

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

In Chapter 1, we defined quality 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 organisation**. 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 organised 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).¹

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 methods² for managing product quality have therefore gradually been developed. These include:

- ▶ quality control (1940-1955);
- ▶ quality management (1955-1970);
- ▶ quality assurance (1970-2000);
- ▶ and 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:

- *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:
 - the less one wants to run the risk of error (clearing a non-compliant product), the larger the sample must be;³

¹ Referring to ISO standard 9001:2000, we prefer to talk about QMS – Quality Management System – to describe the system governing the company's activity.

² 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.

³ 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

- 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.
- *measuring tools*: inspections involve the purchase, maintenance and regular checking of measuring devices.⁴ 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. We will return to FSMS assessments in Chapter 7.

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 (see chapter 7).

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.

⁴ '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:

- ▶ protecting operators’ health;
- ▶ consumer protection and information;
- ▶ fair trading;
- ▶ environmental protection;
- ▶ 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.

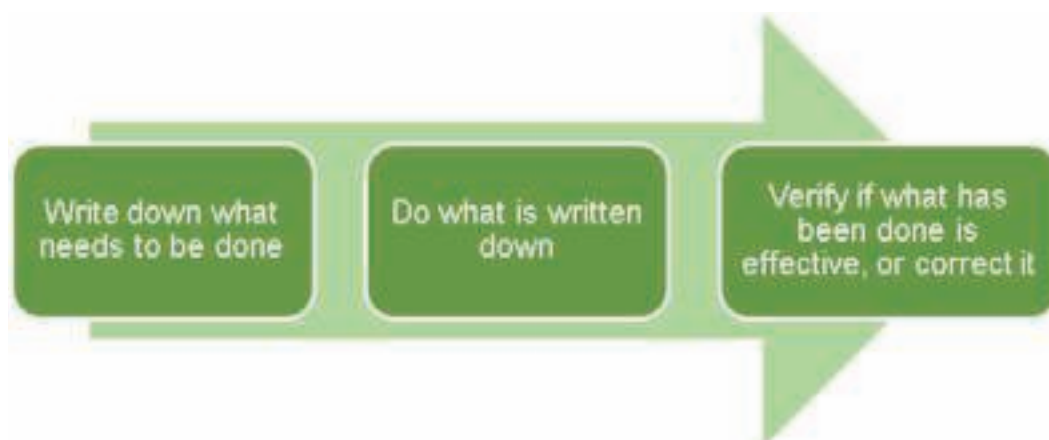
Furthermore, the system in place must include its own monitoring system (self-evaluation) to ensure that everyone strictly adheres to the system requirements.

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 neutralised 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 organisation.

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

Organisations 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 organisation. They should create and maintain an internal environment in which people can become fully involved in achieving the organisation's objectives.

3. Involvement of people

Staff at all levels are the essence of an organisation and their full involvement means their skills can be used to the organisation'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 organisation in achieving its objectives: this is the system approach to management

6. Continual improvement

The continual improvement of the overall performance of an organisation should be a permanent objective of the organisation.

7. Factual approach to decision-making

Effective decisions are based on analysis of data and information.

8. Mutually beneficial supplier relationships

An organisation and its suppliers depend on each other and mutually beneficial relationships enhance the abilities of both organisations 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 analysing 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 recognised,⁵ the fact that this approach enables the company's activities to be better formalised, 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**

⁵ 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.).

certain 'formality' which is not in fact always absolutely necessary: a quality policy, quality manual, management reviews. If poorly conceived, misunderstood or 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.

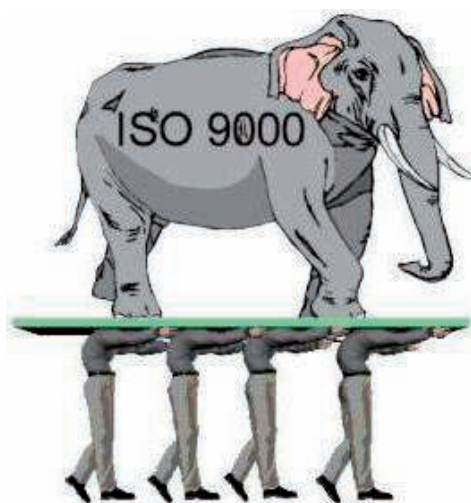
Such a management approach must therefore always be implemented as part of overall 'quality approach' objectives, avoiding unnecessary bureaucracy!

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 industrialised countries:

- *the number of ISO certifications decreases over time;*
- *it is the most poorly organised companies and those which have a strong need to formalise 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, colour, 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 (see also chapter 9). 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.⁶

This is why it is often necessary for the company to implement a Quality Management System (QMS) whose '**scope**' is **broader** 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.

⁶ 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

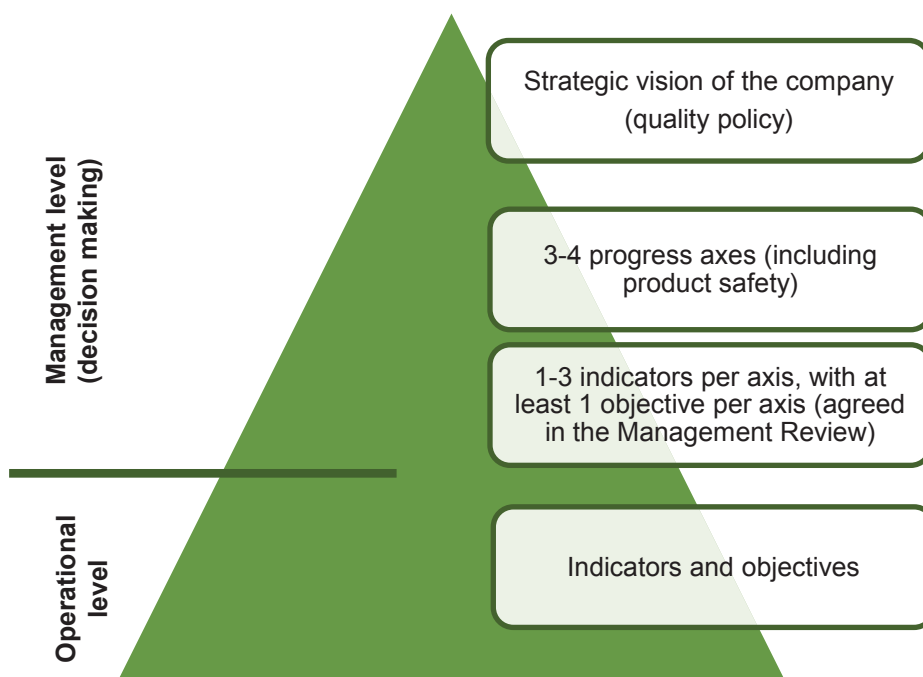
The food 'safety policy' for the company's products must include a definition:

- ▶ 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 mobilise 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 mobilising 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:



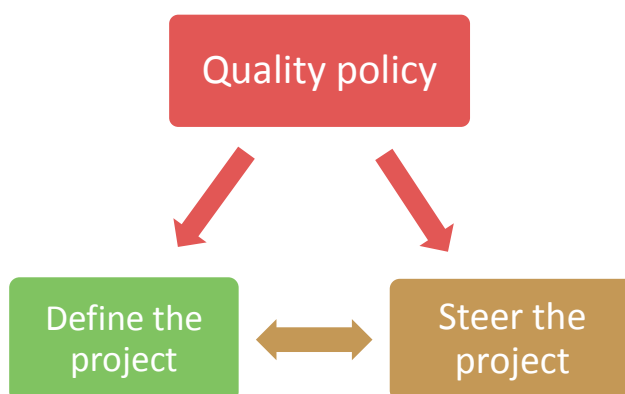


6.2.4. Working with a 'Project Approach'

- 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 summarised 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

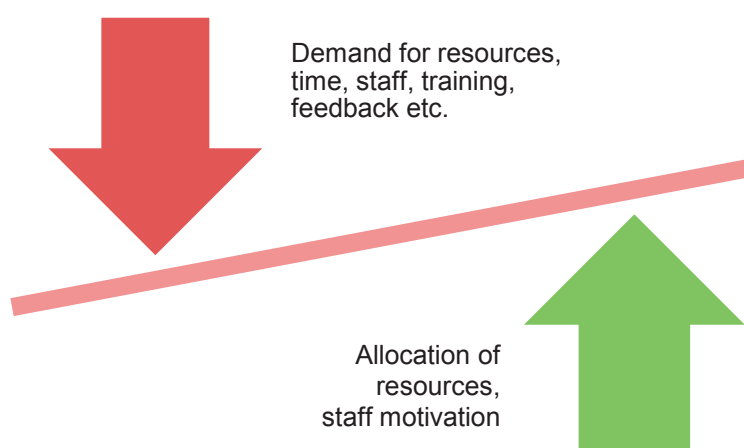
The company's senior management has responsibility for the product safety policy and the food safety management system, including its monitoring and record-keeping methods.

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 organised 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 analysing 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 realises the scale of the FSMS project, and the importance of their commitment to the success of the policy.

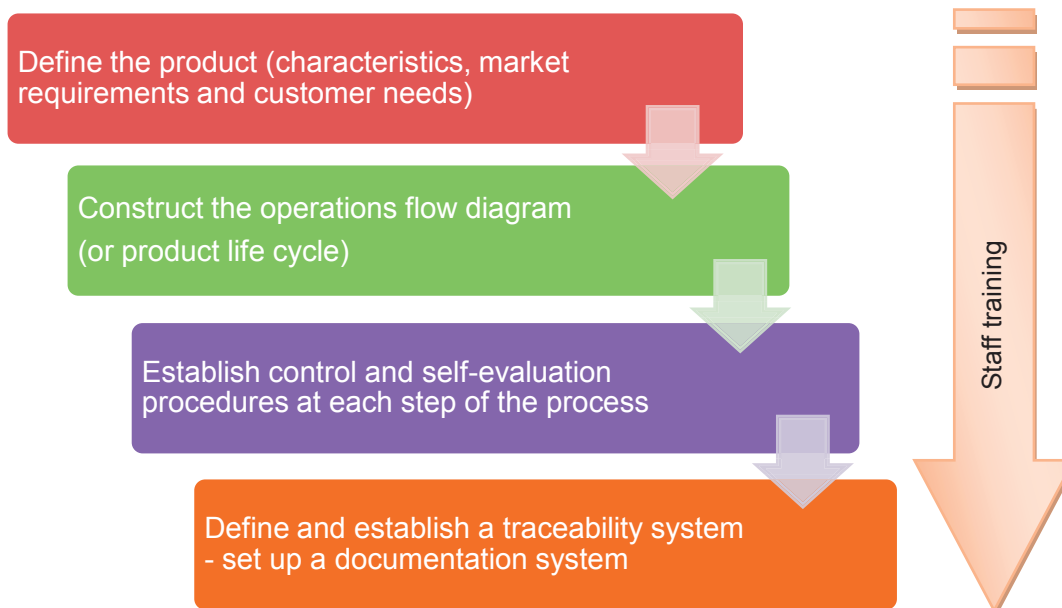
To help the quality and traceability manager to convince their senior management, **an external consultant can be very helpful at this stage**. However, everyone needs to be aware that:

- ▶ 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 organisational 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.). This point has already been discussed in detail in chapters 1, 3 and 4.
- Meet customers' needs, by answering each of the following questions (for further details, see chapter 8):
 - 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 analyse 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.*

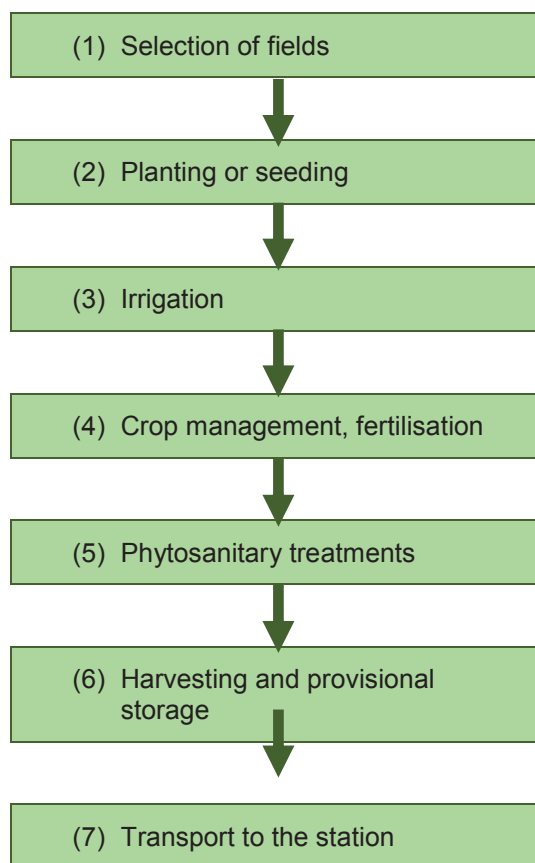
*It involves drafting a '**flow chart**' to represent the operations carried out in the company **in a logical sequence**.*

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



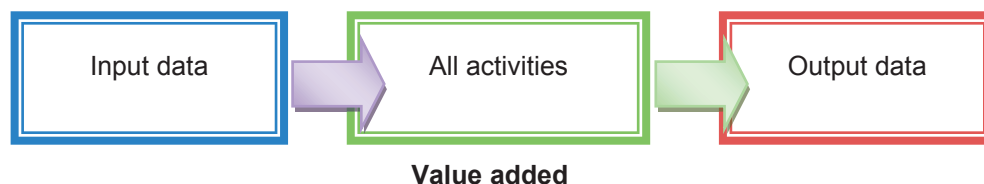
Each activity numbered 1-7 represents a **logical series** of self-contained operations, each with a **beginning and an end**. As a whole, they **give value to the product**. They are part of a **'process'**. This process can be called **'plant production'**

□ **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.⁷ 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 fertiliser, 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.**

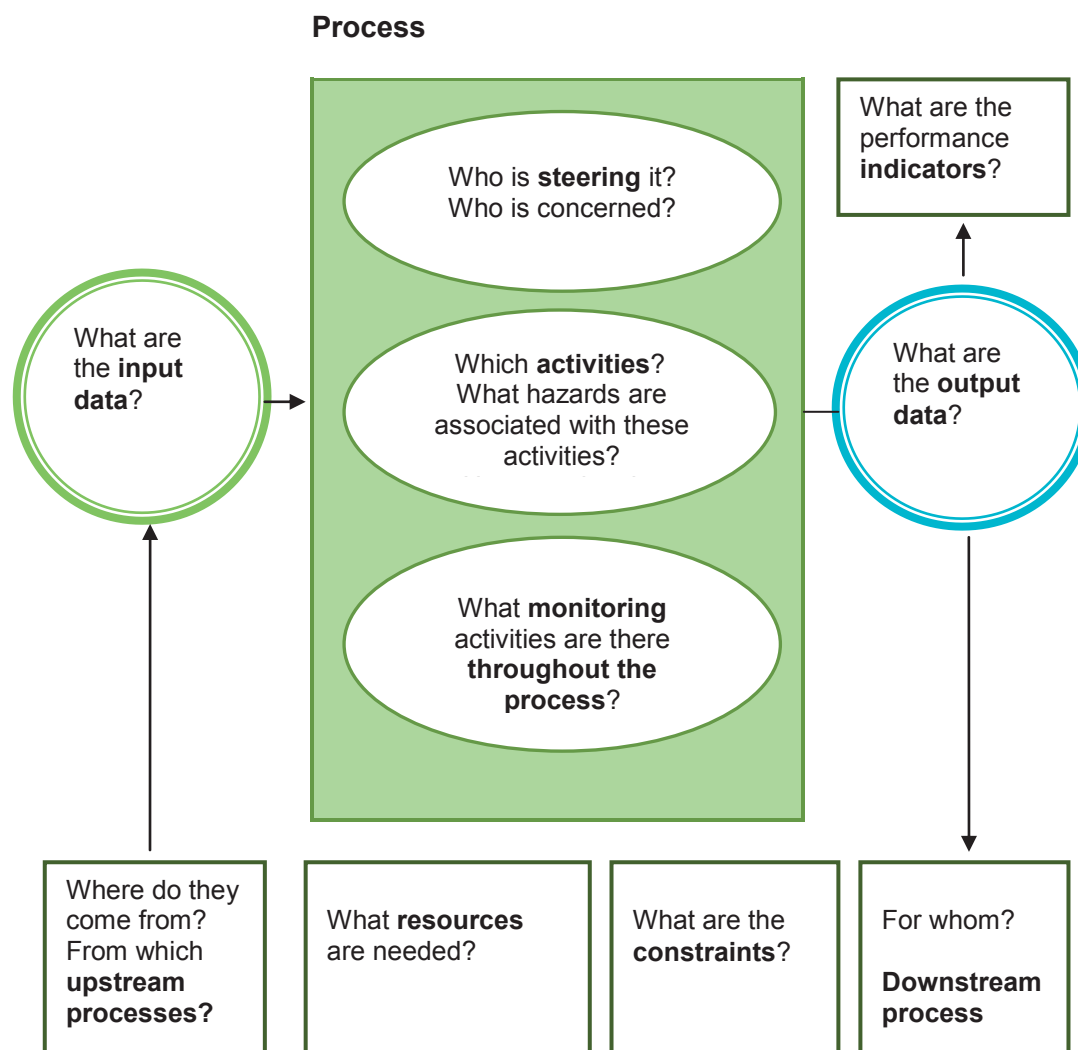
The description of a process includes the **following aspects:**

- ▶ 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.

⁷ 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 formalisation will enable an '**Operating Procedure**' to be prepared on the basis of the process.

Sample process flowchart (hypothetical).

Who?	...what?	...how?/with what?
Crop manager	<pre> graph TD A([Oval]) --> B[Rectangle] B --> C[Rectangle] C --> D{Diamond} D --> E[Rectangle] D --> C </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.

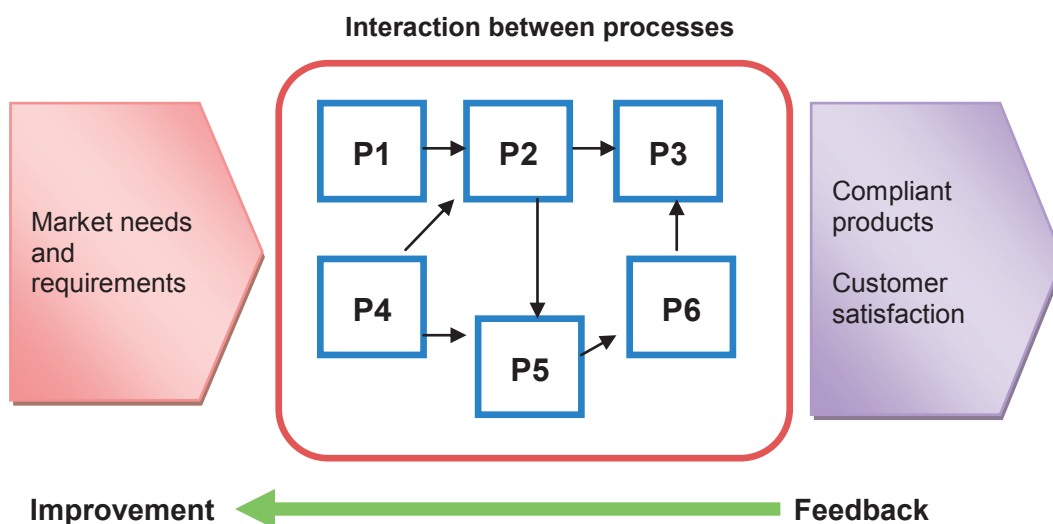
Control points must therefore be set at these interfaces.

▪ **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 organised and the different operations to be performed by a 'systems approach' organised**. 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 organisation'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*

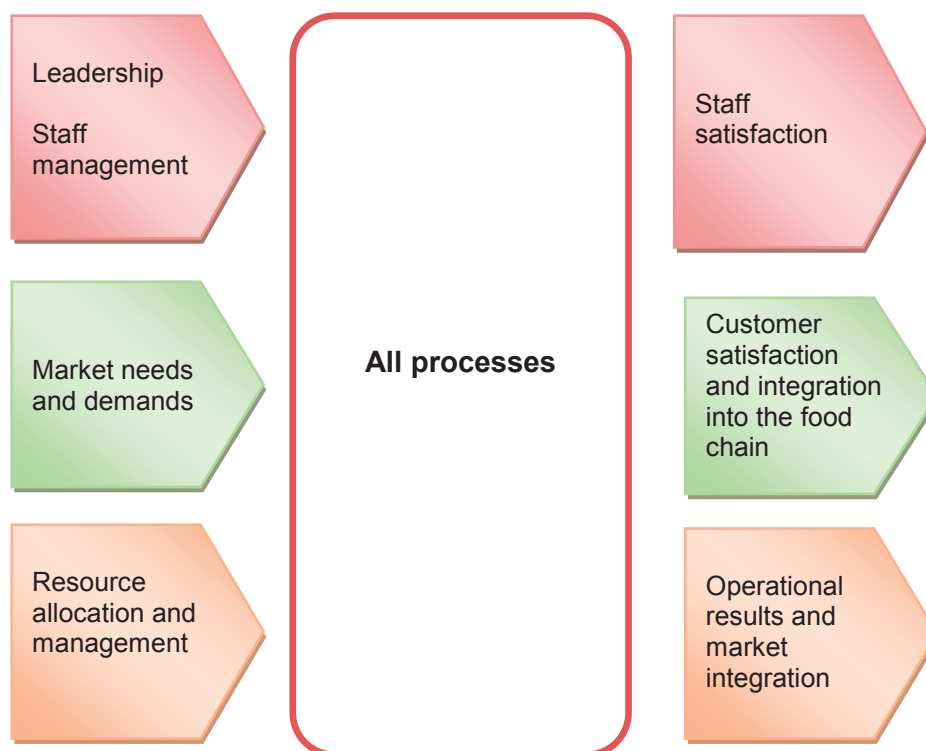
Once all the processes have been mapped, it is helpful to identify the **company's key processes** which are essential to its smooth functioning. **When it comes to hazards, the major risks are generally found in these key processes.**

'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, analyse(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).

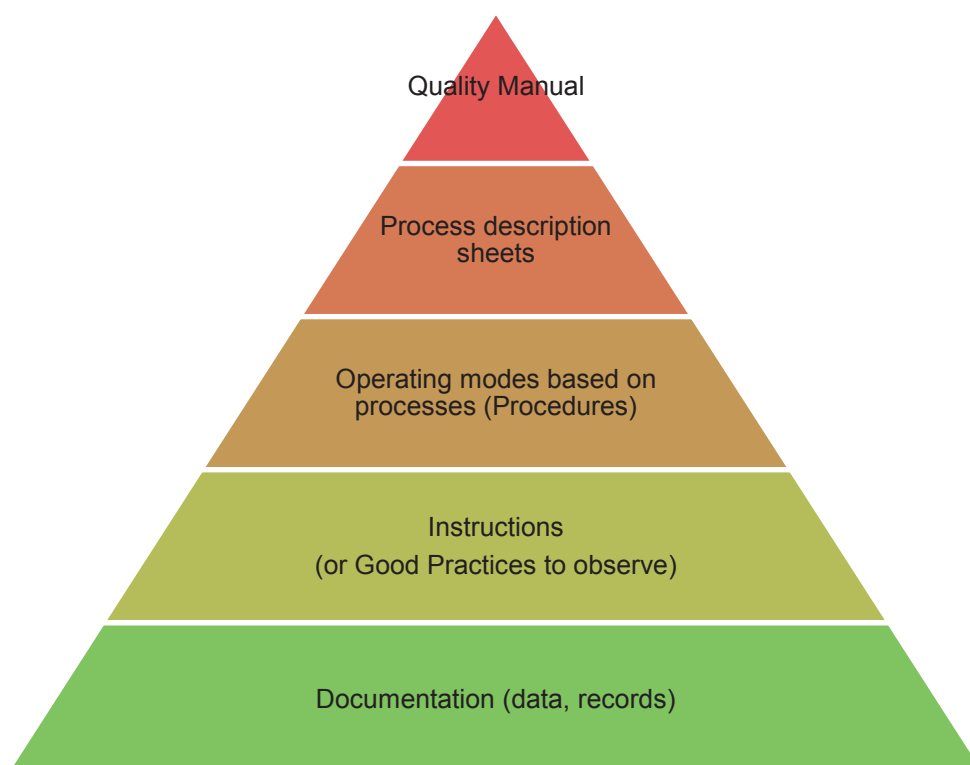
6.3.5. Setting up a documentation system

The 'documentation system' is the repository of all documents needed for managing the FSMS. It **formalises 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 formalise 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 analysing its processes and establishing its control procedures (see PIP manual No 3).

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 formalise who describes the key activities of the process: who does what?
- ▶ Finally, identify the operating procedures or detailed instructions to be formalised for describing certain tasks among the selected activities.

In an agribusiness company, a documentation system will ideally include:

- Explanatory and descriptive documents:⁸
 - 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 authorised 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.
- ▶ be accurate, and therefore updated as often as necessary;
- ▶ comply with current laws and regulations;

⁸ The 'Quality Manual' generally summarises the entire system.

- ▶ 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 utilise the current operating procedures, which are sometimes ignored in favour 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 analysing staff skills and skill requirements**. The 'Training Plan' will be formalised 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 analysing and scheduling training, the following are distinguished (see also manual 8):

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. *Behavioural 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

Appendices: Aspects of the documentation system

A.1. Procedures

Procedures are documents that describe the organisational rules and/or processes defined within the company, which formalise '*who does what*' in a simple way. In a general sense, **procedures can be defined as written and formal organisational 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 standardisation 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 formalises the organisational 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).

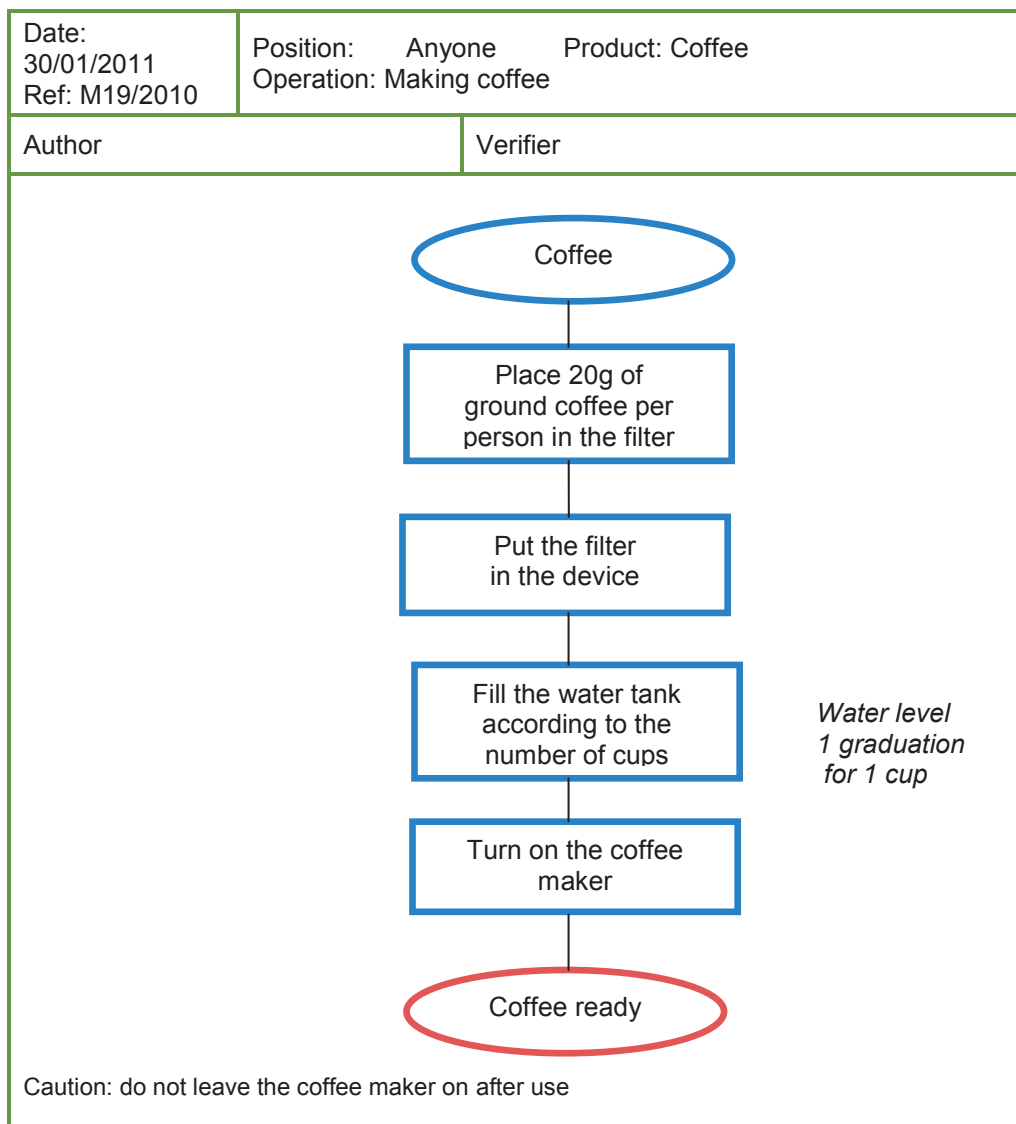


Example procedure: handling a complaint

Steps	Manager	Documents/ Records
<pre> graph TD VC[Verbal complaint] -- Transmission --> R[Recording] WC[Written complaint] --> R R --> AC[Analysis of the complaint] </pre>	Anyone Quality assurance manager secretary	Records card
48 hours ↓ Analysis of the complaint	Quality assurance manager	Report
↓ First response to the customer	Quality assurance manager secretary	Letter
↓ Processing the complaint		
↓ Final response to the customer	Quality assurance manager	Report
↓ Customer confirmation	Quality assurance manager with department concerned	Letter
↙ Corrective action procedure	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 authorised 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 authorised 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 'La Boîte à Outils du Responsable Qualité' ('The Quality Manager's Toolkit') by Florence Gillet-Goinard and Bernard Seno, DUNOD, Paris, 2009.

