Food Quality Management and Control - FQMC

Notes for the course NFOK15011U, at the University of Copenhagen September-November 2024

Lucas Daniel Paz Zuleta, TZS159
MSc student at University of Copenhagen

Last compiled: 10-10-2024

Contents

Chapter 1
Information of the course

1.1 Course content

The course will introduce the concepts of food quality management and control from two different/complementary perspectives:
1: a detailed reading of the ISO 22000 standard, and insight into the use of this standard, including HACCP (Hazard Analysis and Critical Control Points), for the management of food safety.
2: monitoring of the food quality based on process monitoring tools such as Statistical Quality Control (SQC) and Lean Six Sigma to ensure a food product with minimal variation.
Producing food requires understanding of all process steps, and knowledge of the performance of each step is critical to estimate the variability of the final product. Knowing the variability makes it possible to find solutions for adjusting it, if it is not in accordance with the process step and/or end-product specifications. Thus, the idea of measuring, understanding, adjusting, monitoring and controlling variability throughout the production is a key topic of this course.
Quality in this course will be seen both in a wide context; i.e. as proof of product specification meaning that the variability of the food produced is known and below or within an acceptable limit to ensure customer satisfaction, as well as occasionally in a more narrow context; i.e. as food safety meaning that the amount of hazards is below a certain limit.

1.1.1 Learning objectives

The main objective of this course is to provide the students with knowledge on international food safety management system standards and food quality monitoring and verification tools. After completing the course, the students should be able to:

Knowledge

Describe how food safety is achieved, using HACCP, according to international standards on food safety management (e.g. ISO 22000). Show overview of how the above mentioned food safety management system standards can be applied in the food industry. Describe how food production quality should be measured to ensure that process variation is under control. Describe how to gain insight into a process using quality by design to be able to optimize a process.

Skills

Apply ISO 22000 for food safety management. Use SQC and sampling technologies to monitor and verify process and product specifications. Communicate problems and solutions within food safety management. Use monitoring systems (e.g. real-time measurements), Six Sigma and SQC like tools to get knowledge of and to monitor quality control points in a food production and also to understand how the measurement uncertainty of process steps will influence the uncertainty/variability of the food product parameters.

Competences

Evaluate whether existing and/or new control strategies are appropriate in order to achieve safe and robust food products. Evaluate how the raw materials and production steps can be monitored to get an even better control of the final food product.

1.1.2 Teaching and learning methods

Lectures, project work, and seminars. The lectures introduce theoretical and practical aspects of international systems on quality/food safety management and control. The project work and seminars will help the students to interpret and obtain an understanding of the above mentioned aspects.

1.1.3 Exam

The exam will be an ITX exam with a duration of 4 hours. The exam consists of multiple choice questions (50% of the grade) and 1-2 essay questions (50% of the grade) where the students will be asked to analyze and solve a problem related to the course content. The exam will be based on the course literature and the lectures.

Chapter 2
Lecture Notes

2.1 05.09.24 - Meassurements

2.1.1 Agenda

The agenda of this lecture is:

- Monitoring a food process – why?
    * Variability of a process
    * Type of variations
- Characterization of a process by measuring
- Classification of process analyzers/sensors
- Correlations between measurements

2.1.2 Variability

Variability in the food industry can take many shapes, such as:

- Raw materials
- Equipment
- Operators
- Environment

These variables holds a big influence on the final product, and therefore it is important to monitor the process to ensure a consistent product. Therefore the overall food quality is correlated to the variability of the process.

Raw materials

The quality of ingredients can vary due to factors like soil quality, weather conditions, and transportation. This directly impacts the final product's consistency and taste.

Equipment

Variations in equipment calibration or wear and tear can lead to inconsistencies in processing, such as uneven cooking or mixing.

Operators

Human error or differences in skill levels among workers can introduce variability in tasks like sorting, measuring, and packaging.

Environment

Factors like temperature, humidity, and cleanliness of the production facility can also contribute to variability in food quality.

2.1.3 What is quality?

By understanding and monitoring these variables, food manufacturers can identify and address sources of variability to improve product quality and consistency.
Quality can be defined as the degree of excellence of something. In the context of food production, quality can refer to the characteristics of a product that meet or exceed customer expectations. This includes factors like taste, appearance, texture, and safety. **BUT** Quality can also refer to the consistency and reliability of a product, meaning that it meets the same standards every time it is produced.
Here are listed some examples of quality attributes in food production:

- **Performance** (Will the product do the intended job?)
- **Reliability** (How often does the product fail?)
- **Durability** (How long does the product last?)
- **Serviceability** (How easy is it to repair the product?)
- **Aesthetics** (What does the product look like?)
- **Features** (What does the product do?)
- **Perceived Quality** (What is the reputation of the company or its product?)
- **Conformance to Standards** (Is the product made exactly as the designer intended?)

This shows that quality is a multifaceted concept that encompasses many different aspects of a product or service.
A good rule of thumbs is that with a increasing variability, the quality of the product decreases. This is depicted in figure 2.1.

A definition of *Quality Improvement* is the reduction of variability in processes and products. The next part of the lecture will focus on how to measure and control this variability.

2.1.4 Variability

Variability is inherent in every process, and it can be classified into two main types: "Natural" or common cause variation and "special" or assignable cause variation. In common the variability can be measured.

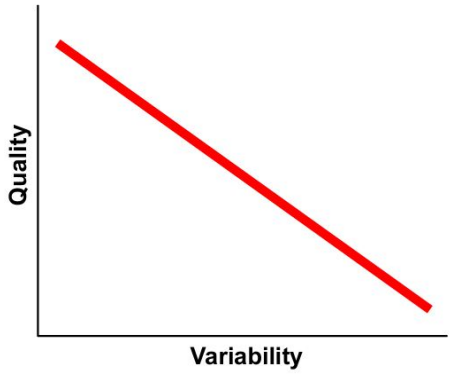

Figure 2.1: A picture of the correlation between variability and quality

Statistical Process Control (SPC)

This is the variability which is also called the common cause variation. This is the variability that is inherent in the process itself, and it is caused by factors that are part of the normal operation of the process. This type of variation is predictable and can be managed through statistical process control methods. This can affect virtually every production process, from manufacturing to service industries. The SPC follows a probability distribution, so e.g. mean and standard deviation can be calculated for at normal distribution. If the distribution of outputs falls within acceptable limits, the process is said to be in control. If the distribution falls outside of these limits, the process is considered out of control and corrective action is needed. The objectives is to check if we are in control or otherwise act on it.

Natural Variations

Natural variations, also called common cause variations, are inherent in the process and are caused by factors that are part of the normal operation of the process (Examples can be poor process design, inadequate equipment and procedure). These variations are predictable and can be managed through statistical process control methods. For example, the temperature of an oven may naturally fluctuate within a certain range during baking, leading to variations in the final product. The natural variations may be identified by the operators, but only management can eliminate common cause variations.

Assignable Variations

This is generally caused by factors that are not part of the normal operation of the process, and they are often due to human error, equipment failure, or other external factors. Because of this, the variations can often be traced back to a specific reason. These variations are unpredictable and can be more difficult to manage than common cause variations. For example, if a machine malfunctions during production, it can lead to defects in the final product. Assignable variations are also known as special cause variations, and they require immediate corrective action to bring the process back into control (Eliminate the bad cause and incorporate the "good" cause). An example is when someone drops their child at the productions site, and the child runs around and touches the equipment. Or that a machine explodes.

Measure through sampling

To measure the process, we take samples and analyze the sample statistics. If only the natural causes of variation are present, the output of a process forms a distribution that is stable over time and is predictable. This is also called normal operating conditions (NOC). If assignable causes are present, the process output will be unstable and unpredictable over time. This is also called abnormal operating conditions (AOC).
W. Edwaerds Deming, a famous statistician, once said: *"Putting out fires is not improvement of the process. Neither is discovery and removal of a special cause detected by a point out of control. This only puts the process back to where it should have been in the first place."*. This is a good rule of thumb to follow when measuring and analyzing processes.
To measure variability, the Six Sigma: DMAIC method should be remembered.

- **D** - define the problem
- **M** - map out the current process
- **A** - analyze and identify the cause if the problem
- **I** - implement and verify the solution
- **C** - control and maintain the solution

2.1.5 Variability through measurements

To measure variability, we need to use measurements. Measurements can be used to characterize a process and identify sources of variability. There are four main types of measurements that we will worked with in this course: *In-line, On-line, At-line, and Off-line* see figure 2.2 for an example of a visual representation.

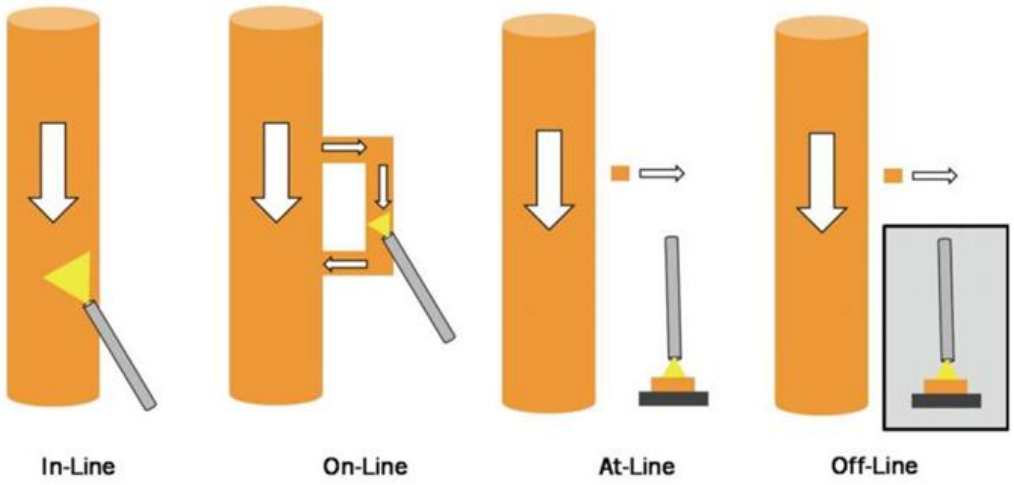

Figure 2.2: The four types of measurements from most complicated and fastest to the simplest and slowest method

2.2 05.09.24 - ISO 22000:2018 - A food safety management system standard

Management is the way in which an organization manages the inter-related parts of its business in order to achieve its objectives. There were given a link which can be used to get more information: https://www.iso.org/manageme

system-standards.html (5/9/2018)
Standard (= scheme), this describes the set of rules/requirements on which the system of an organization are based...
Here are some examples of Food Safety Management System Standards:

- BRC Global standard – Food
- IFS
- SQF
- ISO 22000
- FSSC 22000
- For more examples, see QM-textbook, pp. 7-12

2.2.1 Deming Circle

The Deming Circle, also known as the PDCA Cycle (Plan-Do-Check-Act), is a continuous improvement model developed by W. Edwards Deming. It consists of four key steps:

- **Plan** - Identify an opportunity and plan for change.
- **Do** - Implement the change on a small scale.
- **Check** - Use data to analyze the results of the change and determine whether it made a difference.
- **Act** - If the change was successful, implement it on a wider scale and continuously assess your results. If the change did not work, begin the cycle again.

The PDCA cycle promotes ongoing evaluation and refinement, leading to gradual, sustained improvement in processes or products. This is meant to be a continuous cycle, with each iteration building on the last and can be depicted in figure 2.3.

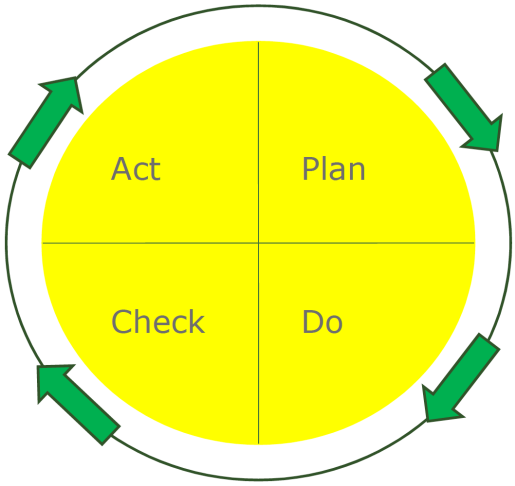

Figure 2.3: A picture of the circular thought behind the Deming Circle

A more thorough illustration of the four steps can be seen from the following figure 2.4.

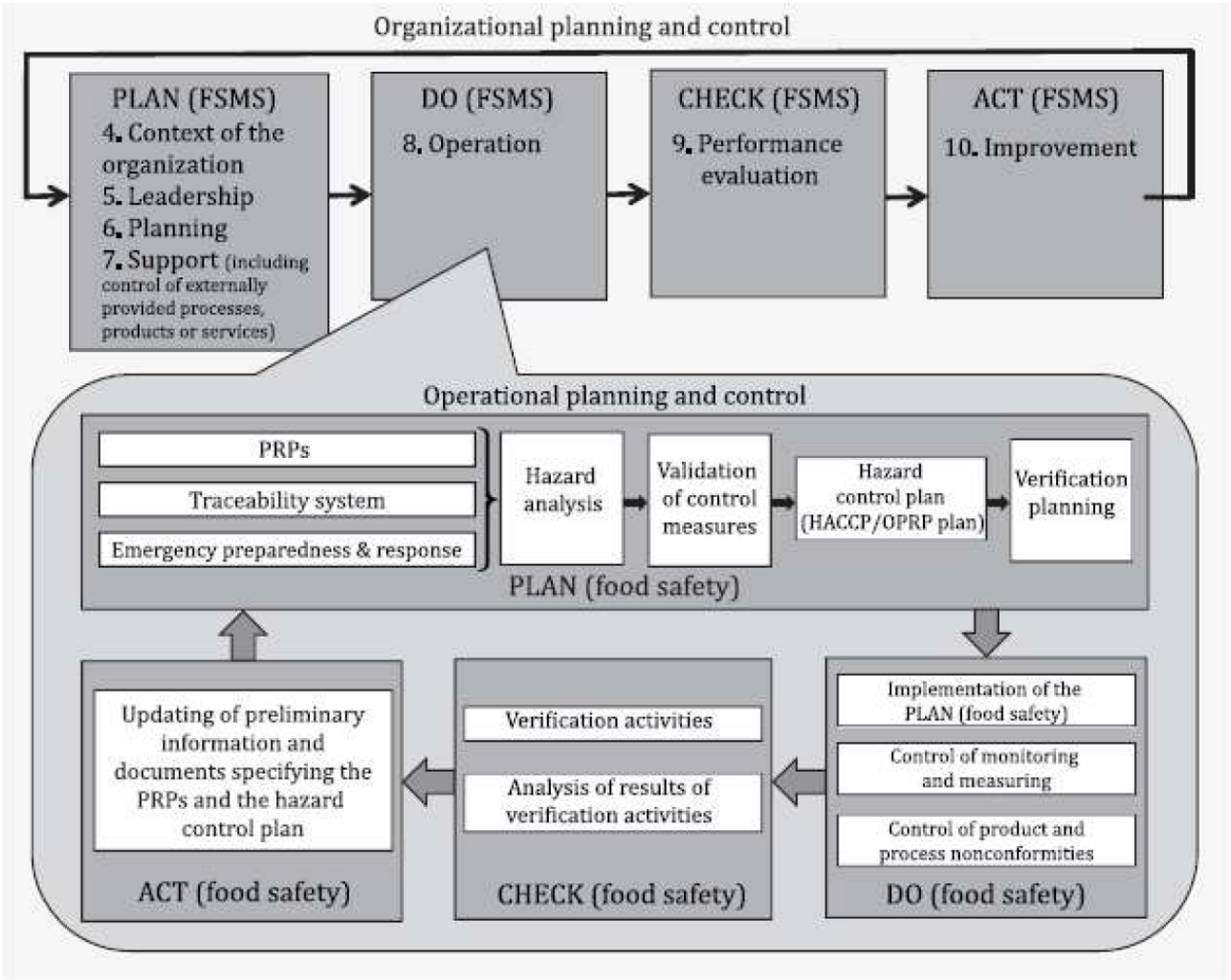

Figure 2.4: A thorough illustration of the Plan-Do-Check-Act cycle

2.2.2 ISO 22000

Here are three keypoints of the ISO 22000:

- It combines the prerequisite and operational prerequisite programmes (i.e. GMP) and HACCP requirements of Codex Alimentarius and quality management requirements of ISO 9000
- It reduces confusion about Food Safety Management System Standard requirements, since it defines the elements of key standards required by leading retailer chains in a single standard and defines the Codex HACCP system as the "standard within the standard" to be used
- however, the standard is generic, i.e. organizations/companies have to think themselves!

There are 10 chapters in the ISO 22000 standard, chapter 4-10 are the main chapters. The first three chapters are the introduction and the scope of the standard. Thus chapters 4-10 are the main chapters of the requirements of the standard.

- Chapter 1: Scope
- Chapter 2: Normative references
- Chapter 3: Terms and definitions
- **Chapter 4: Context of the organization**
- **Chapter 5: Leadership**
- **Chapter 6: Planning**
- **Chapter 7: Support**
- **Chapter 8: Operation**
- **Chapter 9: Performance evaluation**
- **Chapter 10: Improvement**

2.3 05.09.24 - HACCP - step 9: monitoring procedures

HACCP stands for: (H)azard (A)nalysis and (C)ritical (C)ontrol (P)oints The intention behind this is:

- The internationally recognized procedure to ensure the production of safe foods
- Over the last 50 years, HACCP has evolved from
- 3 principles to
- 7 principles to
- 12 steps (incl. the 7 principles)
- Codex Alimentarius CAC/RCP 1-1969

The HACCP consist of 12 steps (Codex Alimentarius CAC/RCP 1-1969), 5 preliminary steps and 7 principles. The 12 steps are:

- 1 - Assemble HACCP team
- 2 - Describe product
- 3 - Identify intended use of the product
- 4 - Construct process flow diagram for the product
- 5 - Verification of process flow diagram
- 6 - Conduct a hazard analysis
- 7 - Determine critical control points (CCP's)
- 8 - Establish critical limits for each CCP
- 9 - Establish monitoring procedures for each CCP
- 10 - Establish corrective actions for each CCP
- 11 - Establish verification procedures for each CCP
- 12 - Establish record keeping and documentation procedures

2.4 10.09.24 - Group presentation of case 1

The group presentation of case 1 was held by 2 groups. This ensures the students to get a better understanding of the case from different points of views. The topic of the presentation was about yogurt production and the quality of the product and the process. The 2 groups were divided such as one group made a presentation and the other group was the opponent group. The opponent group had to ask questions about the presentation and the group that made the presentation had to answer the questions. The groups were evaluated by the teacher and the other students.

2.4.1 Group 5 (KCK Yogurt A/S - Presentation)

There is problems with *Listeria monocytogenes*.
All parameteres that can/must be measured/monitored are:

- **Quantity**
  Measured by weighing the milk container truck before and after intake to determine how much milk was delivered
- **pH**
  Measured at intake with a pH-meter to monitor microbiological activity
- **Temperature**
  Measured in-line using a thermometer
- **Fat, Protein, Carbohydrate content**
  Measured at-line using Milkoscan
- **Antibiotics**
  Measured at-line using Milksafe^{TM}
- **Organoleptic characteristics**
  Identified by a dairy operator at intake and for the end-product
- **Pathogens**
  Measured by BactoScan FC and at-line

Not all the measurements are needed real-time, thus some measures can be done off-line. Some measurements are needed real-time, here are some examples of real-time measurements:

- **Temperature**
  Measured continuously and needed in real-time throughout the process
- **pH (Raw Milk Intake)**
  Measured at intake but real-time
- **pH (Post-Inoculation)**
  Measured continuously and needed in real-time after inoculation to track the acidification process
- **Critical Parameters**
  e.g. temperature, post-inoculation pH, which must be measured continuously for real-time monitoring

2.4.2 Group 2 (KCK Yogurt A/S - Presentation)

2.5 10.10.24 - Food Safety Management

hej med diagram
starter noter

Chapter 3
Group Work

3.1 Case Exercises

3.1.1 Case 1 (Intro Case; Parma Ham A/S) - 03.09.24

Information

> The information given for this case is as follows:
> - Production capacity: 330.000 raw hams per year
> - 70 well-educated staff members
> - Production of Parma ham
> - Has experienced huge problems with Salmonella and
> - Staphylococcus aureus during the production of Parma ham
> - Therefore, Parma Ham A/S has obtained an ISO 22000 certification

Company Policy

> The information given for this case is as follows:
> - Parma Ham A/S will produce high quality Parma ham safe for human consumption.
> - The Food Safety Management System (FSMS), complying with the requirements given in "DS/EN ISO22000:2018", shall ensure that legal requirements as to food safety are fulfilled at any time.
> - The FSMS shall ensure that customer requirements as to food safety are fulfilled at any time.
> - The presence of Salmonella and Staphylococcus aureus shall be reduced to an acceptable level at Parma Ham A/S.
> - All staff members at Parma Ham A/S shall be aware of the food safety policy and the FSMS.

Salmonella ssp.

The information given for this case is as follows:

- Pathogenic Gram negative bacterium
- Naturally found in the intestinal tracts of mammals, birds, amphibians and reptiles but not in fish crustaceans or mollusks
- Causing salmonellosis
  Nausea, vomiting, abdominal cramps and fever
  Zoonotic infection
- The infective dose of Salmonella is thought to be extremely variable, relatively high for healthy individuals and very low for at-risk individuals, such as the elderly or medically compromised.
- Facultative anaerobe
- Minimum water activity for growth is 0.94
  (max. 8% salt in water phase)
- Able to survive in dried foods
- Min(/max) temperature for growth is 5 (46)°C
- Min(/max) pH for growth is 3.7 (9.5)
- The presence of Salmonella can be prevented by: heating food sufficiently to kill the bacteria, holding chilled food below 5°C, preventing post-cooking cross-contamination and prohibiting people who are ill or are carriers of Salmonella from working in food operations

Staphylococcus aureus

The information given for this case is as follows:

- Pathogenic Gram positive bacterium
- Humans and animals are the primary reservoirs for Staph. aureus. Staph. aureus can be found in the nose and throat and on the hair and skin of 50 percent of healthy individuals. However, the bacteria can be found in air, dust, sewage and surfaces of food-processing equipment. Staph. aureus can produce a toxin if allowed to grow in food. The toxin is not destroyed by the cooking or canning processes
- Staph. aureus food poisoning causes nausea, vomiting, abdominal cramping, watery or bloody diarrhea, and fever
- Facultative anaerobe
- Min(/max) temperature for growth is 7 (50)°C
- Min(/max) pH for growth is 4 (10)
- S. aureus has the ability to grow and produce toxins in food with very little available water (aw 0.86, 20 percent salt in water phase), which would prevent the growth of other pathogens.
- The presence of Staph. aureus can be prevented by: minimizing time/temperature abuse of food, especially after cooking, and requiring that food handlers engage in proper hygiene.

Organizational Structure

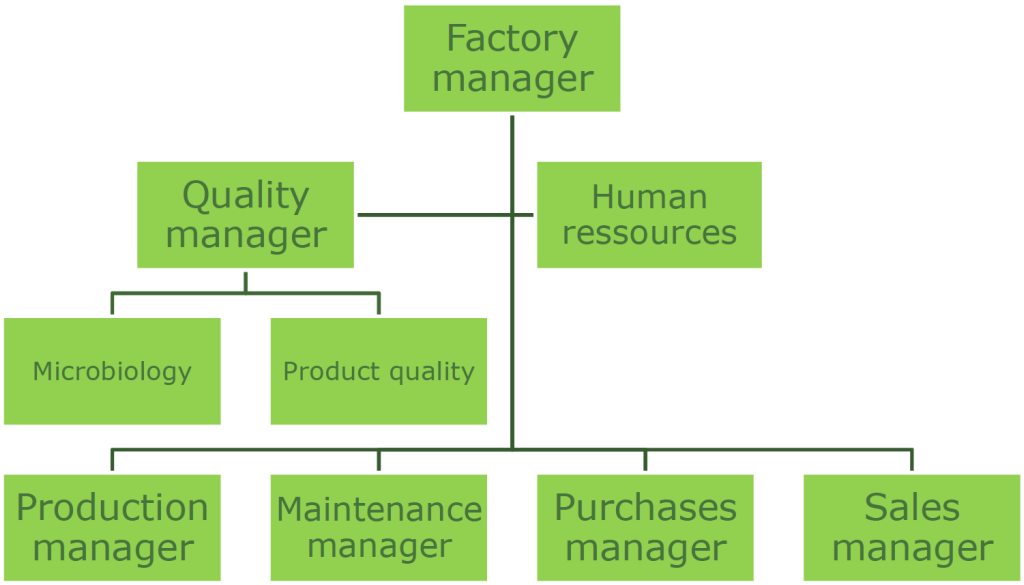

Figure 3.1: Organizational structure of Parma Ham A/S

Responsibilities

The information given for the organizational structure and roles is as follows:

- The Factory Manager is responsible for:
  - The overall management of the factory, including the implementation of
  - The FSMS.
  - Shall ensure adequate ressources for development and implementation of the Food Safety Management System and for continually improving its effectiveness
- The Quality Manager is the overall responsible for:
  - The Food Safety Management System
    * Development
    * Implementation
    * Maintenance
- The Production Manager is responsible for:
  - The production of the Parma ham and for inspection of raw materials
  - The production staff is divided into several sections, each with a section leaders
  - The section leaders are responsible for
  - Ensuring that all staff members have the necessary competencies
  - Ensuring that all staff members have the necessary food safety awareness
  - Education and training of staff members

Information continued:

- The Sales Manager is responsible for:
  - Customer focus
  - Investigating the requirements and expectations of customers
  - Investigating whether these requirements and expectations are fulfilled
- The Purchasing Manager is responsible for:
  - Supplier focus
  - Ensuring that purchased products conform to specified purchase requirements
  - Specified purchase requirements
    * Approval of products, procedures, processes and equipment
    * Qualification of personnel
    * QMS/FSMS
  - Supplier audits

3.1.2 Easy Case 1 - 10.09.24

In this easy case, we are tasked to sit 30 minutes by ourselves and write down the answers to the following questions. After the 30 minutes, we will discuss the answers in our designated groups and prepare a presentation for 15 minutes. One group will be assigned to hold a presentation of the easy case. The following background and tasks has been given to us.

Background

You are a food safety manager at a mid-sized food processing company. Your company specializes in producing juice products, and maintaining high standards of food safety and quality is paramount. Recently, your company decided to implement ISO 22000:2018 to enhance its food safety management system and improve process control. As part of this initiative, you are tasked with developing a comprehensive monitoring procedure targeting biological and physical hazards, as well as integrating Statistical Process Control (SPC) methods to manage variability in the production process.

Task

The following bulletpoints are the tasks that you need to address in this case:

- Define three natural and three assignable variations in the context of SPC and juice production and their relevance to food safety management.
- Identify three control measures targeting biological (*Salmonella*) or physical (glass pieces) hazards in juice production.
- Provide examples of sensors or measurement techniques that can be used to monitor these control measures to ensure they are effective.

Personal Notes

Bulletpoints from the background:

- Product = juice
- Implementing ISO 22000:2018

- Monitoring procedure targeting biological and physical hazards
- Integrating Statistical Process Control (SPC) methods

Answers to the task:

Three natural variations which can affect the production of juice and food safety management:

- Seasonal variations in the raw materials which can affect the quality of the juice and the growth of pathogens
- Variations in the temperature of the production environment which can affect the growth of pathogens
- Variations in the pH of the juice which can affect the growth of pathogens or the stability of the product

Three assignable variations which can affect the production of juice and food safety management:

- Equipment malfunction in the production line
- Human error in the production process
- Contamination of raw materials or final product

Three control measures which can be implemented to target biological or physical hazards in juice production:

- Heat treatment of the juice to kill pathogens which can cause foodborne illnesses e.g. *Salmonella*
- Filtration of the juice to prevent glass pieces from entering the final product
- Cleaning and sanitation of the production environment for overall good manufacturing practices

Examples of sensors or measurement techniques that can be used to monitor these control measures:

- Temperature sensors to monitor the heat treatment process of the juice. Thus ensuring that the pathogens are killed
- pH meters to monitor the pH of the juice. Thus ensuring that the product is stable and safe for consumption. Also in-line pH sensors can be used to monitor the pH continuously
- Random sampling of the incoming raw products to ensure the composition and quality of the raw materials.
- Testing of equipment to ensure that they are functioning properly and not contaminating the final product or leaving glass pieces in the juice
- Training employees to ensure that they are following good manufacturing practices and are trained in operating the equipment properly
- Perform tritration on cleaning detergent to ensure that the cleaning is effective and that the equipment is sanitized properly
- In-line X-Ray screening of the product to ensure that there are no glass pieces in the the product

3.1.3 Case 5 - 08.09.24

While analyzing the given information of the 5 machines, Cp, Cpk_u and Cpk_l values have been calculated. In general, it can be said that, a high Cp value indicates good potential capabilities, a centered Cpk_u and Cpk_l indicates a mean within the upper and lower limits. While looking at the Cpk values for both the upper and the lower, only the lowest value is used. If the lowest Cpk value is above one, the machines capability process is acceptable. The calculations are shown in the table 3.1 below.

Table 3.1: Cp, Cpk_u, and Cpk_l values for the 5 machines. The green colours indicate that the machine is acceptable, the red colours indicate that the machine is not acceptable. The blue colours indicate that the lowest Cpk value is higher than one, whereas the apricot colours indicate that the lowest Cpk value is lower than one.

Machine	Std devs	Mean	Cp Value	Cpk_u Value	Cpk_l Value
Machine A	0.05	16.0°C	2.00	2.00	2.00
Machine B	0.02	16.2°C	5.00	1.67	8.33
Machine C	0.10	16.2°C	1.00	0.33	1.67
Machine D	0.05	15.9°C	2.00	2.67	1.33
Machine E	0.20	16.0°C	0.50	0.50	0.50

Chapter A
Appendix