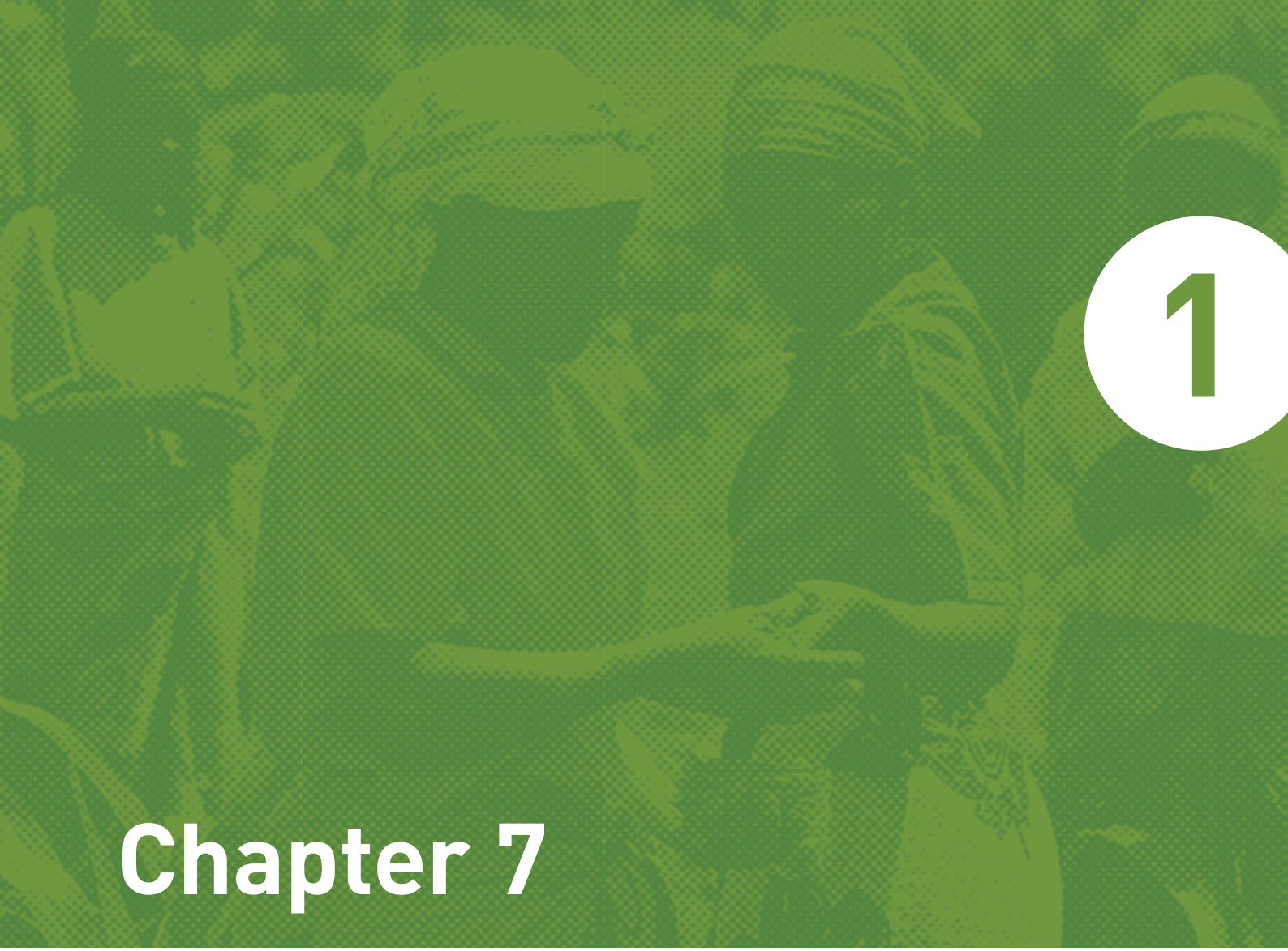

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Chapter 7

The internal control and FSMS certification process

7.1. The continual improvement principle

7.1.1. The normal range of a process

Hazard prevention is the best way to minimise 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 (see Chapter 6). '**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[1]
- 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.).[2]

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.

The principle of continual improvement is symbolised by the '**virtuous circle of continual improvement**' (also called the '*Deming Wheel*'). It is typified by an iterative four-step successive cycle (PDCA):

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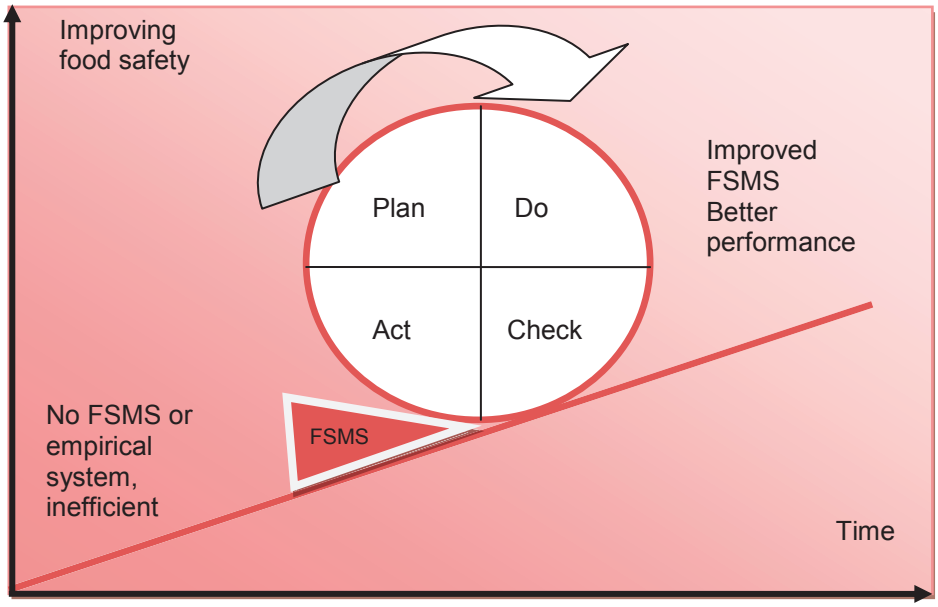
1 Note that in this case, this means that the pH-meter is able to measure a pH half unit with sufficient reliability!

2 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).

- ***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,[3] 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[4] but without this preliminary work, measurement will not be possible and therefore no evidence of the approach's effectiveness will be possible!

[3] 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.

[4] 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. CO2 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).

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:

- *Does the FSMS meet the goals set by the company in its food safety and quality policy for its products?*
- *Does the FSMS meet customers' requirements?*
- *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 organisations). 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 analysed 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 described in Chapter 3 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 (fertiliser, compost, pesticides, biocides etc.); of irrigation water, washing water etc.; of soil or leaf analyses, in order to adjust the fertiliser;
- **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).[5]

❑ 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);

[5] 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 specialising in audits.**

❒ **Organising 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!);
- formalise 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 recognised 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!

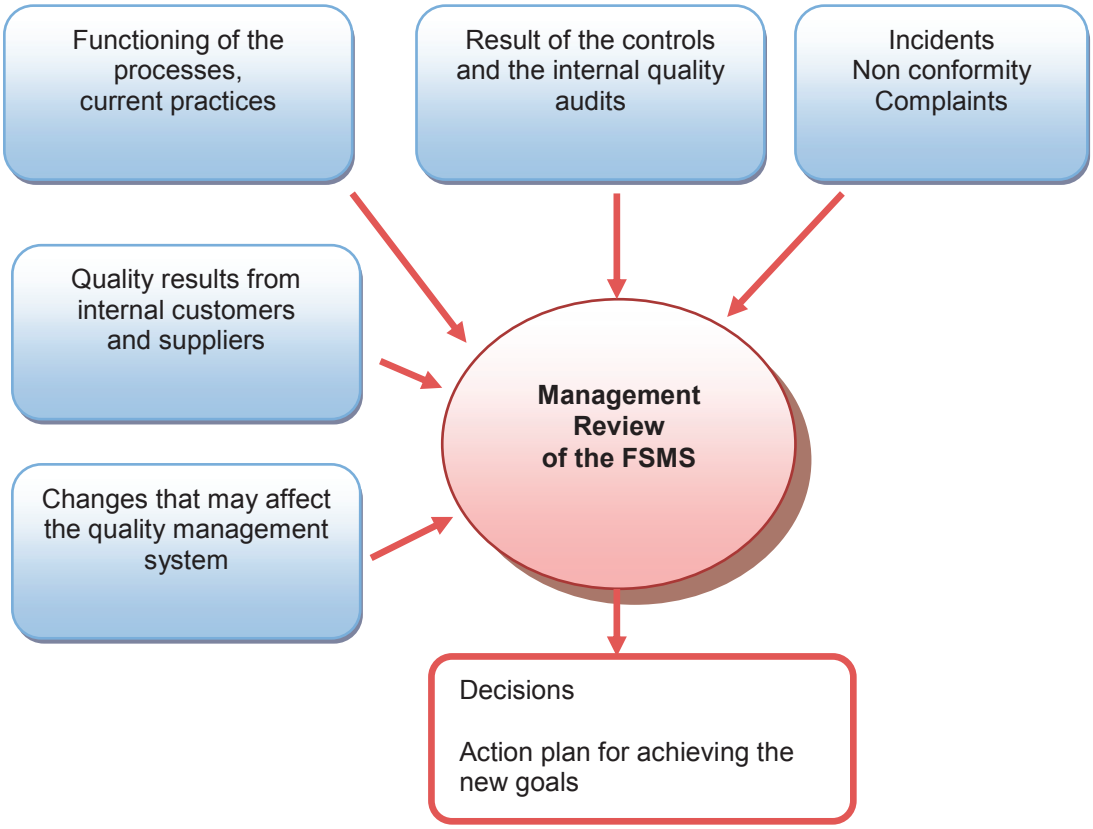
A summary of the internal audits will be presented during the *Management Review*: this must be an opportunity to highlight best practices identified, ensure they become widespread and capitalise on progress made audit after audit.

7.2.4. Management Reviews

The 'Management Review' of the FSMS is simply a **review and decision-making meeting** organised 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 at 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 the 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.[6] 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.

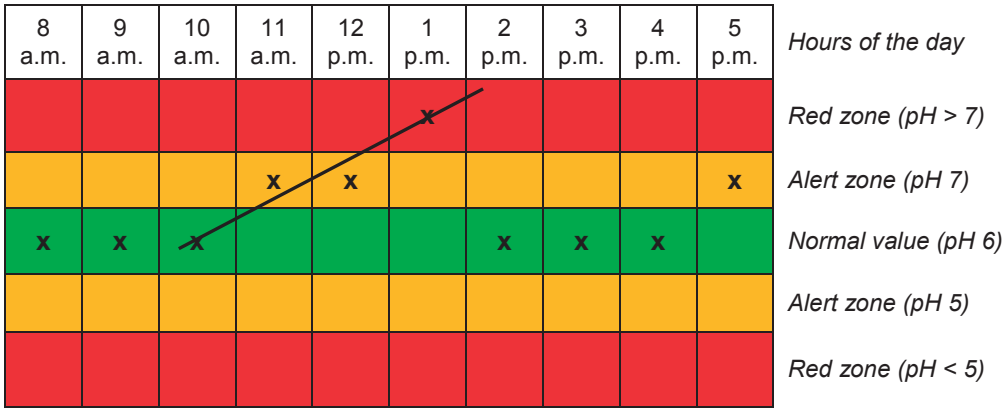
By way of example, we present, ranging from the simplest to the most complex, some additional techniques that are easy to implement, such as:

- 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



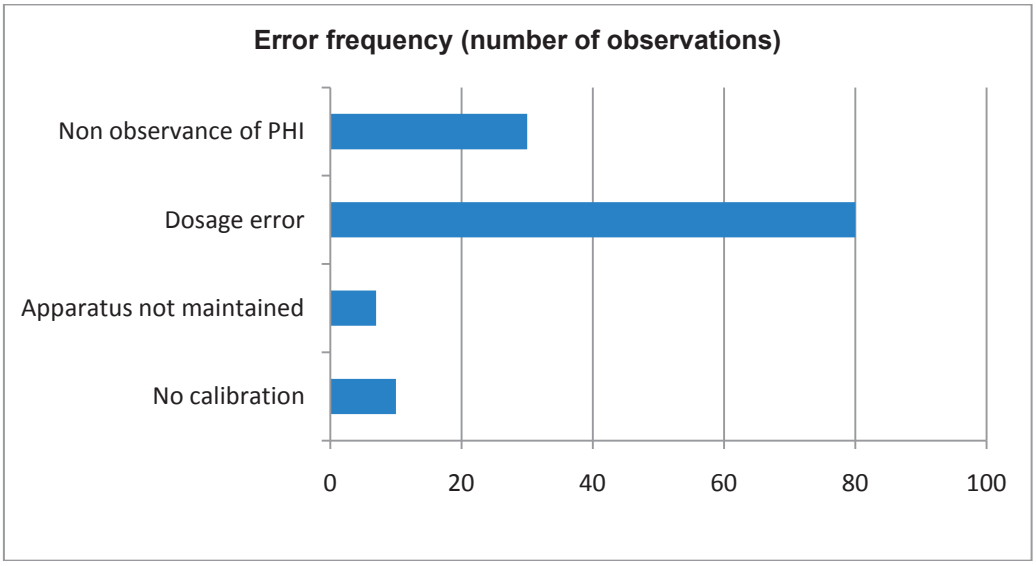
At 1 p.m., the pH is too high. The operator corrects the pH of the bath and returns it to a value close to that instructed. The work can continue. Note that as the procedure itself has not been changed, the same deviation will recur later on.

❒ 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.

[6] For example, some of the elements discussed below were taken from the book 'La boîte à outils du responsable qualité' ('*The quality assurance manager's toolkit*') by Gillet-Goinard and Seno, published by DUNOD, Paris, 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[7] – 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

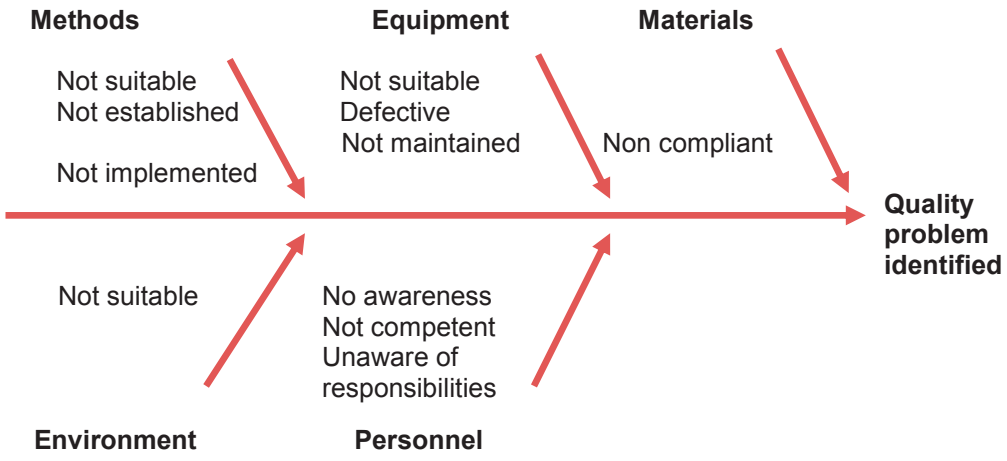
The Ishikawa diagram method (also called the **cause-and-effect diagram, fishbone diagram or Fishikawa**) is **a tool for classifying all causes** that may be at the source of a problem. This method has already been mentioned in previous chapters. The grouping of the causes of non conformity is based on 5 categories: Personnel, Environment, Methods, Materials, Resources

It is interesting that it is also **a communication tool for explaining a phenomenon.**

[7] 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 X 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?*

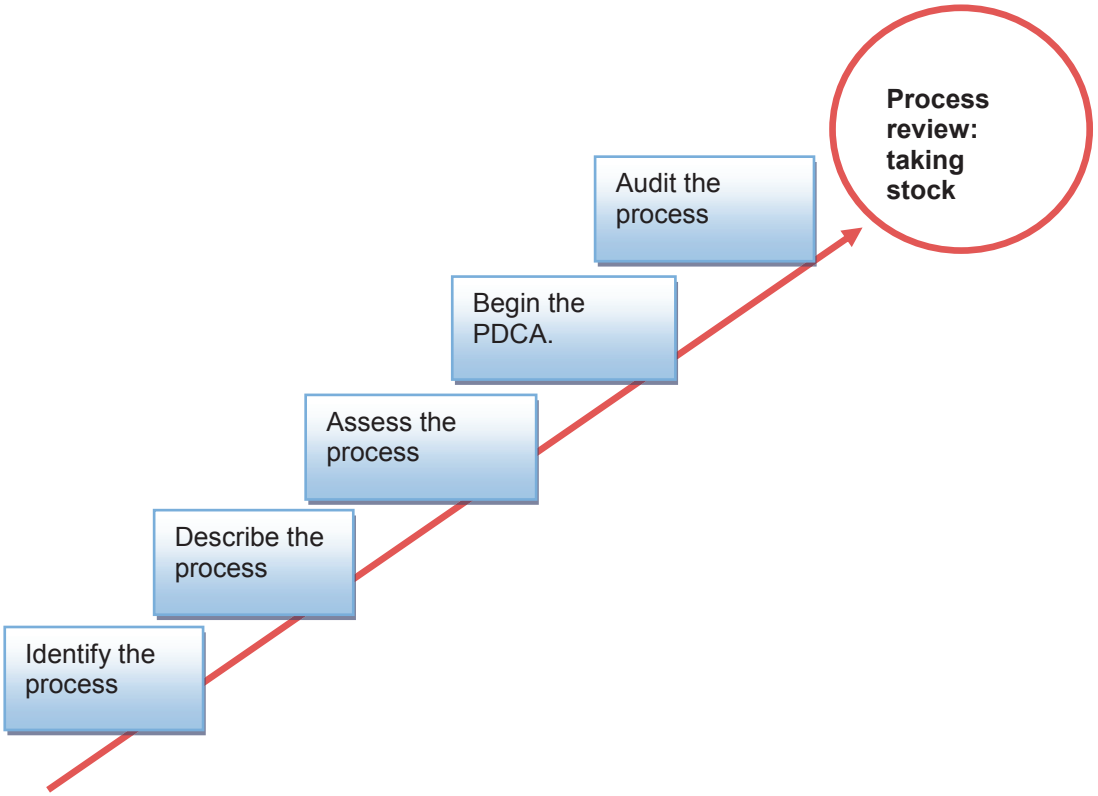
Example: quality risk analysis of the ‘packaging’ process where C (Criticality) = S (Severity) x L (Likelihood)

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 summarising 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 **analyse 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 authorised? 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 formalised (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 formalised? 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 analysed 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**'.[8] 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).

[8] 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, Fourth Edition, 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 recognised 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 recognised 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 analyse 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 (see chapter 8), 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.

❒ **Organising 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 favourable, 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.

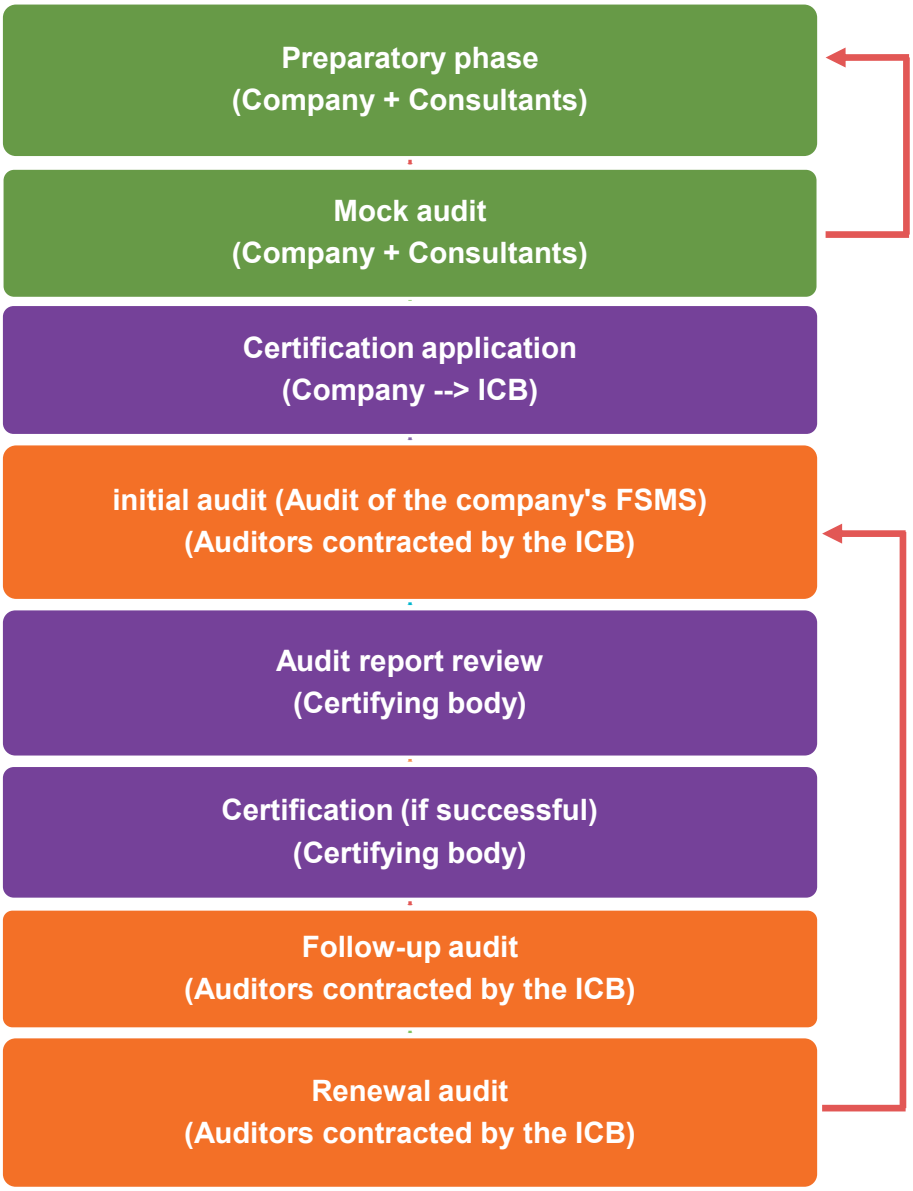
(3) The **renewal audit**: this is an audit similar to the initial audit. A periodic certification renewal audit (e.g. **every 3 years**) places the company within a continual improvement approach against which it is also evaluated over the years. Certification then becomes reliable evidence of the company's 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.

Number	Control points	Compliance	Minimum requirement level	Supporting evidence
1.1	**Description of the producer/orchard**			
1.1.1	Is the company/operator registered with the competent authority?	Yes ☐ No ☐ N/A[9] ■	3	
1.1.2	Are the orchards identified and/or coded?	Yes ☐ No ☐ N/A ■	3	
1.1.3	Is a plan of the plots in production available?	Yes ☐ No ☐ N/A ☐	2	
1.1.4	Have all the plots being cultivated been identified and/or coded?	Yes ☐ No ☐ N/A ☐	3	
1.1.5	Are records relating to the operations performed at each unit (orchard or plot) available?	Yes ☐ No ☐ N/A ■	2	

[9] 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
1.2	**Environment of the production site/orchard**			
1.2.1	Has a risk assessment been carried out for potential sources of contamination and on the effectiveness of reasonable measures to protect the fruit?	Yes ☐ No ☐ N/A ☐	2	
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 ☐	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 ☐	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 ☐	3	
1.2.5	Is the orchard regularly cleared of mangoes that have fallen to the ground?	Yes ☐ No ☐ N/A ☐	3	

Number	Control points	Compliance	Minimum requirement level	Supporting evidence
1.3	**Site design and layout**			
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 ☐	3	
1.3.2	Are staff facilities designed and used so as to reduce risks to product safety?	Yes ☐ No ☐ N/A ☐	2	
1.3.3	Is respect for biodiversity (fauna and flora)considered in the production site/orchard's layout?	Yes ☐ No ☐ N/A ☐	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 ☐ No ☐ N/A ☐	2	
1.3.5	Are measures in place to maintain site security, specifically to limit access to the site?	Yes ☐ No ☐ N/A ☐	1	

Number	Control points	Compliance	Minimum requirement level	Supporting evidence
2.1	**Staff hygiene and maintenance**			
2.1.1	Does the site have staff facilities for washing hands with soap and clean water?	Yes ☐ No ☐ N/A ☐	3	
2.1.2	Do workers have access to clean toilets?	Yes ☐ No ☐ N/A ☐	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 ☐ No ☐ N/A ☐	2	

2.1.4	Are staff informed of and trained in following hygiene procedures and related activities (plant protection treatments, transport and harvest)?	Yes ☐ No ☐ N/A ☐	3	
2.2	**Hygiene of the premises and maintenance**			
2.2.1	A plan for maintenance and cleaning is provided; does it include cleaning frequencies?	Yes ☐ No ☐ N/A ☐	2	
2.3	**Waste management**			
2.3.1	Is there a waste management plan throughout the production site?	Yes ☐ No ☐ N/A ☐	1	
2.3.2	Is waste regularly removed from the production area?	Yes ☐ No ☐ N/A ☐	2	
2.3.3	Is hazardous waste treated?	Yes ☐ No ☐ N/A ☐	2	

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 O2 and CO2 in a controlled atmosphere outlined	X		
7.4	O2 and CO2 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 harmonise 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 fertiliser 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[10]

Each lot should be controlled (or inspected), but not necessarily analysed.[11] Every lot to be analysed is **sampled separately**.

[10] If in doubt when taking samples, ISO 18593 will be used as reference standard.

[11] 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.

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 analysed. **It is obtained by assembling all basic samples.** This overall sample is preferably homogenised at the laboratory. 'Identical' samples can be taken from the homogenised 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:**

- 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).