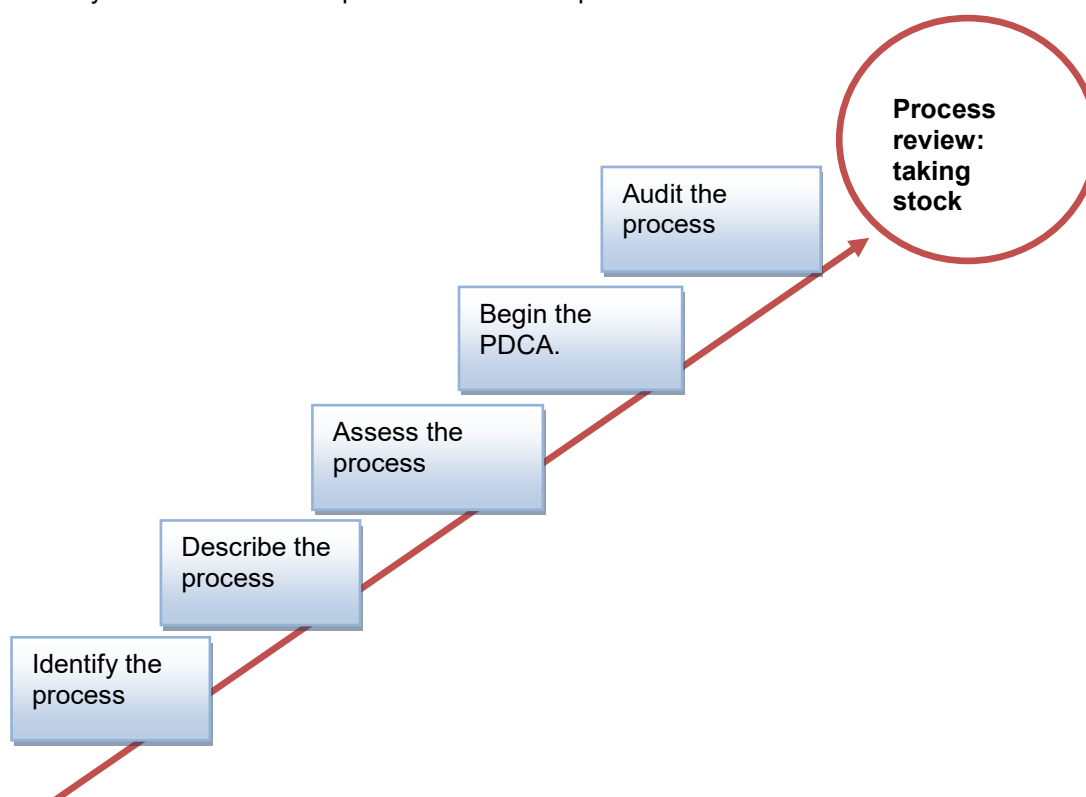
Key activities	Possible errors	S	L	C	Cause	Preventive action	Monitoring
Packaging	Poorly glued boxes	5	5	25	Malfunctioning machinery	Preventive maintenance	Visual control
	Error in the number of packages per pallet	5	3	15	Human error	Education	Control through spot checks
	Damaged boxes	3	3	9	Malfunctioning machinery	Preventive maintenance	Visual control

The exercise is fully effective when it is a group effort. This tool focuses on preventive actions rather than control measures. It adapts the control plan and **brings quality under control**.

#### ❑ Process review

The process review is a meeting, chaired by the process manager with the presence of all operators involved, to enable them to make an objective point about the effectiveness

of its process and decide as necessary on actions needed to improve it. It therefore naturally fits into the '*Check*' phase of the PDCA process.



This review is carried out as part of the process's monitoring and supervision. This allows for taking stock of the process and summarizing it with the management during the senior management review.

To use this method effectively:

- carry out a comprehensive and well-balanced assessment of how the process is working using indicators and other data (non-conformities, complaints, audit reports etc. over a period of approximately one month);
- verify the achievement of the set objectives, determine the effectiveness of the process and devise an appropriate action plan;
- involve those responsible for the process's major activities, but also include a representative of the customers and the suppliers.

Preparing the process review is very important. Before holding the meeting, the manager should collect the following information:

- the process identity sheet;
- the report from the previous review;
- the current objectives and action plan;
- customer feedback, status of non-conformities and incidents;
- internal and external audit reports;
- status of corrective and preventive actions;



- proposals for improvements/suggestions from staff and customers about the process;
- key performance indicators and results of monitoring activities.

To **analyze the process**, the following data needs to be gathered (using the Ishikawa diagram, for example):

- **About the raw materials:** What is quality and reliability of the suppliers? What data do we have (e.g. specifications, certificates)? What is the quality of the raw materials used? Are the products used authorized? Do they have a MRL?
- **About the staff:** How long have they been with the company? What is their level of skill and motivation? Are responsibilities defined? Are the staff educated about quality? Are temporary staff employed? Are staff who are unwell excluded from the workplace? Is there a staff register?
- **About the resources:** What state is the machinery in? Are the resources suitable? Are they maintained? Is there a data sheet available?
- **About the methods:** Are the working methods defined? Are they formalized (e.g.: written procedures and instructions)? Are the existing documents known? Are they applied? Are they updated?
- **About the controls/measurements:** Are the controls to be carried out formalized? Are the inspections defined applied? Are the devices used tested? Are the characteristics to be inspected defined? Are product standards clarified?
- **About the environment:** Does this process allow the activities to be carried out satisfactorily: pollution? Water? Light, atmosphere, noise?
- **About the indicators:** Are there quality indicators for the finished product and at different stages of the process? Is customer satisfaction measured? Are customer complaints recorded? Are incidents analyzed in terms of frequency and severity?

There is no limit to the type and number of questions to ask.

The manager and staff involved in the process take a step back in order to examine the results objectively. The tool is an aid to decision making to improve the process.

But the **effectiveness of a process review depends on how well developed the company is**: successful participatory process reviews will be conducted in companies where management by processes is genuinely operational, once an FSMS has been established and the team has been operating with a quality management approach for a few years.

## 7.3. Third-party verification FSMS certification

### 7.3.1. Why seek external verification and by whom?

Inspections and audits carried out by external inspectors and auditors are generally called '**third party**'.<sup>8</sup> They are carried out especially **as part of certification of the company** (according to conditions and frequencies defined in the verification procedure) and/or its products.

'Certification' provides companies with **an external and independent guarantee of the conformity of its quality management system (FSMS) with the selected standard** (compliance with legal requirements and compliance with other commercial requirements specified in a quality standard or private standard).

It is therefore conducted:

- When a **certificate of conformity** to certain standards is required. Some customers may request proof of compliance with a standard or with specific requirements through an audit conducted by an ICB ('**independent certification body**').
- **After a customer complaint.** The purpose of the external audit in this case is to ensure that the non-conformity that led to the complaint is under control and will not reoccur.

Verification will be carried out by an inspector or auditor appointed by an ICB who in this case is acting through its private inspection organisation.

**Skill, knowledge of the industry and the products, the ability to carry out this mission, impartiality and efficiency are the basic criteria for any auditor and any inspection and control body.**

Evidence of these aptitudes is confirmed by **accreditation from these independent certifications bodies**.

Auditors and inspectors **appointed by the certification bodies** carry out the audits and controls at the request of the companies (private certifications), but sometimes also at the request of the authorities (e.g. self-evaluation certification systems).

<sup>8</sup> Remember that audits referred to as '*first party*' audits are internal audits carried out by members of the company, and '*second party*' audits are those conducted by customers of the company or other people acting on their behalf.

### Some useful definitions

**Inspection:** Examination of foods or food, raw materials, processing or distribution control systems, including testing during production and finished product testing, in order to verify that they conform to requirements.

**Audit:** Systematic and functionally-independent examination to determine whether the activities and related results comply with planned objectives.

**Certification:** Procedure by which official certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems and examination of finished products.

(From: Codex Alimentarius, *Food Import and Export Inspection and Certification Systems*, 4<sup>th</sup> ed., Rome 2009).

In general, inspection involves directly determining compliance with the specifications of a unique product, which are often complex or tangible, or of a limited set of products. Meanwhile, certification is essentially about indirectly determine the compliance of products manufactured in large batches.

Inspection also often involves **professional judgement** on the basis of general requirements, while product certification is done against standards or other **normative documents** (EC - CERTIF 97/5 EN, 1997).

### 7.3.2. Standards and types of certification

#### ❑ Standards applicable

The **standard EN 45011** describes the general requirements for bodies operating product certification systems if they wish to be recognized as a competent and reliable body. Certifying a product means giving assurance that this product meets specific requirements, such as standards, regulations, specifications and other normative documents. A product certification system may include, for example, tests or type examinations, testing or inspection of all products or of a particular product, testing or inspection by lot, assessment of the design, which may be associated with an inspection or assessment of production as well as inspection of the suppliers' quality management system. Inspection and certification of the products can be seen as similar operations and their definitions sometimes overlap.

**EN 45012** defines the general requirements for a third party body responsible for certifying quality management systems in order to be recognized as a competent and reliable body. Certification of quality management systems involves assessment, determination of compliance with a quality management system standard in a specific field of activity and inspection of the supplier's quality management system. Inspection will be performed according to **ISO/IEC 17020:1998** (which replaces EN 45004) on '*General criteria for the operation of various types of bodies performing inspection*'. This European standard specifies the general competencies criteria for independent

certification bodies (ICB) performing inspection, regardless of the sector concerned. It also specifies **the independence criteria**.

Specific standards have been developed to measure compliance against a standard and issuing a certificate by an accredited certifying body (ICB):

- for product or process certification, **according to standard EN 45011**:
  - Organic farming, Certificate of Compliance of Self-evaluation Systems
  - GLOBALG.A.P.
  - BRC
- quality assurance system certification, **according to EN 45012**:
  - ISO 9001
  - ISO 22000
  - ISO 14001

#### ❑ Individual certification

An **individual operator** (producer, packer or processor) may apply for certification of its QMS with an independent certification body (ICB) accredited for that purpose. During the inspection, all holdings and the packaging and processing station(s) where the products listed are grown, packaged or processed will be inspected.

If the inspection results (initial inspection, renewal or extension) are conclusive, a certificate is **issued to them on an individual basis**.

#### ❑ Group Certification (association, cooperative, grouping or other)

A **grouping of operators** (cooperative, association, economic interest grouping of producers/packers/processors, exporters with contractual associations with producers) may apply for certification of its QMS with an ICB accredited for that purpose. The application for certification will mention in full all information needed to **identify all associated producers**, the contact information and areas/varieties of their respective holdings.

In order to carry out the inspection, **sampling of the operators** to be inspected is calculated (for example based on the square root of the total number of operators registered under GLOBALG.A.P). The certificate is **issued to the grouping** with an attached list of the producers meeting the certification requirements.

### 7.3.3. External inspections

The aim of inspection (external audit) by the ICB is to validate the FSMS established by the company **based on the legal requirements** applicable in the sector and, usually, also to issue a 'certificate'. In addition to the legal requirements concerning food safety and hygiene, the inspector will verify certain legal requirements on product quality (quality criteria).

A **contractual agreement** should be established between the company and the ICB which sets out the scope of the assessment (this is a commercial act, a paid 'service' sought by the company). Strict **confidentiality** of the inspectors and the ICB is required.

Inspection by the ICB will include:

1. information prior to the visit (inspection date, name and qualifications of the inspector, documents to be collated, length etc.);
2. an introductory meeting (presentation of the inspection method, schedule etc.);
3. review of the documentation;
4. review of application in the company of all regulatory requirements and/or others (visits, interviews, FAQs etc.);
5. a meeting to discuss any non-conformities identified;
6. an inspection report.

The management and all staff members may be questioned. Furthermore, during the inspection the ICB may decide to take and analyze samples, particularly if the internal controls carried out are not deemed sufficient by the inspector.

The length of the inspection will depend on the following parameters:

- initial inspection, monitoring or supervision;
- size of the company, including the number of production sites;
- type of process;
- type of products;
- number of workers;
- number of non-conformities identified during the previous inspection.

For a **combined inspection**, the ICB should first conduct the FSQMS inspection before those of the other commercial quality management systems (e.g.: Bio, GLOBALG.A.P., Fair Trade etc.).

### 7.3.4. Certification of the FSMS

#### ❑ Certification preparatory phase

This is generally the longest phase (often 2-3 years between the project formulation and the audit application). It begins with **choosing a quality standard** and studying its various requirements in order to first estimate the gap between the company's actual circumstances and its goals, and second to plan the implementation of actions required to achieve compliance. External support in the form of advice and training will often be necessary in order to save time.

It will conclude with a '**mock audit**' (also called a 'diagnostic audit') preferably carried out by an expert contracted by the company for that task. The 'mock audit' is conducted exactly like a certification audit. Its conclusions will determine whether the company is ready to apply for certification from an ICB and if necessary correct the last remaining major non-conformities.

The mock audit is followed by a formal application for a certification audit from an ICB. The ICB will appoint an accredited auditor.

#### ❑ Organizing certification audits

To obtain an FSMS certification, the company should undergo:

1. An **initial audit**: this aims to demonstrate that the FSMS meets the requirements. The traceability system will be audited in great detail and a full inspection will be performed, with an in-depth visit to the production sites, buildings and premises, storage spaces, transport facilities etc. The initial audit concludes with an audit report presented to the company and to the certification body, which will review it. If this review is favorable, a 'certificate' is issued (or the process may continue after a follow-up audit).
2. A **monitoring audit/follow-up audit**: inspection of the FSMS takes place **every year** (or at most every two years) to check if it still meets the legal or other requirements. This is a less detailed audit. If major non-conformities were found during an inspection, the ICB may decide on a 'follow-up' inspection to verify whether suitable corrective actions were implemented following the inspection report. External inspections are sometimes carried out unannounced.
3. The **renewal audit**: this is an audit similar to the initial audit. A periodic certification renewal audit (e.g. **every 3 years**) places the company within a continual improvement approach against which it is also evaluated over the years. Certification then becomes reliable evidence of the company's progress and can validly form a basis for customer confidence.



When the company has successfully passed its FSQMS inspection, it may receive a '**Certificate of Compliance**' (according to a template established by the ICB).

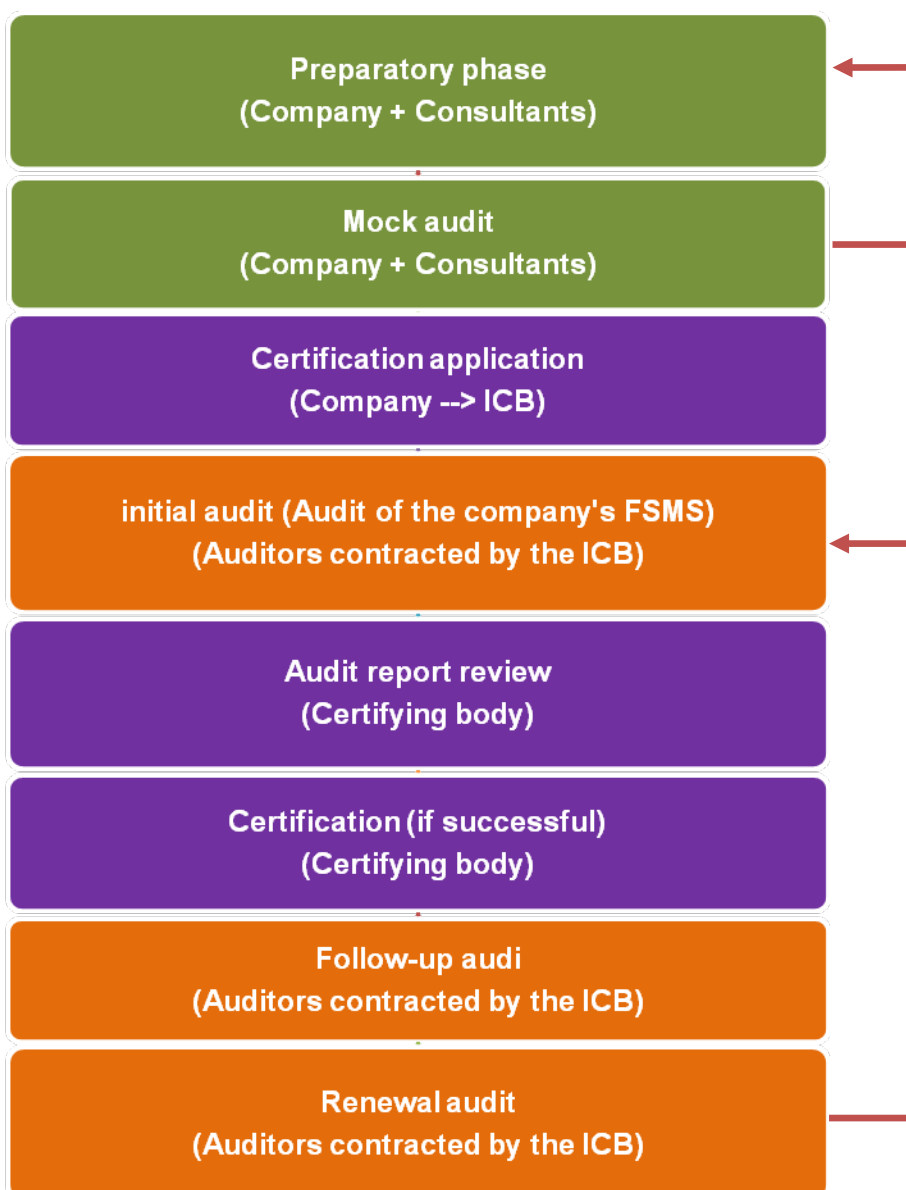
The standards body (e.g.: GLOBALG.A.P.) is informed about the issue of the certificate. It may publish (e.g. on its website) the list of certified national companies, the certificate number, its scope and **expiry date**.



The ICB should normally notify on request its procedure for appealing against the outcome of its inspection and any decision not to grant certification. Appeals should be lodged in writing to the ICB within days of receipt of the inspection report. The ICB should contact the company to provide the result of its inquiry following the appeal.



**The general certification flowchart is as follows:**



# Appendices


## A.1. Example self-evaluation checklist (mango production)

In this example, a 'minimum requirement level' has been set for each point, according to their importance to the safety and quality of the product.

During inspection, all level '3' points should, for example, be met (100% compliance), 75% of those at level '2' should be met and those at level '1' will be recommendations.

Such a checklist therefore combines a number of requirements to be met and a level of compliance.

*N/A: Requirement Not Applicable – All answers must be supported with clear evidence.*

 indicates the control points which cannot be answered with N/A.

Number	Control points	Compliance	Minimum requirement level	Supporting evidence
<b>1.1</b>	<b>Description of the producer/orchard</b>			
1.1.1	Is the company/operator registered with the competent authority?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	3	
1.1.2	Are the orchards identified and/or coded?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	3	
1.1.3	Is a plan of the plots in production available?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	2	
1.1.4	Have all the plots being cultivated been identified and/or coded?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	3	
1.1.5	Are records relating to the operations performed at each unit (orchard or plot) available?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	2	

Number	Control points	Compliance	Minimum requirement level	Supporting evidence
<b>1.2</b>	<b>Environment of the production site/orchard</b>			
1.2.1	Has a risk assessment been carried out for potential sources of contamination and on the effectiveness of	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	2	

	reasonable measures to protect the fruit?			
1.2.2	Is the production site located far away from polluted areas, areas prone to flooding, pest infestations and/or areas where solid or liquid waste cannot be removed effectively?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	2	
1.2.3	Is the production site/orchard located near or at a short distance from abandoned orchards or areas infested with fruit flies?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	2	
1.2.4	Is the production site/orchard maintained so as to control any risk of product contamination, including by fruit flies?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	3	
1.2.5	Is the orchard regularly cleared of mangoes that have fallen to the ground?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	3	

Number	Control points	Compliance	Minimum requirement level	Supporting evidence
<b>1.3</b>	<b>Site design and layout</b>			
1.3.1	Does the design and layout of the production facilities allow the application of good food hygiene practices, including protection against cross-contamination during and between operations?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	3	
1.3.2	Are staff facilities designed and used so as to reduce risks to product safety?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	2	
1.3.3	Is respect for biodiversity (fauna and flora) considered in the production site/orchard's layout?	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	

1.3.4	Does the site have adequate storage places (stores to stock the products and/or storage area for the harvest) against contamination and damage to the products?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	2	
1.3.5	Are measures in place to maintain site security, specifically to limit access to the site?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	1	

Number	Control points	Compliance	Minimum requirement level	Supporting evidence
<b>2.1</b>	<b>Staff hygiene and maintenance</b>			
2.1.1	Does the site have staff facilities for washing hands with soap and clean water?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>	3	
2.1.2	Do workers have access to clean toilets?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	2	
2.1.3	Are hygiene rules properly applied and displayed: do not smoke, do not eat or drink, do not chew gum, keep fingernails short?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	2	
2.1.4	Are staff informed of and trained in following hygiene procedures and related activities (plant protection treatments, transport and harvest)?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>	3	
<b>2.2</b>	<b>Hygiene of the premises and maintenance</b>			
2.2.1	A plan for maintenance and cleaning is provided; does it include cleaning frequencies?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	2	
<b>2.3</b>	<b>Waste management</b>			
2.3.1	Is there a waste management plan throughout the production	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	1	

	site?			
2.3.2	Is waste regularly removed from the production area?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.3.3	Is hazardous waste treated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

## A.2. Example checklist completed during an internal audit

Example for an internal audit at a kiwi station

KEY: C = compliant

NC = non-compliant

A = acceptable

RISK ANALYSIS, HACCP MANAGEMENT		C	A	NC
1.1	HACCP training of the site manager			X
1.2	Team's training and knowledge of the risks	X		
1.3	Ownership of the Good Hygiene Practice guide	X		
1.4	Existence of HACCP plan			
1.5	Definition of responsibilities in organisation and control			
1.6	Resources allocated to these managers (equipment, time)			
1.7	Staff notification of audit results			X
1.7	HACCP audit			X

BODILY AND CLOTHING HYGIENE		C	A	NC
2.1	Hygiene guidelines displayed	X		
2.2	Dress code	X		
2.3	Pharmacy	X		
2.4	Annual medical check-up for employees	X		
2.5	Clothing and procedures for visitors			X

CLEANING AND DISINFECTION OF EQUIPMENT AND PREMISES		C	A	NC
3.1	Disinfectant approved by the ministry of agriculture	X		
3.2	Cleaning and disinfection products: data sheets			X
3.3	Safety sheet displayed			X
3.4	People trained in cleaning/disinfection			X
3.5	Cleaning products stored separately from fruit and vegetable work areas			X
3.6	Scheduled cleaning and disinfection	X		
3.7	Grading area: floors, walls	X		
3.7	Packaging area: carpet, conveyor belt	X		
3.9	Packaging area: brushes	X		

3.10	Cold storage area: floors, walls	X		
3.11	Shipping area: floors, walls	X		
3.12	Harvest containers			X
3.13	Waste containers			X
3.14	Area around waste area			X
3.15	Toilets/showers/changing rooms	X		
3.16	Packaging storage area			X
3.17	Visual inspection of the cleaning	X		
3.17	Cleaning and disinfection register		X	
3.17	Corrective action in case of defective cleaning			

LAYOUT OF THE PREMISES MANAGEMENT OF THE FACILITIES		C	A	NC
4.1	Drinking water supply	X		
4.2	Analyses of drinking water if water is off-grid			X
4.3	Disposal of waste isolated from the fruit and vegetable work area	X		
4.4	Waste disposal	X		
4.5	Protected lighting (fragments of glass)	X		
4.6	Handwashing point		X	
4.7	Toilets (1 per 10 people, including seasonal workers)	X		
4.7	Soap, disposable hand towels		X	
4.9	'No smoking' and 'please wash your hands' signs		X	
4.10	Preventive maintenance planning	X		
4.11	Record of maintenance carried out (internal and external)	X		
4.12	Use of food safe grease in the food area	X		
4.13	Inspection of the status of the food area paint work in contact with the products		X	

HARVEST AND RECEIPT		C	A	NC
5.1	In possession of plant protection index	X		
5.2	Crop notebook completed (register of treatments applied)	X		
5.3	Analysis of plant protection product residues carried out	X		
5.4	Corrective action in the event of MRL exceedance	X		
5.5	Monitoring the safety of fruit and vegetables on receipt	X		
5.6	Corrective action in the event of a food safety problem	X		
5.7	Box pallets guaranteed 'for food contact and without contact with hazardous materials'		X	



PROCUREMENT OF SUPPLIES		C	A	NC
6.1	Written purchase order	X		
6.2	Receipt inspection (reference standard, quantity, integrity) + registration	X		
6.3	Stock-keeping			
6.4	Specific storage	X		
6.5	Hygienic storage of packaging		X	
6.6	Data sheets for cleaning/disinfection products			X
6.7	Safety sheet for cleaning/disinfection products			X
6.7	Data sheets for waxes	Not applicable		
6.9	Packaging data sheet	X		

COLD AND CONTROLLED ATMOSPHERE STORAGE		C	A	NC
7.1	Temperature and humidity procedures have been outlined	X		
7.2	Temperature and humidity controls	X		
7.3	Procedures for O <sub>2</sub> and CO <sub>2</sub> in a controlled atmosphere outlined	X		
7.4	O <sub>2</sub> and CO <sub>2</sub> in a controlled atmosphere.	X		
7.5	Recorded inspections	X		
7.6	Corrective action in case of deviations	X		
7.7	Observance of spacing for air circulation			
7.7	Observance of safety procedures during controlled atmosphere maintenance and bottle inspections	X		
7.9	Protection of fruit situated beneath evaporators (dirty water)			X

SHIPPING AND TRANSPORT		C	A	NC
8.1	Inspection of truck cleanliness	X		
8.2	Recommended temperature for the carrier	X		
8.3	Temperature recorded on the transport document and signed by the driver	X		
8.4	Corrective action in the event of a temperature or cleanliness problem	X		

GRADING, PACKAGING		C	A	NC
9.1	Planning replenishment of fluming water	X		
9.2	Replenishments of water recorded			X
9.3	Fluming water disinfection protocol (product, dose)	X		
9.4	Addition of disinfectant recorded			X
9.5	Inspection of safety and absence of foreign bodies in the packages before shipping		X	

9.6	Inspection recorded	X		
9.7	Corrective action in the event of a health problem or foreign bodies	X		

WASTE		C	A	NC
10.1	Airtight waste container	X		
10.2	Rapid removal of full containers from workrooms	X		
10.3	Waste storage area isolated from healthy produce	X		
10.4	Periodic removal/disposal of waste	X		

PEST CONTROL		C	A	NC
11.1	Pest control map showing the location of baits	X		
11.2	Solid baits	X		
11.3	Monitoring consumption of bait	X		
11.4	Pest control devices			X

TRACEABILITY		C	A	NC
12.1	Maintaining plot traceability – grading-packaging-shipment	X		
12.2	Rapid data gathering on upstream traceability (<2 hrs.)	X		
12.3	Rapid data gathering on downstream traceability (<2 hrs.)		X	
12.4	Traceability provisions tested regularly internally (drills)			X

### A.3. Recommendations on sampling for analysis

Each operator should identify the inspections to be carried out and prepare a 'Sampling plan'. The inspections and plan should reflect their duties, the characteristics of their holding, the nature of their products, whether or not inputs are used, and in particular their own risk analysis.

If the producers have to decide for themselves on the frequency of the sampling and testing required as part of their inspection procedures, **it may be useful to for the sector to harmonize these frequencies** (via the 'self-evaluation guide'). One advantage would be to ensure the same level of control for all exporters of the same product.

To avoid difficulties that could arise from differences in legal, administrative or technical approaches to sampling and interpretation of the analysis results in relation to the product lots, it is recommended that operators follow:

- for toxins, the general guidelines of the *Codex Alimentarius*;
- for quarantine pests, the ISPM No. 31 Standard.

A sampling plan should include not only the **sampling method**, but also the **decision-making criteria** applicable to a lot, from the examination of a specific number of sample units and subsequent analysis units of a stated size according to defined methods.

The sampling method applied should ensure that the overall sample (for analysis) is representative of the lot to be inspected.

#### Caution!

Bear in mind that no sampling plan can guarantee with certainty the absence of a given toxin or (micro-)organism in a product.

**Sampling plans should also be realistic (against the requirement level) and economically viable (in terms of the resources available)!**

To develop a sampling plan, the operator should consider:

- the homogeneous or heterogeneous **distribution** of toxins or (micro-) organisms on/in a product lot;
- **the acceptance level**: this is the number of non-compliant units tolerated in a lot (also known as 'AQL' or acceptable quality level);
- **the detection level**: this is the lowest percentage of non-compliant units that can be detected in a lot (by sampling and the observation technique or measure used) with a given effectiveness level and a set confidence level;
- **the detection efficiency**: this is the likelihood that the inspection or analysis of the sample would detect a non-conformity (MRL exceedance or presence of a pest);
- **the confidence level**: this is the likelihood of discovering a lot whose percentage of non-compliant units is greater than the detection level (a confidence level of 95% means that 95 times out of 100 the sampling will discover a non-compliant lot).

#### ❑ Definition of a 'lot'

On the basis of the sampling plan, **there should be a relevant and precise definition by the operator what they will consider a 'lot'**.

The 'lot' will represent an identifiable quantity of product (fresh or dried mango) which will be shipped in one batch and for which the operator has determined that they have common characteristics such as:

- their origin: mangoes harvested at a single plot or orchard, at about the same time, processed in the same way with fertilizer and plant protection products;
- their variety;
- the type of unit packaging, shipper or markings.

#### ❑ Predicting the number of analyses required

When setting up the inspection programme with sampling, it is necessary to distinguish **different scenarios** that will govern how the number of analyses to be carried out on a lot (in order of priority) is determined:

- the number of analyses is required by regulations (national, regional or international) or international 'Guidelines' (e.g.: ISMP No. 31 standards or principles established by the *Codex Alimentarius – CAC/GL 50-2004*);
- the number of analyses is set on the basis of the risk analysis;
- the number of analyses is required by the customer (e.g. GLOBALG.A.P. private or voluntary standards, specifications etc.);
- the number of analyses is estimated in the absence of sufficient information.

#### ❑ Taking and preparing samples<sup>9</sup>

**Each lot should be controlled (or inspected)**, but not necessarily analyzed.<sup>10</sup> Every lot to be analyzed is **sampled separately**.

Insofar as possible, the '**basic samples**' should be taken from different parts of the whole lot. Any deviation from this rule should be justified and documented in a supporting file (or report).

The '**total sample**' is the one that will be analyzed. **It is obtained by assembling all basic samples.** This overall sample is preferably homogenized at the laboratory. 'Identical' samples can be taken from the homogenized overall sample for the purposes of any counter testing (in the event of appeal and arbitration).

During sampling and sample preparation, care should be taken to avoid any changes that may alter the toxin number or content or affect the analyses or representativeness of the overall sample.

It is important that the laboratory receives a representative sample of the product which has **not been damaged or modified** during transport and storage. The sample should be protected from foreign contamination due to air, environment, packaging of the samples, sampling devices or poor handling. Each sample is placed into a bag or clean container made from inert material which offers adequate protection. During inspections, each official sample taken will be sealed at the place it was taken and identified.

Samples should be **clearly and fully identified** with adhesive tape, a label or marking of suitable size so as to contain information about the sample. Instructions/documents must identify each lot unambiguously and clearly indicate the origin, date and place of sampling, along with any other additional information that may be useful to the laboratory (e.g. analyses to be carried out on the sample, net weight or volume).

It is advisable to submit the sample to analysis in the original, unopened packaging (sample bag, box, carton etc.).

In the case of microbiological analyses (water, dried products), the **temperature** at the time of collecting the samples and their receipt at the laboratory is also often useful to the laboratory when interpreting the results. Samples should be protected from heat.

The following equipment should be available in sufficient quantities and should be used when **taking samples for microbiological analyses**:

<sup>9</sup> If in doubt when taking samples, ISO 18593 will be used as reference standard.

<sup>10</sup> A documentary and/or visual control is mandatory for each shipped lot. However, an analysis of the physico-chemical or microbiological parameters is not necessarily required for each lot.

- sample bags, numbered bags, clean/sterile or disposable containers;
- clean knives, scissors, tongs;
- **for water: sterile containers with hermetic sealing system;**
- insulating box (polystyrene cool box) for transporting samples such as water (able to cool with sufficient cooling elements);
- disinfectant wipes for cleaning hands and forearms before taking the samples;
- markers, paper towels;
- thermometer (alcohol).





# Chapter 8

## Market Access Strategy

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## 8.1. Business positioning and market access strategy

### 8.1.1. Introduction

Before making investments to set up a food safety management system (FSMS), the fruit and vegetable entrepreneur/exporter must formulate its own clear and explicit **strategic objectives** and **study the extent to which its products are geared to the markets it is targeting**.



The **steps of this analysis** must cover all the company's functions as well as its environment.

#### 1. Products and markets

##### Products:

What products are exported?  
What is the: packaging / quantity / period / frequency?  
What freight volumes are available?  
Transport by air, ship, road?

##### Markets:

**Export:**  
Country(ies) / products / price  
  
**Local market:**  
Products / quantity / price

##### Customers:

Importer  
Collective food services  
Large and medium retailers  
Group purchasing organizations (GPO)

#### 2. Production context – product sources

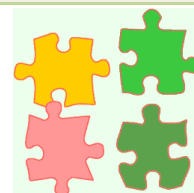
##### 4 possible situations:

- **Vertical Integration: 100%** of the products supplied are subject to control – total traceability must be guaranteed.
- **Some of the products are subject to control:** Although only a part of the supply is subject to control, total traceability can be guaranteed.
- **Products collected directly from farms with continuous control and oversight** by an extension agency / supervisor and technical advisor: the grower receives guidance and supervision to manage the site and the soil, the crops and production programmes, use of fertilizers, irrigation, protection of the harvest, safety of pesticides, waste management, hygiene and workplace safety. In this case, traceability can be ensured in various manners.
- **Products collected directly from farms with or without specific guidance other than technical information on the use of pesticides and assistance from the country's extension services.** Traceability control is highly relative if not impossible, entailing serious risks that regulatory requirements have not been met, in particular those on the use of pesticides.



### 3. Partners and alliances / competition

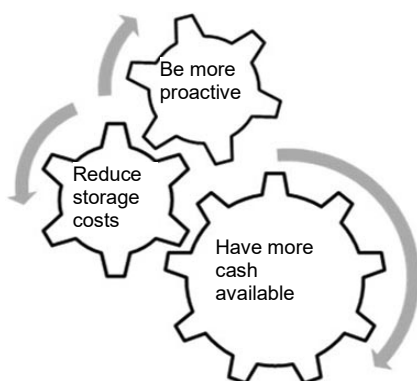
- Does the company have partners?
- Is it part of an alliance?
- Who are the competitors and what are their products?
- How many suppliers are there, in addition to the farmers?
- What is the relationship with these suppliers?



### 4. Analysis of the company's know-how and activities

#### Know-how:

- What is the company's know-how? How has it evolved? How does it make the company stand out among the others?

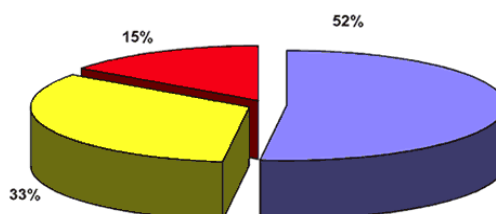


- Which company activity is most visible to customers?
- Which company activity is most visible to its employees?

#### Type of activities:

- The company has one or several business activities: farm production, transport, storage, packaging, for one or several products, extension and production supervision services, etc.
- Does the company occasionally provide other services such as shipping, personalized labelling, purchase of additional related products, agronomist expert services, and so on?

*In these cases the company's different activities must be considered in segments in order to analyze the evolution of each one separately.*



### 5. The company's organization and its resources

#### Status:

- Public limited company, private limited liability company etc.
- Impacts on its functioning

#### Capital:

- Who holds the capital?

#### Financial resources:

- What financing can the company count on? Self-financing ability, working capital, etc. Available funding (financiers, eligibility for national or international)

#### Jobs and available workforce / work organization:

- How many people does the company employ?
- How is the work divided up in the company?
- What is the employees' management style?
- How many management levels have been established?
- What are the qualification levels?
- What is the staff turnover rate?

programmes, etc.)	
	<b>Installations and equipment:</b> <ul style="list-style-type: none"> <li>What kind of installations and equipment does the company have (buildings, logistics, storage, packaging, number of lorries, warehouses, etc.)?</li> </ul>

## 6. The company's business position

- **Trader**  
Very small scale, irregular sales schedule, whenever the opportunity arrives.
- **SME – generic exporter**  
Regular sales to a fixed clientele (one or two shipments per week); most sales in bulk; almost all through wholesalers.
- **Large exporter - generic**  
Regular sales to a fixed clientele almost daily; sales in bulk and pre-packaged; most sales to wholesaler chains, but also to small supermarkets.
- **Top-of-the-range producer / exporter**  
Regular supplier to top-level supermarkets and distributors; most of the products sold are pre-packaged in quality packaging and combinations of products are available.
- **Producer / exporter with high added value**  
Top-of-the-range producer / exporter with one or more tightly controlled processing lines that manufacture ready-to-eat produce.

### 8.1.2. What is the company's strategy?

#### A company's export capacity is determined by several factors:

1. the nature and **volume** of the products to be exported,
2. the company's ability to provide a **constant flow of the product** in similar conditions from one shipment to another, from one growing season to another,
3. the **capacity to meet** regulatory and market **requirements** that differ from one market to the next, with requirements of varying complexity to fulfil.

The producer/exporter has several objectives:

- satisfy market requirements in terms of **quality** and **safety**;
- provide a **constant supply of products** in order to meet demand;
- ensure the products' **traceability**;
- make sure that only **authorized inputs** are used and that pesticide residues remain within authorized limits (MRLs);
- control costs;

- and, if possible develop new products or reach out to new markets.



*The company must decide which market it wishes or is able to target **in the light of its investment capacity.***

The company's policy and strategy thus depends on its ability and willingness to meet all the demands of the market it has targeted:

- **market access requirements:** marketing standards, compliance with standards, use of pesticides and respect for MRLs, plant protection and phytosanitary controls, whether or not to use GMOs, and so on;
- **food safety requirements:** sanitary and phytosanitary rules, hygiene, product traceability, etc.;
- **specific requirements imposed by buyers/importers/distributors** regarding the product's organoleptic quality (taste, smell, color etc.), packaging and labelling, concerns about the environment and preserving animal species, health and safety at the workplace, workers' social welfare, ethical values, and company management.

The ability to meet all these requirements calls for **tight control of the produce supply process** in addition to compliance with regulations and market standards on packaging, storage and shipment.

The company's response must take into account the fact that in most cases producers/exporters must cope with the **recurring challenge** of **satisfying a market's immediate and seasonal needs with** products grown by **small-scale farmers on the basis of arrangements or contracts that are more or less official and formal.**

#### Before taking any decision:

Before it defines any business development strategy the entrepreneur/exporter must be fully aware of and understand all regulatory and market requirements currently applied and in the making, and for all markets: local, regional and exports.



*If the company wishes to increase its production/export volumes it must **ascertain that its supply sources are reliable** and that the products obtained from its suppliers are safe and traceable.*

Depending on the means available, in particular the different product sources and the market in view, the company must define its strategic position and decide whether it wishes to operate as a:

- **Producer / exporter – with high added value:** Top-of-the-range producer / exporter with one or more tightly controlled processing lines to manufacture ready-to-eat produce
- **Top-of-the range producer / exporter:** Regular supplier to top-level supermarkets and distributors. A majority of the products sold are pre-packaged in quality packaging and combinations of products are available.
- **Large exporter - generic:** regular sales to a fixed clientele almost daily; sales in bulk and pre-packaged. Most sales to wholesaler chains, but also to small supermarkets.
- **SME – generic exporter:** regular sales to a fixed clientele in one or two shipments per week. Most sales in bulk; mostly through wholesalers.
- **Trader** – very small scale, irregular sales schedule, whenever the opportunity arrives.

**There are two general types of strategy:**

1. **Continue as a small business**, keeping overhead down and participating in bulk or niche markets on a seasonal basis, all the while complying with regulations, especially those on food safety. The supply process must be controlled (specifications, signed agreement with producers, and so on).
2. **Invest in modern facilities with greater control capacity and systems** that guarantee all the food safety and traceability requirements, and also meet buyers' specific requirements (private standards). This means being able to sell to the most demanding clients, who will require value added products and, if possible, will also pay a good price for this (top quality pre-packaged products, for example).

## 8.2. The European Union market for fruit and vegetable exports

### 8.2.1. A diversified market



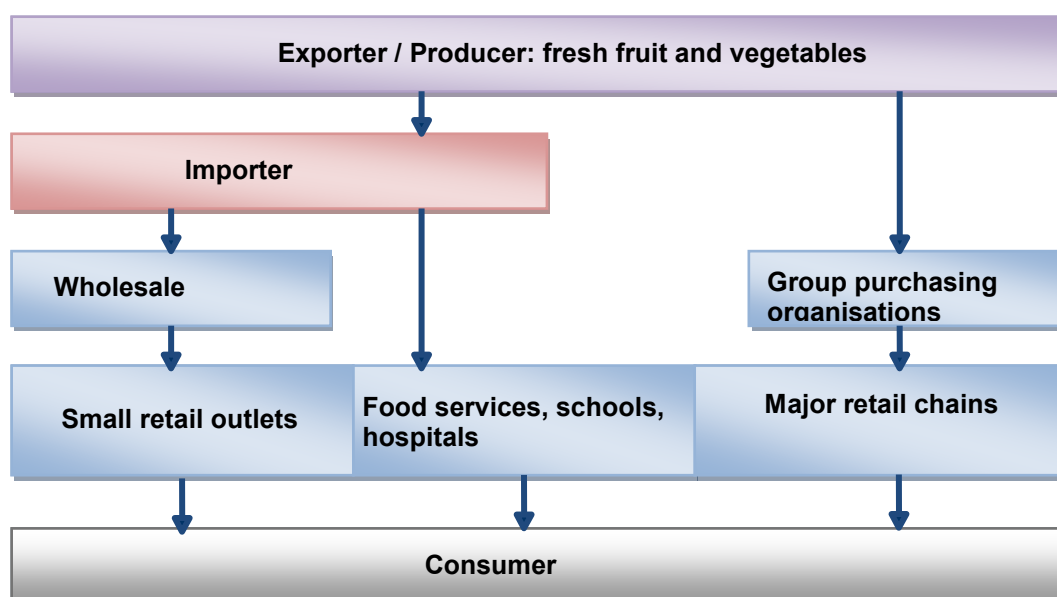
*In Europe, fruit and vegetable wholesaling and retailing varies widely from one EU country to another.*

**European consumers have a strong and constant interest in the issues of food safety and product traceability.**

*They are actively concerned, as shown by the 2010 Eurobarometer. Some 99% of food hygiene and plant protection regulations have been harmonized in the EU.*

Conditions for access to European markets cover a wide range:

- exporters can consign their products to European importers;
- importers can re-expedite or sell the products to regional distribution centers, group purchasing organizations, wholesale markets for retailers and other buyers, or for individual or collective food services (restaurants, hospitals, schools);
- exporters can send their products directly to regional distribution centers or purchasing organizations that supply their supermarkets or food service members.



Although European product safety regulations have been fully harmonized, there is **clear diversity in other types of requirements** regarding the environment, ethics, local criteria etc., not to mention other quality levels set by importers. This lack of uniformity is seen not only among **different countries** in Europe, but also among **different segments** of the same national market.

This diversity reflects **disparities in market structure**, retailing culture and consumer preferences in terms of quality, **consumer tastes**, packaging standards and demand for continual supply. For example:

- wholesale markets tend to be more flexible about product quality, especially when the supply becomes scarce;
- British supermarkets (and the country's top scale restaurants) have the most stringent requirements whereas other buyers in the UK and in other EU countries are more flexible.

### 8.2.2. Characteristics and requirements of European buyers

#### □ The quality approach of the Large and Medium Retailers ("LMR")

A **growing share** of fresh produce (including imports) is sold to supermarket chains. This sales method either bypasses the traditional wholesale market (the case in the UK) or entails vertical integration between retailers and wholesalers (in Germany and Scandinavia).

Country	% LMR Market (in value)	Market share in % (in italics: those that impose GLOBALG.A.P.)
BE	73%	Carrefour 26%, Delhaize 22%, Colruyt 15%
NL	70% fruit 78% vegetables	<i>Superunie 30%, Albert Heijn 30%, Schuitema 15%, Aldi 9%, Laurus 8%</i>
DE	75%	<i>Edeka 22%, Rewe 15%, Lidl-Kaufland 12.5%, Aldi 12%, Metro 9%</i>
IE	70%	<i>Tesco 28%, Dunnsore 23%, Supervalu 19.5%</i>
ES	40%	Mercadona 15%, Carrefour 14.2%, Eroski 9.4%, Auchan 7.2%, El Corte Ingles 7%
IT	42% (65% North, 30% South)	Coop Italia 16%, Auchan 12%, Carrefour 10%, Conad 10%, Esselunga 6%
PL	25%	<i>Tesco, Carrefour, Auchan, Metro</i>

Source: UBIFRANCE/DSA/agroalimentaire/Service des produits végétaux, 2007.

It is surprising to see how many companies in northern Europe oblige their suppliers to comply with private certification schemes (most often of the GLOBALG.A.P. type).

Despite a trend towards concentration among major retailers, among Europe's supermarkets there are still wide discrepancies in requirements, competition strategies and supply agreements:

- hypermarkets prevail in Great Britain, and discount retailers are also present on the market;
- in Germany, however, the discount retailers prevail, and a limited number of hypermarkets are also found;
- hypermarkets predominate in France;
- in Italy, however, shoppers still prefer the traditional grocers.

**Buyers for the large and medium retailers set requirements that differ from one country to another and from one chain to another. The following, for example, are the requirements of two supermarket chains:**

#### **CARREFOUR (French supermarket chain)**

- Global specifications applicable to all the group's products and suppliers.
- Specifications cover the process from production to packaging, aimed at respect for the environment, food safety and personnel management.
- Product registration by growing area.
- Product control plans (tasting, plant protection product residues, approval, etc.).
- Internal reporting system to measure progress.
- Regular audits by an independent body.



#### **TESCO (British chain)**

- Standards for growers and packing stations focusing on good agricultural practices, food safety and personnel management.
- Mandatory staff training.
- Inspections by the client.



#### **□ The quality approach of other buyers<sup>1</sup>**

Some major operators (group purchasing organizations) implement a **growth strategy based on competitive prices and cuts in their operating and procurement costs**. This type of competition exists in France, Germany, and much of Southern Europe, reflecting consumer preferences in these areas.

<sup>1</sup> Following S. Jaffee, "From Challenge to Opportunity: Transforming Kenya's Fresh Vegetable Trade in the Context of Emerging Food Safety and other Standards in Europe", *PREM Trade Unit*, 2003.



Other firms focus their **strategy on differentiation of their products and related services**. This is the major form of competition among most of the UK's leading supermarket chains.

Even among countries where a handful of multi-chain companies have come to account for the majority of fresh produce and broader grocery sales, there **remain differences in their systems for procuring produce**:

Quality approaches differ from one EU country to the next:

- **In the UK**, retail consolidation has included efforts to centralize produce procurement and consolidate supply chains through so-called category management. The major retail chains now essentially bypass the wholesale markets and appoint a limited number of agents to source and even promote a certain range of produce (i.e., citrus fruit and vegetables). For any one category of produce, the firms appoint only two or three category managers who will organize and oversee production and delivery from both domestic and foreign sources. These category managers have become the gatekeepers to the supermarkets.

#### Quality approach in the United Kingdom

- Initiatives developed are essentially private.
- Private labels are replacing the official quality marks.
- The ACCS (England) and SQL (Scotland) programmes for cereal and oil protein crops have been extended to other crops.
- Concept based on certification of farms: requirements for agricultural practices, traceability and market.
- Third-party inspections.

*Source: The European Commission and Quality, 2002, Mrs Peutz.*

- **In France**, many supermarket operators use a more decentralized system for procuring produce with individual or clusters of shops having more regional and local approaches—including purchases from wholesale markets. The Rungis wholesale market outside of Paris remains a major force in the French fresh produce market, especially in the import of fruit and vegetables.

#### Quality approach in France

- Private labels exist alongside official quality marks (label rouge, AOC, etc.).
- Farm qualification programme (the French national standards for integrated farming): requirements related to agricultural practices, traceability and respect for the environment.
- Third-party inspections.

- **In Germany**, wholesale markets have experienced a relative decline but they still play a major role in servicing the retail trade and fresh produce markets in general.

### Quality approach in Germany

- A national mark policy, the C.M.A., managed by the German Agricultural Marketing Board, of the Ministry of Agriculture, and controlled by the Chamber of Agriculture.
- Superior quality mark.
- Price differential on the order of 30%.
- Not available for imported products.
- The Ministry of Agriculture is exploring the possibility of adapting the ISO 8001 standard to agricultural production.

Source: EFAC, 2002

- The countries in **northern Europe** have traditionally set great store by the concepts of environmental protection and animal welfare.

### Quality approach in Sweden

- Stringent requirements on quality management, environmental protection and animal welfare.
- Strong development of the farm assurance scheme since 1995 based on the ISO 8001 and ISO 14001 standards.
- Private initiative by the Swedish Agricultural Federation (L.R.F.) to comply with export market requirements (United Kingdom).

### Quality approach in Denmark

- Integrated farming quality label for beef and veal and pork.
- VAREFAKTA mark certifies the product's conformity with the information given on the product label.
- All products.
- The mark is familiar to 80% of the population.
- It is both possible and desirable for imported products to be labelled.
- Farm certification programme (KVAMILLA) is underway: it is a synthesis of the ISO standards 8001 and 14001 under third-party control.

Source: EFAC, 2002

## 8.2.3. Basic regulatory requirements for European markets

### ❑ The producer's liability

We will not repeat here the information already given in Chapters 1 and 2 on hygiene and food safety regulations and requirements. Nevertheless we should stress the concept of

'Liability for defective products' under Directive 85/374/EEC of 25 July 1985<sup>2</sup> (amended by Directive 1999/34/EC of the European Parliament and of the Council).

**The producer is liable for damages caused by a defect in his product.**

- Damage: moral or physical harm to someone. It results from personal injury or damage to any item of property other than the defective product itself.
- Defect: A product is defective when it does not provide the safety which a person is entitled to expect.



The victim ('injured person') can claim compensation for damages if he can prove:

- the existence of the damage;
- the product's defect;
- the causal relationship between defect and damage.

In this context the term '**producer**' is understood to mean any person acting in a professional capacity who assumes the role of a producer by placing his name, mark or any other distinguishing feature on the product, or who imports a product into the European Union for sale, hire, leasing or any other form of distribution. If the producer or importer cannot be identified, each supplier shall be treated as the producer unless he informs the injured person, within a reasonable time, of the identity of the producer, importer, or entity that supplied the product.

**Conclusion (the company's attitudes and responsibilities)**

Any operator, consumer or concerned party can, at any time, request proof of a foodstuff's safety at a given point along the chain of responsibilities. The exporter, a participant in the chain of responsibilities (from farm to fork), must therefore comply on a permanent basis with food safety regulations and be able at all times to provide proof of conformity.

In any case the company must develop a "due diligence" approach to its food production and management practices. In other words, it should do what has to be done in a conscientious and responsible manner.

These requirements are expressed in the **obligation** of each firm involved **to set up a food safety management system** based on the HACCP approach.

<sup>2</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJEC, L 210 of 7 August 1985.

Requirements for application of the HACCP or equivalent method		
Steps	Required under regulations	Required by purchasers
Farm production from growing to harvest (primary production)	European regulation on hygiene: risk analysis and application of rules of hygiene (Good Practice Guides, inspired by the HACCP method)	HACCP or equivalent risk control methods are required by some buyers, such as group purchasing organizations and supermarkets (primarily in Great Britain)
After harvest: receiving, grading, packaging, storage, distribution.	European regulation on hygiene: HACCP or equivalent method is mandatory.	HACCP requested HACCP controlled when buyers require conformity with the BRC standard or ISO 22000

#### ❑ Product information and monitoring by consumers

The products must provide information in order to guarantee that:

- all operators along the food chain receive accurate and understandable information so that they can handle, store, process, prepare and present the product in a correct and fully safe manner;
- the lot can be easily identified and withdrawn or recalled if necessary;
- consumers are sufficiently informed about the safety of their food so that they can understand the importance of the information displayed on a product, make an informed choice adapted to their individual situation, and know the best methods for storage, preparation and use of their food to prevent contamination from foodborne pathogens or their spread or survival.

There should be a clear distinction between information intended for operators or merchants and information for consumers, especially on the product label.

#### ❑ Marketing standards for unprocessed fruit and vegetables

Since 1 July 2009 marketing **standards** on the **size and shape** of 26 kinds of produce have been **repealed**.<sup>3</sup> This measure, adopted amidst a rise in food costs, aimed to **reduce food waste** and to give consumers the largest possible range of food items. The marketing standards set under **Regulation (EC) No. 2200/96** of 28 November 1996,<sup>4</sup> however, have been **maintained for 10 types of fruit and vegetables**: apples,

<sup>3</sup> Apricots, artichokes, asparagus, aubergines, avocados, beans, Brussels sprouts, carrots, cauliflowers, cherries, courgettes, cucumbers, cultivated mushrooms, garlic, hazelnuts in shell, headed cabbage, leeks, melons, onions, peas, plums, ribbed celery, spinach, walnuts in shell, watermelons, and chicory.

<sup>4</sup> The implementing rules are given in Regulations (EC) Nos 1580/2007 and 1221/2008. Several other European regulations are also related to marketing standards in the fruit and vegetable sector. Examples are: Regulation (EC) No. 907/2004 amending the marketing standards

citrus fruit, kiwi fruit, lettuce, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes.<sup>5</sup>

These ten types of produce account for **75% of the value of EU trade**. Marketing standards lay down the following characteristics:

- botanical definition of the product;
- minimal characteristics, maturity criteria;
- classification by commercial value categories;
- grading;
- tolerance limits for products that do not meet quality or size specifications;
- provisions on presentation, uniformity, packaging;
- provisions on labelling: identification of the packager and shipper, type of product, product origin, market characteristics (category, grading, number of units, net weight);
- official inspection mark.



**N.B.:**

National authorities can authorize the sale of **non-standard** items.

**In this case they must be labelled in a way that distinguishes them** from products in the other categories: 'Extra', 'Category I' and 'Category II' (this latter category applies, for example, to produce of irregular shape, size or color).

The European marketing standards also impose:

- the obligation to place on the market quality products that are healthy, reliable and marketable, thus that meet obligations on contaminants (heavy metals and pesticide residues);
- conformity with the application of microbiological criteria and in general with codes of hygienic practice.

In the **absence of specific standards** for the produce imported, and in particular in case of dispute, **reference to the Codex Alimentarius standards is mandatory** (WTO agreement):

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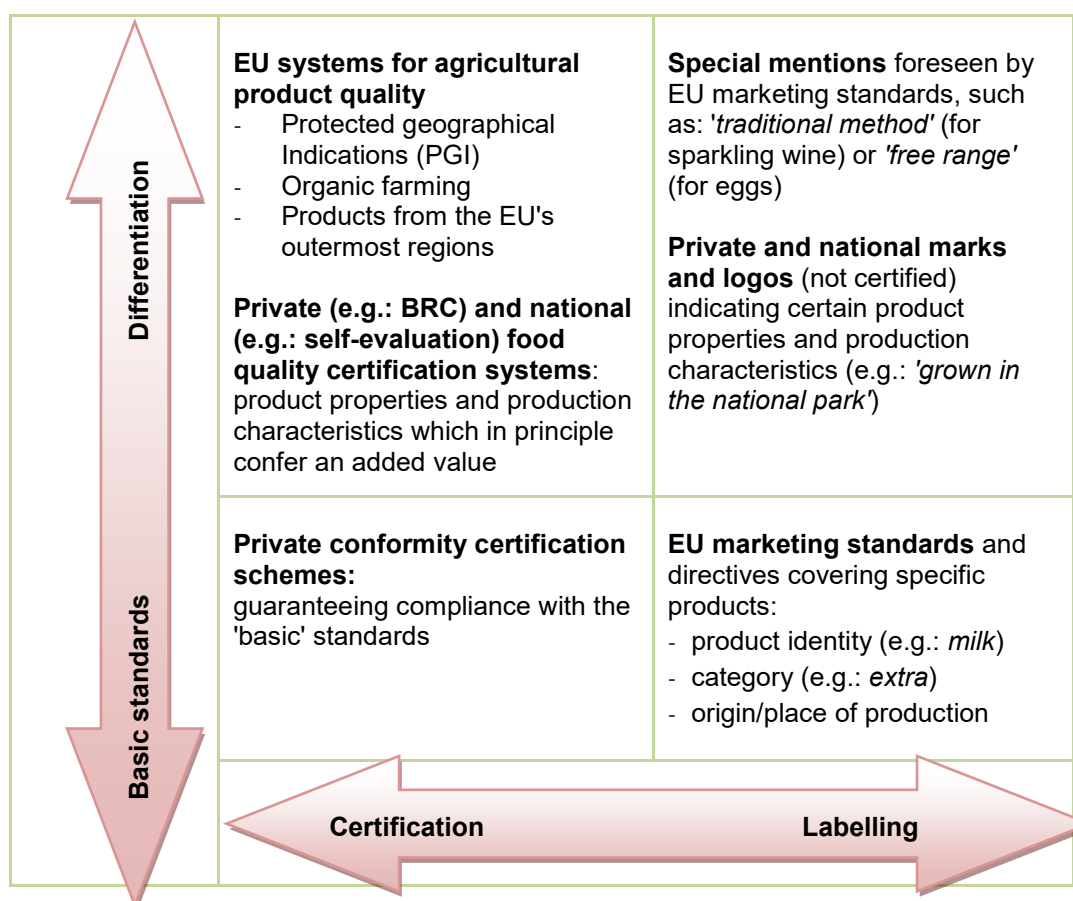
applicable for fresh fruit and vegetables with regards to presentation and labelling, and Regulation (EC) Nos 1148/2001 and 2379/2001 regarding checks of conformity. They are presented in COLEACP training Manual "Regulations, norms and private standards.

<sup>5</sup> For these ten types of fruit and vegetables, import from other countries is only possible if the product complies with these specifications or equivalent standards.

**Codex standards are available for the following products at least:**

Avocado	Maize
Banana	Mango
Carambola	Mangosteen
Chayote	Mexican lime
Ginger	Nopal
Grapefruit	Papaya
Guava	Pineapple
Limes	Pummelo
Litchi	Tannia
Longan	

Market labels and standards can be classified as follows:



**Official inspections of conformity with marketing standards and certificates**

The EU Member States verify conformity with the relevant standards at all stages of marketing, during transport, and on import from other countries. Each State has designated a single competent authority for this task.

In collaboration with the national authority, the European Commission can also conduct its own inspections.

**Authorization for placing on the market is subject to certain conditions:**

- a ‘Certificate of conformity’ delivered by the competent authorities after examining sample lots (form EUR 1). The EU can also accredit a conformity assessment body in the exporting country (e.g.: Morocco).
- a ‘Certificate of origin’ delivered by the competent authorities of the exporting country.

❑ **Standards on residues of pesticides and other chemical contaminants**

Samples to check for MRLs and other contaminants (such as lead and cadmium) are analyzed **as soon as the lots enter customs** (at the ‘entry point’ – ports or airports). This work is done by the authorized public bodies in each EU member state.

Although the nature of checks and their consequences on business transactions vary from one country to another, unsatisfactory analysis results can hinder the company's efforts to ensure a constant trade flow since it may face stricter controls after falling under suspicion.<sup>6</sup>

**Private inspections by distributors/importers, however, hold more serious consequences at the business level.**

The authorities in Great Britain publish the name of operators/distributors that sell produce which do not respect MRLs. This is an efficient deterrent because it can tarnish a retailer's reputation. The retailer thus conducts tight checks on its suppliers and is quite hard on those that do not meet its standards.

This process has led several major British supermarkets to ask their suppliers (whether a local farmer or an importer/distributor) to control residue levels. Purchasing organizations and supermarkets also run residue checks.



Consumers' associations closely monitor the British supermarkets' endeavors on pesticides. (e.g.: BEUC – European Consumers' Union; Food collective; *Friends of the Earth*, UK; *Test-Achats*, Belgium).

Exporters report that a growing number of their customers ask about pesticides. On the other hand, these exporters are not always aware that their customers have their consignments analyzed for residues.

<sup>6</sup> According to data of the EU Food and Veterinary Office (FVO) in Dublin, exceeding the MRL rarely leads to official coercive measures, except in the case of repeated violations of the levels by the same country/supplier. In such a case, non-EU suppliers run the risk of having their products detained, having restricted market access or even being banned from the European market.



## ❑ Standards on phytosanitary requirements: to avoid the proliferation of pests

**Phytosanitary inspections** are conducted at EU borders to prevent the introduction and/or halt the spread of organisms that are potentially harmful to plants. These are the so-called '**quarantine**' pests.

**Plants and plant products** from countries outside the EU, including fruit and vegetables that are **on a list** drafted by the competent national authority of each country, based on the annexes to Directive 2000/29/EC, must be **accompanied by a 'phytosanitary certificate'**.

Phytosanitary certificates are required for most vegetables and for most countries of origin.

This certificate is issued by the responsible body of the consigning country, based on the model drawn up by the International Plant Protection Convention (IPPC) and FAO, and written **in the language of the destination country**.

The National Plant Protection Service inspects the products on entry into the EU importing country. The inspection consists in control of the documents, visual identification, and a visual or laboratory plant health examination, either on a representative sample or on the entire lot.

To facilitate checks at the point of entry into the importing territory (the list of points is published in the country's official journal), the importer, duly registered in the official register, must **inform the national plant protection services at least 24 hours before the arrival of the plant products**.

Phytosanitary non-conformity can incur sanctions that include:

- placing the lots in quarantine,
- prescribing treatments,
- destroying the lots ,
- possible criminal proceedings, that can be accompanied by additional penalties of publication or posting of the official decision.

## ❑ Standards relating to Genetically Modified Organisms (GMO)

In order to be sold in the EU, genetically modified products or those containing GMOs **must be authorized** following a risk assessment by the EFSA (the **official list** is published in the *OJEU*). After a 'moratorium' period<sup>7</sup> (imposed *de facto* since 1998), new European regulations entered into effect in 2003 and **imposed traceability and labelling standards for products containing over 0.9% GMO**.



<sup>7</sup> It was not prohibited to grow GMOs, as the 18 authorisations delivered between October 1991 and October 1998 remained valid, but a moratorium was placed on delivery of new authorisations.

**Regulation (EC) No. 1830/2003<sup>8</sup>** concerns the traceability and labelling of genetically modified organisms. In particular it sets a threshold of 0.9 % for '*adventitious traces*' below which labelling is not mandatory.

Authorizations issued from 2004 to 2010 concerned the placing on the market of GMO products used in the food sector. In March 2010, the European Commission authorized cultivation of a transgenic potato (BASF's Amflora).

Fruit and vegetables imported into the European Union are inspected for the presence of GMOs as part of the issuance of the **conformity certificate (labelling checked)** and the **phytosanitary certificate**.

#### 8.2.4. Classification of markets

Markets can be classified as follows:

##### ➤ **Markets with basic requirements**

###### **Level 1:**

**The produce must comply with the rules in force:** this is the case for importers who sell to wholesale markets or directly to retailers, to collective and individual food services, and to supermarkets or purchasing organizations that do not require special requirements.

###### **Level 2:**

**The produce must comply with the rules in force and also meet additional requirements** set by the importer or buyer (special organoleptic qualities or geographical requirements). In particular they must also be prepared to meet new obligations on product traceability.

Level 2 clients are the same as those for level 1. Some purchasing organizations have introduced a procedure to approve their suppliers through importers to whom they notify their requirements, in particular regarding the precise origin of products and information available on their production and packaging.

##### ➤ **Markets with stringent requirements**

###### **Level 3:**

**The produce must comply with the rules in force, and be accompanied by proof of conformity certified by the results of analyses** provided by the exporter, or those carried out directly by the importer or the purchasing organization.



<sup>8</sup> Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ L 268/24 of 18.10.2003.

**The buyer has approved the supplier** and requires product traceability. The buyer can check that HACCP self-evaluation and risk control procedures have been organized.

The buyer/importer draws up its own standards which impose additional requirements.

The primary concern of these buyers is adequate and demonstrable internal control of food safety, with occasional external controls by an inspection body.

**Level 4:**

**The produce or their production and packaging conditions must comply with international standards or collective standards. Conformity is attested by a certification or inspection body which issues a certificate.**

The following standards are those most frequently applied:

- for safety and hygiene: GLOBALG.A.P. (primary production) and BRC, IFS, ISO 22000 standard (for conformity with the HACCP method);
- for production modes and social and environmental impact: Organic farming and/or Fair Trade (FLO);
- for ethical requirements: SA 8000, ETI;
- for environmental management: ISO 14001, Rainforest Alliance;
- for quality management: ISO 9001.



Summary of safety requirements	Regulatory obligations	Markets with basic requirements		Markets with stringent requirements	
	Official Controls	Level 1	Level 2	Level 3	Level 4
Regulatory conditions for market access controlled by public authorities					
Respect for marketing standards: product packaging, labelling, marketing conditions	Certificate of origin issued on export Certificate of conformity issued on import.	Application of the rules in force.	Specific procedures to control fully processed products, especially microbiological and contaminant analyses by importers and distributors		
Control of residues	Official controls on import	Respect for MRLs without requiring self-evaluation systems	Analyses requested or conducted by the importers or distributors		
Phytosanitary control	Mandatory phytosanitary certificates issued by the exporting country depending on the product, and systematic inspection by official services of the importing country which consists in control of the documents, identification, and examination of plant health, either on a representative sample or on the entire lot.				
Control of GMOs	Presence of GMOs must be indicated on the label, and GMO products or those containing GMOs must be authorized.			Controlled	
Food safety / hygiene / product traceability					
Production, packaging, transport	Organization of self-evaluation and application of Good Practice Guides for risk control (GAP, GHP, GTP, etc.). Traceability is compulsory	Prerequisite Programmes (PRP/PRPo) HACCP required with internal proof of its application (audits, reviews, etc.) Self-evaluation and FSMS set up Traceability is compulsory			

Summary of requirements of buyers/distributors/importers	Regulatory obligations	Markets with basic requirements		Markets with stringent requirements	
		Level 1	Level 2	Level 3	Level 4
<b>The product's organoleptic qualities</b> (taste, consistency, scent, color etc.)  <b>Or other special features</b> (religious, ethnic or ethical criteria)	Supervision and approval of standards placed under quality marks or official protection		Specific product characteristics and the importer's approval of producers and exporters can be required	The buyers' main concern is adequate and demonstrable internal control of food safety, possibly through external control by an inspection body. Furthermore, the buyers can also impose requirements on product quality, environmental impact, and workers' welfare. The buyers may conduct the controls themselves or request third-party assessment by control bodies.	Conformity with international or collective standards, attested by a certification or inspection body which issues a certificate or affidavit.  Main standards: BRC, IFS, ISO22000
					Organic farming GLOBALG.A.P. ISO 14001
<b>Environment &amp; animal protection</b>	Regulations of the production country applied				GLOBALG.A.P. SA 8000, ETI Fair Trade
<b>Health and safety at the workplace and CSR (corporate social responsibility)</b>	Regulations of the production country applied				Certification under ISO 9001
<b>Company management</b>					

# Chapter 9

## Private standards (PS)

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## 9.1. Private standards

### 9.1.1. The growing number of private standards

The due diligence clause associated with European food safety legislation, together with consumers' growing concerns about what's in their plate, has had repercussions in the agri-food industry. To shield itself against all risks, the private sector has developed **self-regulation systems** or **private standards** (abbreviated here as **PS**), which are based on the food industry's codes of good practice.

The process began in the United Kingdom with codes of Good Agricultural Practice (GAP) and a memorandum of good hygiene practices, which later became the food standard of the British Retail Consortium (**BRC**). These standards in turn inspired a number of similar initiatives by the private sector in other European countries (Jaffe, 2005). Retailers in the fresh produce trade have always asked suppliers to respect their requirements in terms of volumes, supply continuity and price. They are now asking these same suppliers to comply with a series of PS that **cover their production, processing and distribution methods**.

The increasing demands of consumers and civil society (as well as work by quality control NGOs) have spurred the retailing and distribution industry to **pay attention not only to food safety and quality, but also to the source of products**. They must take greater notice of questions regarding labor practices, environment, safety, and social responsibility. Until recently these issues tended to be the reserve of state and international agencies or else NGOs. Under consumer pressure, however, the major distribution chains appear to be getting more involved through specific certification initiatives.

### 9.1.2. The various types of private standards

#### ❑ Private Standards for products, processes and management systems

Private standards generally focus on one of **three categories**:

- products;
- processes;
- management systems.

The first focuses on characteristics related to a product's quality and safety. The second category, process standards, refers to the conditions under which products and services are to be produced, packaged or processed.

Management system standards assist organizations in managing their operations. They are often used to help create a framework that then allows the organization to consistently meet the requirements set out in product and process standards.<sup>1</sup>

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<sup>1</sup> [www.standardsinfo.net/info/aboutstd.html](http://www.standardsinfo.net/info/aboutstd.html).



The PS described in this chapter on food safety and respect for social and/or environmental criteria are process and management system standards.

#### ❑ Subjects areas and origin of these standards

The extended PS family can also be **sub-divided** on the basis of broad **subject areas** (food safety, social responsibility, environment). This classification, however, generally is not relevant since a private standard usually covers several subject areas. This is especially the case for some PS on food safety, which contain various control points relating to **respect for workers' rights** and the **environment** (GLOBALG.A.P, SQF).

In general, **the private sector has been more involved in drafting food safety private standards** while civil society has traditionally played a larger role in establishing PS on the social and environmental aspects of supply chains. (Examples are: Fair Trade, organic production, Sustainable Agriculture Network, Social Accountability International) (Liu, 2009).

At times, however, private industry, civil society and the public sector form coalitions in order to draft **new standards** or **codes of conduct** in certain areas. (International Standards Organization – ISO –, Ethical Trading Initiative etc.).

When it comes to PS on **food** safety, the World Trade Organization (WTO) distinguishes **three broad categories of standards** based on the stakeholders that prepare them:

- 1) **Individual PS** of retail and distribution firms, drawn up by these firms and applicable for a range of operators all along the supply chain (M&S Field-to-fork, *Carrefour's Filière qualité*, Tesco's Nurture, etc.).
- 2) **Collective and national PS**, drawn up by professional associations and/or NGOs (BRC - even if the BRC private standard is now applied at a global level, Assured Food Standards, Freedom Food, etc.).
- 3) **Collective and international PS**, generally applied by supply chains that operate in several regions of the world (GLOBALG.A.P., IFS, SQF etc.) (Henson and Humphrey, 2009). Collective and international PS can also be developed by professional associations and/or NGOs (or even by officially recognized bodies such as the International Standards Organization – ISO).

#### ❑ B-to-B or B-to-C

PS can also be divided into standards that are **Business-to-Business ('B2B')** or else **Business-to-Consumer ('B2C')**.

Individual standardization initiatives are generally intended for consumer communication (B2C). On the other hand, collective food safety standards usually aim to control and reduce risks throughout the supply chain. Consequently they are **not communicated to consumers** (B2B).

Standards that cover social and environmental aspects are primarily B2C (except for standards on ethical production or trade, such as SA 8000, BSCI etc.). B2C standards **often communicate on** the product's features **in the form of a label or mark on the finished product** with the clear aim of distinguishing it from similar products.

Implicit in the B2B approach, unlike B2C, is the fact that the market cannot finance the application of B2B standards with a higher price tag, since the consumer is not informed whether or not the product complies with any such standards.

#### ❑ Best endeavor obligations vs mandatory results

A final way to classify PS can be based on the requirements they focus on – either means (infrastructures, training, systems, inputs, etc.) or results (maximum limits of pesticide residues, intrinsic quality: color, grade, form).

**Most of the PS described in this chapter on food safety or respect for social and/or environmental criteria are standards that lay down best endeavor obligations rather than results.<sup>2</sup>**

The best endeavor obligations laid out in these standards concern the means and actions that a company must implement for the production phase, but also for the processing and marketing phases (AFD, 2010).

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<sup>2</sup> The distinction between best endeavor obligations and results is not always obvious. For this reason literature on the subject can give varying interpretations of these two concepts, and as a result classify the PS in different categories.

## 9.2. Private standards in the area of food safety

### 9.2.1. PS and food safety

Many PS on food safety have been developed for application to food production and processing. They include: **BRC**, **IFS**, the Netherlands' **HACCP**, **FSSC 22000**, **Synergy 22000**, **SQF 2000** (all based on the HACCP principles defined by the Codex), **SQF 1000** and last but certainly not least **GLOBALG.A.P.**

This section will only discuss the above PS, even though other standards obviously exist, in particular individual PS developed by retailing and distribution firms (M&S Field-to-fork, *Carrefour Filière qualité*, Tesco's Nurture etc.).

The **Global Food Safety Initiative (GFSI)** is a not-for-profit foundation created in 2000 and managed by the Consumer Goods Forum. The foundation's key objective is to benchmark (compare and approve) a set of food safety schemes on the basis of its reference document,<sup>3</sup> the **GFSI Guidance Document** which was drawn up in 2007 by a group of eight retailers.<sup>4</sup>

The private standards described below are some of those that have been benchmarked by the GFSI reference document.

The final goal of the scheme is to **limit the growing number of audits** that suppliers must go through by adopting the stance of "one certification for all". In practice, an ACP exporter, already BRC-certified who wishes to work with suppliers certified under SQF 2000 or the IFS should theoretically be spared the process of re-certification under these standards.

The **process** to become certified under a private standards scheme generally includes the following steps:

1. Choosing the standard best adapted to one's activity
2. Ordering/downloading the most recent version of the standard
3. Evaluating one's present situation compared to the standard's requirements
4. Introducing the changes needed to comply with the requirements (infrastructure, procedures, documentation, etc.)
5. Selecting a certification body (proposal, decision and signature of contract)
6. Determining the date, timing and scope of the audit
7. Optional: organizing a pre-audit
8. Realizing the on-site audit at the determined audit date by an auditor competent for the respective product category.

<sup>3</sup> This document is available for downloading from the GFSI website: <http://www.mygfsi.com/>.

<sup>4</sup> Carrefour, Tesco, ICA, Metro, Migros, Ahold, Wal-Mart and Delhaize.

The costs of certification under a PS depend on the size of the company and the systems already in place. For example, a company may have to invest in improving its (production) site or call on an external expert to document its procedures in order to prepare the audit.

### 9.2.2. BRC Food Technical Standard

The British Retail Consortium (BRC) is an association representing a broad range of retailers in Great Britain.



In 1998 the BRC, responding to industry needs, developed the BRC Food Technical Standard<sup>5</sup> to be used to evaluate **food manufacturers**. It is designed to help retailers and brand owners comply with new European regulations on food safety.

Despite its British origin, this private standard is presently applied in over 100 countries throughout the world. The BRC Food Technical Standard is a so called B2B (business to business) standard, meaning that compliance is not demonstrated with a label affixed to the end product.

Conformity with this PS must be **assessed by a third party that is accredited** as an official certification body and one that follows BRC audit rules. BRC thus does not perform audits, but remains owner of the PS and manages the certification process.<sup>6</sup>

### 9.2.3. The Netherlands' HACCP

The first version of the Netherlands' HACCP was launched in 1996 by a national committee of Dutch HACCP experts. HACCP (Hazard Analysis and Critical Control Point) is an approach to hazard analysis that is recognized worldwide. By regulation, HACCP is generally mandatory in all food manufacturing firms.



The *Codex Alimentarius* recognizes HACCP as the reference method for identifying hazards and controlling risks to food safety. The criteria of the Dutch system are based on the seven principles of the HACCP approach as described in the *Codex Alimentarius* Alinorm.

This private standard also covers food processing and is a business to business standard (B2B). The most recent version of this standard<sup>7</sup> contains all the key elements of the **international standard ISO 22000**.

<sup>5</sup> The standard is not publicly available but can be purchased from the BRC website for £ 90 ([www.brcbookshop.com](http://www.brcbookshop.com)).

<sup>6</sup> An on-line directory of these accredited certification bodies is available at: [www.brcdirectory.com](http://www.brcdirectory.com).

<sup>7</sup> The standard can be downloaded free of charge from the following address: [www.foodsafetymanagement.info/net-book.php](http://www.foodsafetymanagement.info/net-book.php). A complete list of certification bodies can also be found at this address.

#### 9.2.4. Food Safety System Certification 22000

The Food Safety System Certification 22000 is a private B2B standard for food safety management systems which is based on the international standard for food safety management systems (FSMS), ISO 22000:2005<sup>8</sup> and on the publicly available specification PAS 220.<sup>9</sup>



This PS concerns the food **manufacturing (processing) phase**.

The British Standards Institution's (BSI) specification PAS 220 is a document designed to support the implementation of ISO 22000. ISO 22000 explicitly requires the implementation of prerequisite programmes (PRP)<sup>10</sup> and gives a list of topics to consider, but it does not specify what the PRPs should comprise. PAS 220 thus steps in to specify these PRPs for food and food ingredient manufacturing processes.

The idea is for ISO 22000 to be used as an FSMS **generic standard** by all sectors and then to have sector specific documents covering the requirements of each sector.

Manufacturers already certified under ISO 22000 will only need an additional review against BSI PAS 220 to comply with this scheme.

ISO 22000:2005<sup>11</sup> **specifies requirements for a food safety management system (FSMS)** where an organization **in the food chain** needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption.

**It is applicable to all organizations, regardless of size**, which are involved in any aspect of the food chain and want to implement systems that consistently provide safe products.

**Synergy 22000**<sup>12</sup> certification is also based on ISO 22000 combined with either of the two documents below:

- Technical Specification ISO TS 22002-1 Prerequisite programmes on food safety – Part 1: Food manufacturing

<sup>8</sup> ISO 22000:2005 Food Safety Management Systems – Requirements for any organization in the food chain.

<sup>9</sup> The international standard ISO 22000 and the specification PAS 220 can be ordered from ISO and/or British Standards Institution. They can be used together with the additional requirements found in the certification scheme FSSC 22000 (Food Safety Standard Certification), which can be downloaded free of charge from the site [www.fssc22000.com](http://www.fssc22000.com). A checklist of PAS 220 requirements is available in the FSSC 22000 scheme documents. These requirements need to be checked and reported in every audit. A similar audit checklist with the ISO 22000 requirements is in preparation and will be published upon completion on the FSSC 22000 website.

<sup>10</sup> Prerequisite programme (PRP): basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption (ISO 22000).

<sup>11</sup> The international standard ISO 22000:2005 can be ordered from the ISO Website: [www.iso.org](http://www.iso.org) (price: CHF 124).

<sup>12</sup> The set of documents is available from the Synergy Website: [www.synergy-gss.com](http://www.synergy-gss.com).

- PRP 22000 (Synergy) for any organization in a food chain.

Unlike the private standard FSSC 22000, the combination of the ISO standard with the private standard PRP 22000 is applicable to the entire food chain as well as to related activities (from primary production, storage, transport and processing up to distribution). The combination of ISO 22000 & ISO TS 22002-1 is applicable only to the food processing or manufacturing step of the food chain.

### 9.2.5. GLOBALG.A.P.

#### □ Background

EUREPG.A.P. was set up in 1997 by retailers belonging to the Euro-Retailer Produce Working Group (EUREP). The driving forces behind this initiative were British retailers together with supermarkets in continental Europe. It was later decided to change EUREPG.A.P.'s name to GLOBALG.A.P. in order to reflect the aim to make the G.A.P. the dominant international standard and to prevent confusion with the growing range of public sector and civil society stakeholders.

**GLOBALG.A.P. is thus a private sector body**<sup>13</sup> that sets standards used to certify agricultural products throughout the world. The aim is to draw up one standard for **Good Agricultural Practices** with different applications per product, adaptable to agricultural practices worldwide.

**GLOBALG.A.P.**

GLOBALG.A.P. is a **pre-farm-gate standard**,<sup>14</sup> which means that the certificate covers the process of the certified product from the planting of seedlings, including all farming activities up until the product leaves the farm. GLOBALG.A.P., like the other food safety standards, is a business-to-business standard and is therefore **not directly visible to consumers**.

GLOBALG.A.P. certification is carried out by over 100 independent and accredited certification bodies in more than 100 countries.<sup>15</sup>

#### □ Benchmarking and national interpretation guidelines

As many other on-farm assurance systems were in place before GLOBALG.A.P. was set up, a solution had to be found to encourage the development of regional management systems in order to spare farmers multiple audits.

Several national or regional farm assurance schemes have now successfully completed their benchmarking process and are recognized as an equivalent to GLOBALG.A.P.

<sup>13</sup> The list of GLOBALG.A.P. members is available at the following address:  
[www.globalgap.org/cms/front\\_content.php?idcat=4](http://www.globalgap.org/cms/front_content.php?idcat=4).

<sup>14</sup> These documents are available on GLOBALG.A.P.'s Website: [www.globalgap.org](http://www.globalgap.org).

<sup>15</sup> The list of accredited certification bodies can be found on the GLOBALG.A.P. Website:  
[www.globalgap.org](http://www.globalgap.org).

GLOBALG.A.P. has also begun to pay greater attention to local producers' needs by creating **national technical working groups** (NTWG). The role of these groups is to develop a set of **national interpretation guidelines** for the standard so that it can be better adapted to the local context.

#### ❑ GLOBALG.A.P. and smallholders

For structural reasons small-scale farmers often find it much harder to comply with the standard's requirements. GLOBALG.A.P. thus applies three approaches to facilitate market access for smallholders:

- Smallholders can form a group and obtain certification together (Option 2).
- In May 2007, GLOBALG.A.P. launched the Smallholders Ambassador and Africa Observer project, with financing from the German Technical Cooperation (GTZ – *Deutsche Gesellschaft für Technische Zusammenarbeit*) and the DFID (UK Department for International Development). The aim is to allow the feedback of smallholders to reach the Sector Committees.
- GLOBALG.A.P. has developed a smallholder manual in collaboration with the GTZ and the Resource Protection Association (GfRS – *Gesellschaft für Ressourcenschutz*).

#### ❑ GLOBALG.A.P. Risk Assessment on Social Practice (GRASP)

GLOBALG.A.P. has also supplemented the food safety standard with an **ethics module**. The **GRASP module**<sup>16</sup> – **risk assessment on social practices**, is a voluntary standard for the supply chain partners.

The audit to assess conformity with the 11 control points **can be performed at the same time as the 'food safety' audit**.

The auditor must nevertheless have followed **specific training** to assess the GRASP module. Furthermore, the GRASP module can only be applied in countries that have developed interpretation guidelines for the 11 control points.<sup>17</sup> Lastly, the GRASP module only applies to companies that are already GLOBALG.A.P. certified.

### 9.2.6. SQF and IFS

The **Safe Quality Food Institute (SQFI)** is administered by the Food Marketing Institute (FMI), an American interprofessional association that represents 1 500 retailers and wholesalers. The SQFI<sup>18</sup> proposes certification programmes that cover the phases of primary production (SQF 1000) and manufacturing/distribution (SQF 2000), as well as certification based on a product's intrinsic quality.

<sup>16</sup> This document is also available on the GLOBALG.A.P. Website: [www.globalgap.org](http://www.globalgap.org).

<sup>17</sup> Austria, Brazil, Chile, Colombia, Costa Rica, Kenya, Morocco, Mexico, Vietnam, South Africa, and Spain. Several other countries are developing national interpretation guidelines (Argentina, Israel, Italy, Peru and the USA).

<sup>18</sup> The standards can be downloaded free of charge at the following address: <http://www.sqfi.com/>. The SQFI has also published a series of documents to facilitate the process to comply with the standard(s).



Following the example of GLOBALG.A.P., the SQFI has launched an **ethical sourcing module** to supplement the SQF 1000 and 2000 certifications. Although it is not mandatory to apply this module, once a company has agreed to implement it, it has to respect the full set of requirements.



Members of the German Retailers Federation (HDE – *Hauptverband des Deutschen Einzelhandels*) – and their French counterparts in the Federation of Trading and Retailing Companies (FCD – *Fédération des Entreprises du Commerce et de la Distribution*) – have developed a standard on food safety and quality for retailer (and wholesaler) branded food products, known as the **International Food Standard (IFS)**.

It is intended to **assess suppliers' food safety and quality systems** based on a **uniform approach**.

IFS Food – a **B2B private standard** – applies to all **post-farm gate stages of food processing**. In 2005-2006 the Italian retailers' federation became interested in the IFS and participated in drafting version 5 of the IFS Food standard.<sup>19</sup>

<sup>19</sup> The IFS can be ordered from the organization's Website (available in approx. 21 different languages): [www.ifs-certification.com](http://www.ifs-certification.com).

## 9.3. Private standards in the field of sustainable development

In addition to food safety, other private standards and schemes covering **social and/or environmental themes** have been developed to meet European consumers' growing concerns about sustainable development.

Today, ACP fruit and vegetable producers/exporters are confronted with a **multitude of terms and concepts** that are connected with and/or define such initiatives: *fair trade, ethical production, social responsibility, sustainable development, carbon footprint, life cycle analysis* and so on

**European authorities have generally not regulated these aspects, unlike food safety**, so it has been up to the private sector and civil society to lay down the rules. The retailing and distribution industry has adopted various initiatives in the form of private standards, 'codes of conduct' and 'multi-party platforms' grouped under their social responsibility policies, with the aim of addressing European consumers' concerns about sustainable development.

### ❑ Sustainable development

A commonly accepted definition of sustainable development is '*development that meets the needs of the present without compromising the ability of future generations to meet their own needs*'.<sup>20</sup> Another way of describing sustainable development is to present it as development that results from **balanced interaction among three pillars: the environment, the economy and the social sphere** (known as the '**3P**' principle: *People-Planet-Profit*).

The concept of 'sustainable development' finds expression in companies through social responsibility (SR) policies.

### ❑ Social responsibility<sup>21</sup>

The term '**social responsibility**' came into common use in the early 1970s, although the concept has existed since the 19th century in different organizations and governments. Social responsibility concerns all types of organizations, **not just commercial enterprises**, and has the ultimate objective of contributing to 'sustainable development'. This explains the determination of the different stakeholders who participated in drafting the new **ISO 26000 standard** (on social responsibility) to use the term 'social responsibility' instead of 'corporate social responsibility' (CSR).

The new **ISO 26000:2010**<sup>22</sup> standard, "*Guidance on social responsibility*", defines the social responsibility of an organization as responsibility for the impact of its decisions and activities on society and the environment through transparent and ethical behavior that:

<sup>20</sup> See G.H. Brundtland, *Our Common Future*, report of the World Commission on Environment and Development', Oxford, OUP, 1987.

<sup>21</sup> As defined in the new ISO 26000 standard.

- contributes to sustainable development, including health and the welfare of society
- takes into account the expectations of stakeholders
- is in compliance with applicable law and consistent with international norms of behavior;<sup>23</sup>
- is integrated throughout the organization and practiced in its relationships.

#### ❑ Private standards on ethical production (or trade)

**Ethical production** (or ethical trade) covers production conditions as well as the functioning of companies. In a distributor/producer relationship, it aims to guarantee and demonstrate to customers that the goods they purchase have been produced in conditions that comply with international labor standards set by the ILO<sup>24</sup> and with the Universal Declaration of Human Rights and the United Nations Convention on Children's Rights.

**Ethical production can also include requirements on the environmental conditions of production** even though most so-called 'ethical' initiatives focus more on working conditions.

Ethical production consequently does not **directly concern production *per se*, but the operating mode and moral values respected** by companies, for instance: workers' rights, child labor and fair pay. Ethical certification therefore concerns the production process rather than the product, which is the reason for the term 'ethical production'. These PS are thus qualified as procedural, rather than product, standards.

Standards and initiatives in this area include:

- Social Accountability 8000 (SA 8000);
- Ethical Trading Initiative (ETI);
- Business Social Compliance Initiative (BSCI);
- SEDEX (Supplier Ethical Data Exchange);
- Global Social Compliance Programme (GSCP).

<sup>22</sup> The international standard ISO 26000:2010 can be ordered from the ISO Website (price: CHF 192), [www.iso.org](http://www.iso.org).

<sup>23</sup> This concept is defined in ISO 26000 as 'expectations of socially responsible organizational behavior derived from customary international law, generally accepted principles of international law, or intergovernmental agreements that are universally or nearly universally recognized'. The standard also points out that these international norms of behavior can evolve over time.

<sup>24</sup> The International Labor Organization (ILO) can be seen as the only international body whose directives are to be considered binding on member States. Some consider that responsibility for establishing international labor standards is granted by the international community to the International Labor Organization, created for that purpose. In fact, the ILO's tripartite structure, which involves representatives of employers and employees, as well as governments, along with its technical expertise in all areas related to working life, gives the ILO the status of a legitimate and authoritative source for international labor standards.

These ethical initiatives<sup>25</sup> (the list is not exhaustive) often cover the same control points and all share the aim of improving working conditions across companies' different supply chains.

However, their individual specifications are such that approaches differ on certain points, which can lead to a duplication of efforts in order to achieve what is nevertheless a common goal.

## ❑ Private standards on fair trade

### What is fair trade?

*"Fair trade is a trading partnership, based on dialogue, transparency and respect, that seeks greater equity in international trade. It contributes to sustainable development by offering better trading conditions to, and securing the rights of, marginalized producers and workers – especially in the South. Fair trade organizations, backed by consumers, are engaged actively in supporting producers, awareness raising and in campaigning for changes in the rules and practice of conventional international trade".<sup>26</sup>*

The fair trade initiative was established in the 1940s and 1950s, in the United States and in Europe, respectively by religious organizations (Protestant church) and non-governmental organizations (NGOs). Politically, the fair trade concept was introduced at the United Nations Conference on Trade and Development (UNCTAD) in 1968.

The slogan '**Trade not Aid**' was devised to denounce inequalities in trading relations between North and South. Fair trade in agricultural products began with tea and coffee in the 1970s, followed by dried fruits, cocoa, sugar, fruit juice, bananas, rice, spices and nuts. With commodities prices dropping on international markets, the idea was to ensure decent earnings to small producers in the developing countries through the payment of a fair price.

A **number of bodies** now provide fair trade certification: Fairtrade Labelling Organization (FLO), *Équitable Solidaire Responsable* (ESR, Ecocert), Fair for Life (Institut für Marktökologie, IMO), etc.<sup>27</sup>

## ❑ Private standards on environmentally friendly production

In addition to social, economic (fair trade) and food safety aspects, some private standards and initiatives focus more on environmental aspects. More efficient use of raw materials, better waste management, protection of water resources, soil conservation, safeguarding of ecosystems and forests, and limitation of greenhouse gases are the

<sup>25</sup> Documents drawn up by these various schemes can be downloaded from their Websites: [www.sa-intl.org](http://www.sa-intl.org), [www.ethicaltrade.org](http://www.ethicaltrade.org), [www.bsci-intl.org](http://www.bsci-intl.org), [www.sedex.org](http://www.sedex.org), [www.gscpnet.com](http://www.gscpnet.com).

<sup>26</sup> In October 2001, the FINE informal network (made up of the leading fair trade organizations) developed a single definition of fair trade accepted by all players in the movement.

<sup>27</sup> Documents drawn up by these various initiatives can be downloaded from their Websites: [www.sa-intl.org](http://www.sa-intl.org), [www.ethicaltrade.org](http://www.ethicaltrade.org), [www.bsci-intl.org](http://www.bsci-intl.org), [www.sedex.org](http://www.sedex.org), [www.gscpnet.com](http://www.gscpnet.com).

challenges that companies will gradually have to meet in a proactive manner at the beginning of the 21st century.

**Organic farming**<sup>28</sup> is based on a number of principles and practices that aim to minimize agriculture's impact on the environment by working the land as naturally as possible. In Europe, numerous private organic standards can be found in the Member States. Most of these standards have their own organic logo. However, they must all at least comply with the EU's harmonized legislation on organic farming. The **Soil Association**<sup>29</sup> in the United Kingdom and **AB mark**<sup>30</sup> in France are just two examples. Both demonstrate compliance using a label for consumers.

Apart from organic agriculture, other B2C standards use a label for European consumers certifying the use of an environmentally acceptable process. The **LEAF Marque**<sup>31</sup> standard, for instance, aims to assure consumers that the product results from eco-responsible practices, while the **Rainforest Alliance**<sup>32</sup> aims to preserve biological diversity on earth and to ensure decent living conditions for producers and neighboring communities by changing agricultural and trading practices and acting on consumers' behavior.

Lastly we should mention the **ISO 14000**<sup>33</sup> family of standards on '**Environmental Management**'. This term refers to what an organization does to minimize the harmful impact of its activities on the environment and to improve its environmental performance on an ongoing basis.

<sup>28</sup> [ec.europa.eu/agriculture/organic/organic-farming\\_en](http://ec.europa.eu/agriculture/organic/organic-farming_en).

<sup>29</sup> Documents on the Soil Association can be found on the association's Website: [www.soilassociation.org](http://www.soilassociation.org).

<sup>30</sup> Further information on the AB mark (in French, with a few documents in English) can be found on the following website: [www.agencebio.org](http://www.agencebio.org).

<sup>31</sup> Documents on the LEAF mark scheme are available on its Website: [www.leafuk.org](http://www.leafuk.org).

<sup>32</sup> Documents on the Rainforest Alliance are available on the organization's Website: [www.rainforest-alliance.org](http://www.rainforest-alliance.org).

<sup>33</sup> Standards in the ISO 14000 family can be ordered from the ISO Website: [www.iso.org](http://www.iso.org).

## 9.4. Conclusions about private standards

The aim of this chapter was to summarize and briefly describe various private standards in the area of food safety, ethical labor practices and respect for the environment that have been developed thanks to individual or collective, national or international initiatives. It is not an easy task, however, to classify or group private standards due to the diversity of these initiatives and their structure.

It is generally understood that the private sector and civil society often react more quickly to emerging social issues than the public sector (Henson and Humphrey, 2009). **This dynamism, however, can create adverse effects for companies wishing to export to the European market. The lack of harmonization among private standards and the multitude of certifications** are just two of many factors that can be significant hurdles for exporting companies.

When different organizations along the food supply chain develop and adopt private standards there are repercussions for the ACP fruit and vegetable sector, particularly in terms of **market access**. And this is especially true for small and medium-sized enterprises.

To sum up, ACP producers who wish to export must now comply not only with new EU regulations, but also with the requirements of importers and distributors. Such requirements usually take the form of private standards and are often more complex and more stringent than regulations. While remaining voluntary – because they are not required by law – standards are becoming indispensable for doing business on the European market and as such are de facto mandatory. Consequently, **in some cases producers lacking certification under a private standard can be excluded from certain key sectors of the European market.**

**Certification requires considerable human, technical and financial resources.** In the case of private food safety standards, certification is not market-financed since compliance is not communicated to the consumer by means of a special label on the product.<sup>34</sup> The multitude of such standards on the European market also obliges an ACP producer operating on different markets with different customers to juggle with a **number of certifications**.

Producers find themselves confronted with an **overabundance of standards**, each of which implies recurring compliance and certification expenses. Generally speaking, it has been seen that the capacity to meet standards varies in terms of countries and stakeholders depending on their size and resources.

On the other hand, for ACP producers, **private standards can also present considerable advantages**. GLOBALG.A.P., for instance, has interpreted regulatory obligations in a document to ensure their practical implementation. **Compliance with standards can increase productivity and competitiveness by reducing the cost of inputs** (pesticides, fertilizers) and by helping agricultural operators to adopt Good Agricultural Practices (GAP), improve hygiene and use modern management methods.

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<sup>34</sup> Consumers cannot be charged a higher sales price if there is no label on the end product.

Private standard certification in some cases may also open up **more attractive markets** (such as the niche markets of fair trade, organic food), **extend the customer base** and thus **increase demand** for fruit and vegetable exports. Such certification may also entail social advantages such as food safety, or workers' health and hygiene (Okello, 2005).

New types of initiatives are also being developed to meet the social, economic and environmental challenges of our planet. **Sustainability is a concept no longer reserved to western societies.** ACP enterprises must also implement it by limiting counter-productive effects and maximizing positive effects for their communities.

The challenge facing ACP companies that export fruit and vegetables to the European continent is to transform these new demands into opportunities to develop and become more competitive.







# Most used abbreviations and acronyms

## Most used abbreviations and acronyms

3-MCPD	3-monochloropropane-1,2-diol
ACP	African, Caribbean and Pacific (Group of ACP States that have signed a series of agreements with the EU, called the 'Cotonou Agreements')
ADI	Admissible Daily Intake
APHIS	Animal and Plant Health Inspection Service
ARfD	Acute reference dose
a.s.	Active substance
As	Chemical symbol for arsenic
$A_w$	Water activity
BASF	<i>Badische Anilin- &amp; Soda-Fabrik</i> (German chemical group, the world's largest chemical group)
BRC	British Retail Consortium
BSCI	Business Social Compliance Initiative
BSE	Bovine Spongiform Encephalopathy
BSI	British Standards Institution
B to B	Business to business (e-business)

B to C	Business to Consumer
BTV	Blue tongue disease (catarrhal fever)
bw	Body weight of the considered group ((adult: 76 kg – child: 14,5 kg)
CCP	Critical control point (under the HACCP method)
Cd	Chemical symbol for cadmium
cfu	Colony-forming unit
CH <sub>2</sub> -CH <sub>2</sub>	Chemical symbol for ethylene
CMA	Central Marketing Agency
CO <sub>2</sub>	Chemical symbol for carbon dioxide
Cr	Chemical symbol for chrome
CSR	Corporate social responsibility
CTCPA	<i>Centre technique de la conservation des produits agricoles</i> (Technical Center for the Conservation of Agricultural Products)
ECR	Emerging Chemical Risks
EEC	European Economic Community
EFQM	European Foundation for Quality Management
EFSA	European Food Safety Authority

EPA	Environmental Protection Agency (USA)
ESR	<i>Équitable Solidaire Responsable</i> (Equitable Solidary Responsible)
ETI	Ethical trading initiative
EU	European Union
EUREP	Euro-Retailer Produce
FAO	Food and Agriculture Organization: UN organization that addresses food security problems in the world
FASFC	Federal Agency for the Safety of the Food Chain
FBI	Foodborne illness outbreak
FCD	<i>Fédération des entreprises du commerce et de la distribution</i> (Federation of Businesses in Trade and Distribution)
FDA	Food and Drug Administration
FID	Foodborne Infectious Diseases
FINE	Informal network of the four main international fair trade federations. Its name is an acronym formed from the names of its members: <b>F</b> for <i>Fairtrade Labelling Organizations</i> (FLO) <b>I</b> for <i>International Federation of Alternative Trade</i> (IFAT) <b>N</b> for <b>Network of European Worldshops</b> (NEWS) <b>E</b> for <b>European Fair Trade Association</b> (EFTA)
FLO	Fairtrade Labelling Organizations International, an association of 20 equitable labeling initiatives located in more than 21 countries
FMI	Food Marketing Institute
FSMS	Food safety management system (see also QMS)

FSS	Food Surveillance System
FSSC	Food Safety System Certification
GAP	Good agricultural practices (set of application conditions that must be defined: dosage, volume, formulation, technique, PHI)
GDP	Good Distribution Practices
GEMS	Global Environment Monitoring System
GfRS	<i>Gesellschaft für Ressourcenschutz</i> (Association for the Protection of Resources)
GFSI	Global Food Safety Initiative
GGHP	Guides to Good Hygiene Practices
GHP	Good Hygiene Practices
GLP	Good laboratory practices
GMO	Genetically modified organism
GMP	Good Manufacturing Practices
GPP	Good phytosanitary practices (set of rules to follow to avoid contaminating the operator or the environment and to avoid residues)
GPO	Group purchasing organizations
GOARN	Global Outbreak Alert and Response Network
GPHIN	Global Public Health Intelligence Network

GRASP	GLOBALG.A.P. Risk Assessment on Social Practice
GSCP	Global Social Compliance Programme
GTZ	<i>Gesellschaft für Technische Zusammenarbeit</i> (German Development Cooperation Agency)
GVP	Good Veterinary Practices
HACCP	Hazard analysis critical control point: system that defines, assesses and prevents food safety problems
HAV	Hepatitis A virus
HAZOP	Hazard and Operability Point
HCl	Chemical symbol for hydrogen chloride
HDE	<i>Hauptverband des Deutschen Einzelhandels</i> (German Retail Trade Federation)
Hg	Chemical symbol for mercury
ICB	Independent certification body
IFS	International Food Standard
ILO	International Labor Organization
IMO	<i>Institut für Marktökologie</i> (Institute of Market Ecology)
INFOSAN	International Food Safety Authorities Network
ISO	International Organization for Standardization. ISO is the international standards body whose members are the national standards institutes of 149 countries

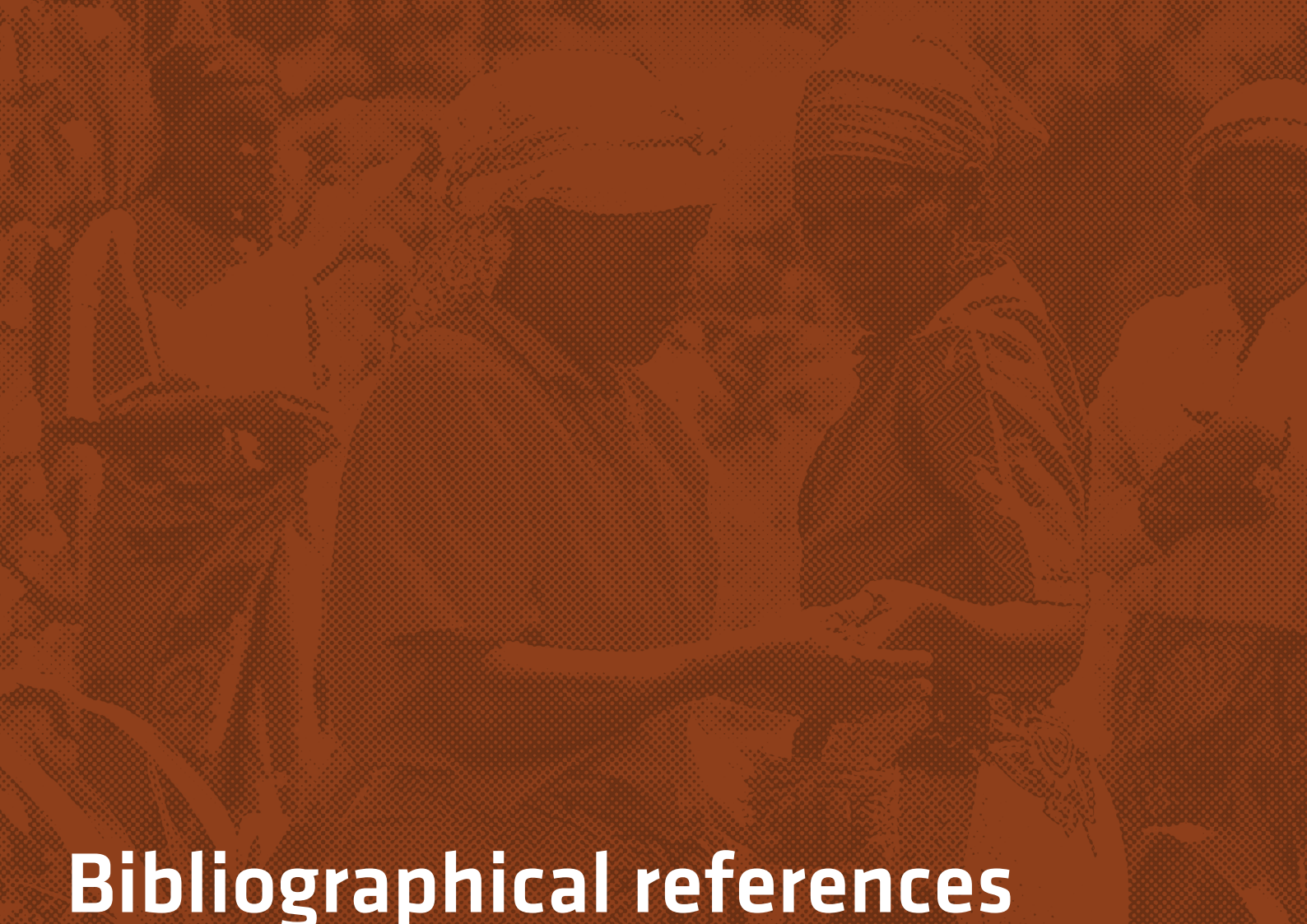
K	Chemical symbol for potassium
LD <sub>50</sub>	Lethal dose 50 (mg/kg bw)
LEAF	Linking Environment and Farming
LP	Large portion
LRF	<i>Lantbrukarnas Riksförbund</i> (Swedish Farmers' Federation)
MCQ	Multiple choice questions
MRL	Maximum residue level
MTE	Metallic trace elements
NASA	National Aeronautics and Space Administration
Ni	Chemical symbol for nickel
NGO	Non-Governmental Organization
OECD	Organization for Economic Cooperation and Development
OIE	World Organisation for Animal Health ( <i>Office international des épizooties</i> )
OJEC	<i>Official Journal of the European Community</i>
OJEU	<i>Official Journal of the European Union</i>
O <sub>2</sub>	Chemical symbol for oxygen



OR	Observed Residue
ORD	Office of Research and Development
OTA	Ochratoxin A
PAH	Polycyclic aromatic hydrocarbons
PAS	Publicly Available Specification
Pb	Chemical symbol for lead
PBDE	Polybrominated diphenyl ethers
PCB	Polychlorinated biphenyl
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
pH	Potential of hydrogen
PHI	Pre-harvest interval (number of days to wait before harvesting)
PPE	Personal protective equipment
PRP	Pre requisit Programs
PRPo	Pre requisit Programs operational
PS	Private, or voluntary, standard

PSD	Pesticide Safety Directorate
PSTI	Predicted Short Term Intake
QMS	Quality Management System (see also FSMS)
QTM	Quality and traceability manager
RASFF	Rapid Alert System for Food and Feed
RH	Relative humidity
SA 8000	A standard considered as the first private international reference standard concerning the rights and respect of the individual on the job
SAI	Social Accountability International
Sb	Chemical symbol for antimony
SEDEX	Supplier Ethical Data Exchange
Sn	Chemical symbol for selenium
SO <sub>2</sub>	Chemical symbol for sulphur dioxide
SQFI	Safe Quality Food Institute
t	Transformation factor, usually = 1, due to lack of data
TNC	Tesco Nature's Choice: a TESCO private standard
U	Unit

UN	United Nations Organization
UNCED	United Nations Conference on Environment and Development
UNCTAD	United Nations Conference on Trade and Development
USDA	United States Department of Agriculture
UV	Ultraviolets
v	Variability factor (1, 5 or 7, according to the weight of U)
WHO	World Health Organisation
WTO	World Trade Organisation
Zn	Chemical symbol for zinc



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AGENCE BIO: [www.agencebio.org](http://www.agencebio.org)

BRC Global Standards: [www.brcglobalstandards.com](http://www.brcglobalstandards.com)

Business social compliance initiative: [www.bsci-intl.org](http://www.bsci-intl.org)

Centre d'information ISO/CEI: [www.standardsinfo.net](http://www.standardsinfo.net)

Centre technique de la conservation des produits agricoles: [www.ctcpa.eu/home](http://www.ctcpa.eu/home)

ECOCERT: [www.ecocert.com](http://www.ecocert.com)

EFSA: [www.efsa.europa.eu](http://www.efsa.europa.eu)

Ethical Trading Initiative: [www.ethicaltrade.org](http://www.ethicaltrade.org)

EUROPEAN COMMISSION: [ec.europa.eu](http://ec.europa.eu)

Fairtrade Labelling Organization: [www.fairtrade.net](http://www.fairtrade.net)

FASFC: [www.afsca.be/home-en](http://www.afsca.be/home-en)

Food Safety Management: [www.foodsafetymanagement.info](http://www.foodsafetymanagement.info)

Food Safety System Certification 22000: [www.fssc22000.com](http://www.fssc22000.com)

FSA (Food Standard Agency): [www.food.gov.uk](http://www.food.gov.uk)

Global Food Safety Initiative (GFSI): [www.mygfsi.com](http://www.mygfsi.com)

GLOBALG.A.P: [www.globalgap.org](http://www.globalgap.org)

Global Reporting Initiative: [www.globalreporting.org](http://www.globalreporting.org)

Global Social Compliance Programme: [www.gscpnet.com](http://www.gscpnet.com)

GRUPO AGROLIBANO: [www.agrolibano.com](http://www.agrolibano.com)

IMO Social Responsibility and Fairtrade: [www.fairforlife.net](http://www.fairforlife.net)

INFOSAN (OMS): [www.who.int/foodsafety/areas\\_work/infosan/en](http://www.who.int/foodsafety/areas_work/infosan/en)

International Food Safety: [www.ifs-certification.com/index.php/en](http://www.ifs-certification.com/index.php/en)

International Federation of Organic Agriculture Movements: [www.ifoam.org](http://www.ifoam.org)

ISEAL Alliance: [www.isealalliance.org](http://www.isealalliance.org)

International Organization for Standardisation (ISO): [www.iso.org/home.html](http://www.iso.org/home.html)

ISO22000.INFO: [www.norme-iso22000.info/home.htm](http://www.norme-iso22000.info/home.htm)

Linking Environment and Farming: [www.leafmarque.com](http://www.leafmarque.com)

Ministère de l'Agriculture, de l'Alimentation et des Affaires rurales Ontario:  
<http://www.omafra.gov.on.ca/english/index.html>

NATURLAND: [www.naturland.de/en](http://www.naturland.de/en)

Occupational Health and Safety Zone: [www.ohsas-18001-occupational-health-and-safety.com](http://www.ohsas-18001-occupational-health-and-safety.com)

OIE -World Animal Health Information System International: [www.oie.int/en](http://www.oie.int/en)

Overseas Development Institute: [www.odi.org.uk](http://www.odi.org.uk)

OXFAM Magasins du monde: [www.oxfammagasinsdumonde.be](http://www.oxfammagasinsdumonde.be)

OXFAM Fair Trade: [www.oft.be](http://www.oft.be)

Rainforest Alliance: [www.rainforest-alliance.org](http://www.rainforest-alliance.org)

RASFF (EC): [ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)

Safe Quality Food Institute: [www.sqfi.com](http://www.sqfi.com)

SGS: [www.fr.sgs.com](http://www.fr.sgs.com)

Social Accountability International: [www.sa-intl.org](http://www.sa-intl.org)

Soil Association: [www.soilassociation.org](http://www.soilassociation.org)

SQFI: [www.sqfi.com](http://www.sqfi.com)

Supplier Ethical Data Exchange: [www.sedex.org.uk](http://www.sedex.org.uk)

Synergy: [www.synergy-gss.com](http://www.synergy-gss.com)

TESCO: [www.tesco.com/nurture](http://www.tesco.com/nurture)

United Nations Global Compact: [www.unglobalcompact.org](http://www.unglobalcompact.org)

USDA-APHIS Center for Emerging Issues (USA): [www.aphis.usda.gov](http://www.aphis.usda.gov)

World Health Organization: [who.int/en](http://who.int/en)

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