



What is Quality?

- **Quality is the foundation for the industry**
- **The term “quality guaranteed” can be:**
 - Manufacturing-based
 - User-based
 - Value-based



Quality Assurance and Quality Control

I would like to start the discussion by asking and addressing the question of “what is quality?” For manufacturers and processors, providing quality food is the goal of the company and is the foundation of the industry. What exactly does quality mean when we use the term “quality guaranteed”? The word “quality” in the term “quality guaranteed” can have different definitions depending on who is doing the evaluation or on what the definition of quality is based. First of all, the definition of quality can be manufacturing-based. Taking this steel-cut oat product as an example, the higher the percentage of oats get cut, the better the quality is guaranteed. Secondly, the definition of quality is user-based. The user is the one who decides, among all different attributes of a product, the particular attribute or attributes upon which the quality will be evaluated. For this ready-to-eat meal kit, its ease of use or whether it can be ready in three minutes might be the key attribute upon which users evaluate its quality. Last but not least, the evaluation of quality can also be value-based. Here, we have a generic brand of cereal and a name brand cereal. We know that we pay different prices for these two products. In this scenario, our expectation of the quality of these two products is impacted by the price we paid. The perception of quality can be highly impacted by the price we paid and our expectations.

What is Quality?

- The assessment of quality can be objective and subjective
- Assuring product quality = make a product what it is, conforming to requirements or specifications set forth for this product based on the available budget



Based on these examples, we can see that the assessment of quality can be both objective and subjective. Acknowledging and understanding the various definitions of quality is important. It helps us determine and justify the degree of control we have over our product quality. Variations and deviations during processing always happen. In the end, assuring product quality really means that we make a product what it is, conforming to the requirements and specifications we set for this product based on the available budget we have. We know that variances will happen, and the evaluation of product quality can be multi-dimensional.

Quality Dimensions

1. Performance

- The primary operating characteristics and features of the product
- They are measurable
- Example: 100 million cultures per gram at the time of manufacture



2. Conformance

The precision with which the product meets specific standards (regulatory standards)

Example: Aflatoxin levels present in animal or human foods

Quality Assurance and Quality Control

Talking about the dimensions of quality, the two key quality dimensions are performance and conformance. Performance represents operating characteristics and features of the products that are measurable. For example, the number of live bacteria present in yogurt. If a dairy company wants to use this “live & active culture” label, it needs to make sure that there are 100 million live culture per gram of the dairy product at the time of manufacture. Conformance represents the precision with which the product meets specific standards (typically regulatory standards). One example I have here is the aflatoxin levels present in corn products. Based on the aflatoxin level, we can decide whether it is safe to be used for animal feed or human food. Many of the conformance standards are food-safety related. In other words, food safety is a part of your product quality.

Safety is Part of Your Product Quality



- ☐ Quality assurance includes ensuring food safety.
- ☐ Use a set of controls to minimize and prevent potential microbiological, chemical, and physical hazard contamination.

Quality Assurance and Quality Control

In this case, assuring product quality covers protecting food safety, and food companies use a set of controls to minimize and prevent potential microbiological, chemical, and physical hazard contamination.

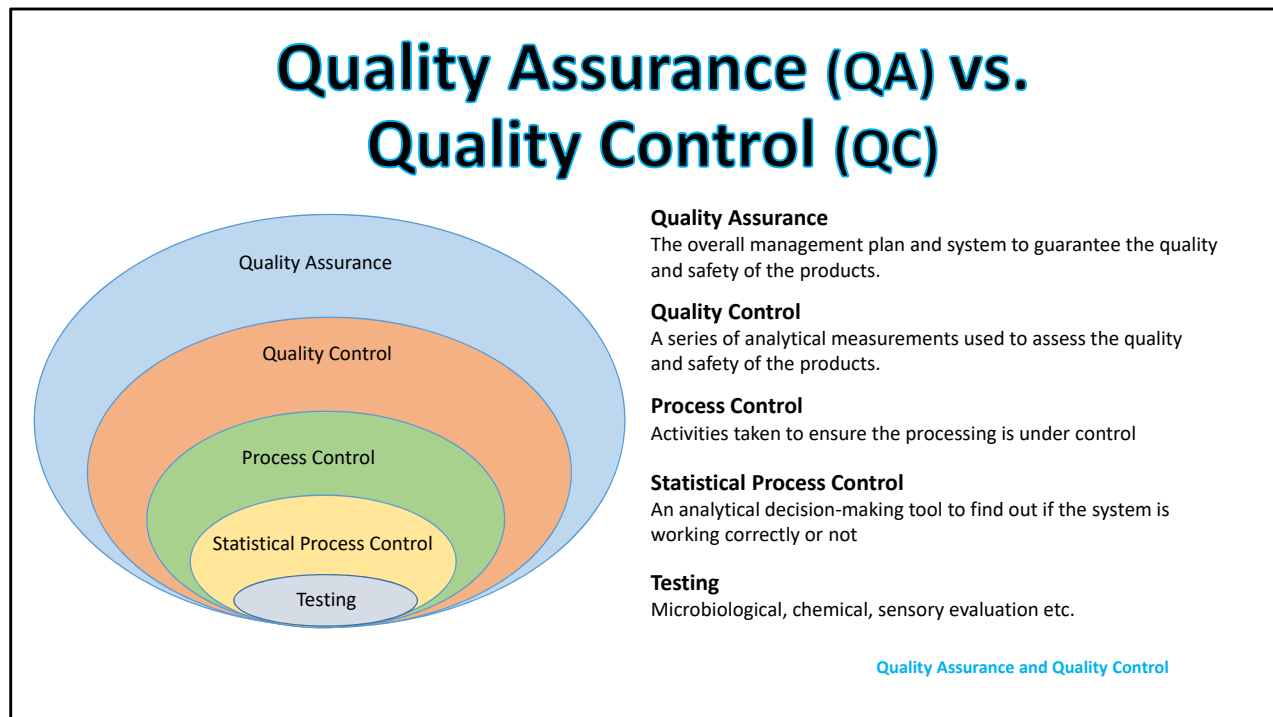
Quality Assurance

- According to the International Standards Organization ISO 9000, QA represents *“all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality”*
- Quality assurance (QA) describes and manages the activities of control, evaluation, audits, and regulatory aspects of a food processing system
- QA consists of an in-house consulting organization to give advice, suggestions, and instructions for improvement
- QA is an advisory function, not a police function



Quality Assurance and Quality Control

According to the International Standards Organization ISO 9000, QA is “all planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.” Quality assurance describes and manages the activities of control, evaluation, audits, and regulatory aspects of a food processing system. A quality assurance team consists of an in-house consulting organization to give advice, suggestions, and instructions for improvement.



Together with quality assurance, another term we often hear is quality control. This slide aims to explain the connections between quality assurance and quality control and other concepts associated with them. Quality assurance includes quality control, which represents the series of analytical measurements used for assessing the quality and safety of products. Quality assurance puts a lot more emphasis on the management and management system. It makes sure that the company or industry has an efficient management infrastructure and communication plan to ensure that the quality control measures work. Process control is part of quality control. It represents activities taken to ensure the processing is under control. Within process control, statistical process control is an analytical decision-making tool we can use to determine if the system is working correctly or not. To do that, we first have to collect data and numbers based on the testing program. These tests include but are not limited to microbial tests, chemical tests, and sensory evaluations.

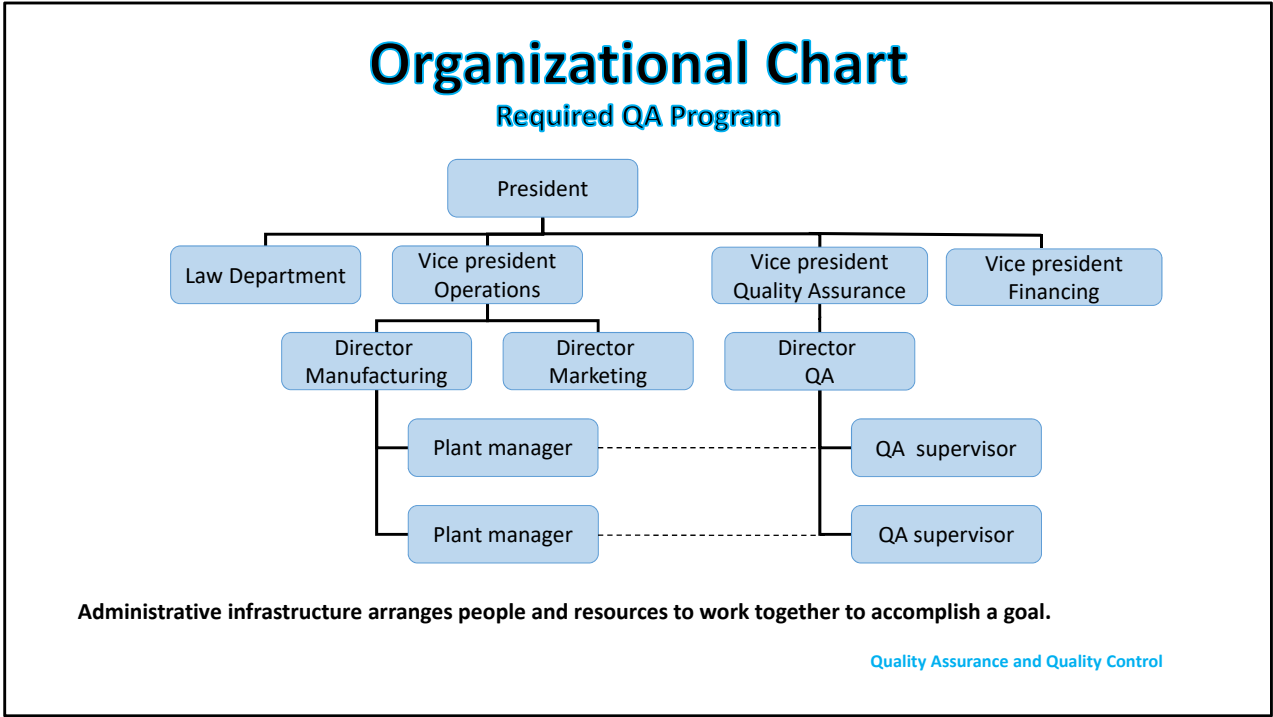
Management and QA

- **Management must provide proper job instructions to all employees**
- **Time and effort are required in order to involve all personnel and get them trained**
- **An efficient communication plan is needed so that the chief executive can communicate efficiently and clearly with people making decisions at the plant level**
- **Line workers must be empowered and become individual QA/QC stations**
 - **Steering committee**

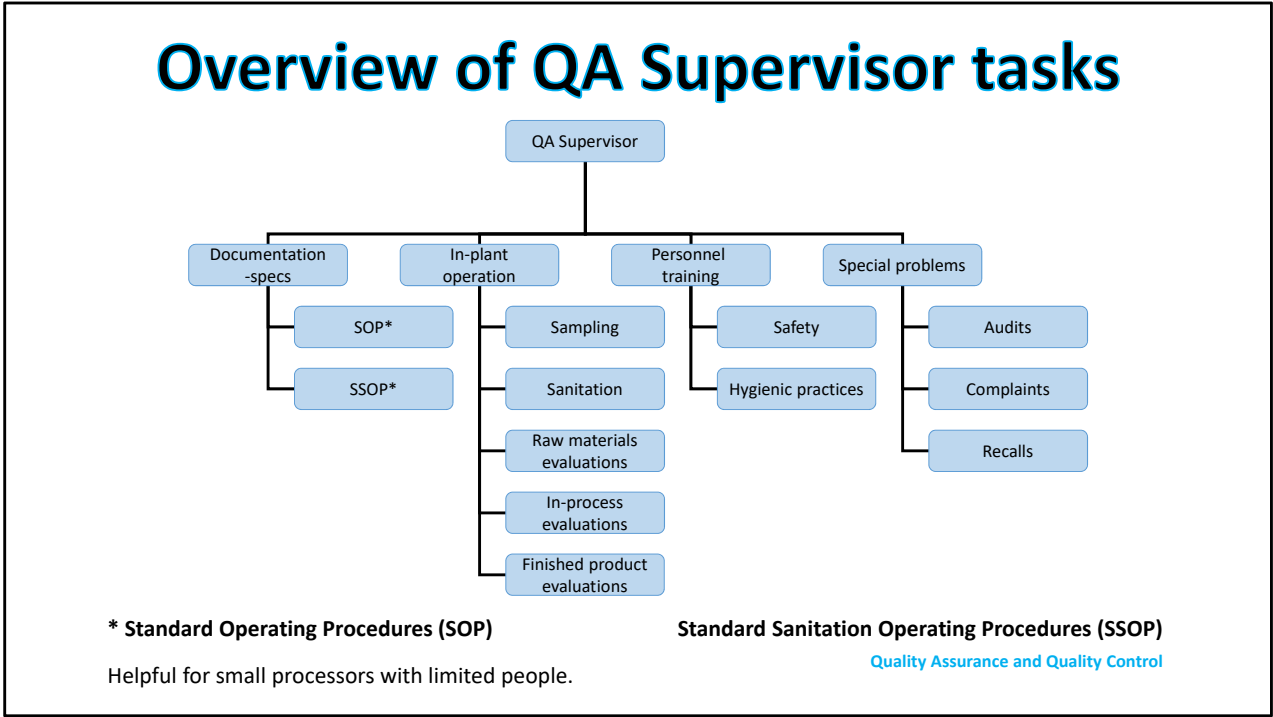


Quality Assurance and Quality Control

As we just discussed, management is very important for quality assurance. A successful QA program depends on an efficient management system. Management needs to provide proper job instructions to all employees. Time and efforts are needed in order to properly train all personnel. An efficient management system also relies on communication plans so that chief executives can communicate clearly with people making decisions at the plant level. Vice versa people who work at the plant level can also report a problem to higher management in a timely fashion before it leads to a bigger problem. This is the reason why modern QA seeks to empower line workers, such as forming steering committees, to get them involved in routine inspection programs or internal audits.



Based on that, when looking into various QA programs, the first requirement is an organizational chart. Different formats of organizational charts can be prepared. The example on this slide aims to show the overall structure and management infrastructure of a company. It shows not only the upper management team but also the management structures at the level.



This one chart shows the responsibilities and jobs of a QA supervisor. The two charts can be used together so that employees at all different levels understand to whom they report problems and the responsibilities of all managerial personnel.

QA system

- Programs are needed to build up the QA system
- Different QA/QC programs are required
 - Types of products
 - Cookies vs. cauliflower packaged in a field
 - Sizes of the business
 - Segments of the food production chain
- Programs include a set of controls implemented and verified by the responsible person



Quality Assurance and Quality Control

Within a quality assurance system, there are many programs. Depending on the type of products, the size of the businesses and the segment of the food production chain the companies are in, the programs required might be different. However, they all share the same goal of setting up a series of controls to ensure product quality, including safety, with results verified by responsible personnel.

QA/QC Programs

- Required QA/QC programs
- Optional QA/QC programs

Organizational chart
Current good manufacturing practice
Sanitation program
Pest control program
Allergen program
Weight control program
Metal detection program
Inspection program
Regulatory inspection program
Lot coding program
Customer complaint program
Recall program
Receiving program
Shipping program
Hold/defective material program
Glass, hard plastic, and wood program
Loose-material program
Security and biosecurity program
Supplier certification program
Food safety programs (HACCP or Food Safety Plan)

Starting from this slide, we will talk about the required and optional QA/QC programs. Here is the list of required QA programs. Including...

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Within these programs, I will highlight the cGMP, sanitation program, pest control program, allergen program and food safety programs, such as the HACCP and Food Safety Plans if you are under the new Preventive Control regulation.

Required QA/QC programs

- **Current good manufacturing practice**

21 CFR Part 117 “Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food”

- Personnel hygiene
 - Facilities
 - Sanitation
 - Processes and controls*
 - Pest control
 - Training
 - Records*
- * New regulations greater emphasis



Current good manufacturing practice, 21 CFR Part 117 has been one important foundation for our food safety programs. It provides guidelines for personnel hygiene, facility design and maintenance, sanitation operations, processes and controls, pest controls, employee trainings, and record keeping. The updated cGMP puts a lot of emphasis on processes and controls as well as record keeping.

Required QA/QC programs

- **Sanitation program**

- Foundation for HACCP and a key component for Food Safety Plan
- Soil vs. microorganisms (Cleaning vs. sanitizing) as well as allergens
- Methods of cleanup: dry vs. wet
 - Dry: top-down approach
 - Wet: Manual, clean-in-place (CIP), and clean-out-of-place (COP)
- A written sanitation standard operating procedures(SSOP) is very important
- Master sanitation plans based on the equipment and operation schedules (daily, per shift, or monthly)
- Safe storage and usage of chemicals (sanitizers and detergents)
- Training records and verification



Sanitation is another critical QA program. If you are familiar with the Hazard Analysis Critical Control Point (HACCP) process, sanitation is the foundation program or prerequisite. For the new preventive control regulations, sanitation can be part of your Food Safety Plan. When developing sanitation programs, the key is to get all employees to understand the differences between cleaning and sanitizing. While cleaning is designed for removing soil such as oil and proteins, sanitizing targets microorganisms. Without an efficient cleaning program, sanitizing results can be compromised. Dry and wet cleaning can be chosen based on the products you make. Dry cleaning is commonly used for a processing plant that does not want moisture. For dry cleaning, the top-down approach is most efficient. For wet cleaning, the washing, rinsing, and sanitizing can be done manually or via CIP or COP. A written sanitation standard is important. Master sanitation plans that are designed based on equipment and operation schedules are critical. For sanitation programs, safe storage and use of sanitizers and detergents are also important. A chemical inventory that lists chemicals used for cleaning and sanitizing is needed. Last but not least, as a required program, training records as well as daily cleaning and sanitizing records need to be kept and verified.

Required QA/QC programs

- **Pest control program**

Integrated pest prevention program

- Sanitation serves as the foundation for efficient pest control programs
- Mechanical control
 - E.g. the use of mechanical rodent catching traps
- Biological control
 - E.g. the use of parasitic wasps or bacteria-based products for fly control
- Chemical control
 - Safe use of pesticides
- Cultural control
 - Changing the habits or behaviors of employees and visitors



Rodent Trap



Bug Zapper



Wasp Catcher

The next required program is pest control. For this program, the part I would like to highlight is the importance of having an integrated pest prevention program. An integrated pest control program has two parts: the use of mechanical, biological, or chemical control (or the combination of any two of them) and the implementation of culture control. For mechanical, biological, and chemical controls, although many companies choose to hire contractors, it is still the company's responsibility to ensure that an efficient sanitation program is implemented. Sanitation is the base for effective pest control. Before choosing a contractor and a control method, a company needs to check with contractors and make sure that the proposed control method is effective, and the chemical used has been approved by the EPA or other regulatory agencies. If using chemicals, the application methods, spray or bait, need to be determined as well to avoid introducing chemical hazards to the final products. Cultural control, which emphasizes changing employee behaviors, is another important component. This part needs to be connected with your GMP employee training program and visitor GMP. One needs to make sure that employees and visitors don't introduce pests into the processing plant.

Required QA/QC programs

- **Allergen control program**
- One of the fastest growing areas of concern within the food industry is allergen identification and control.
- It is also a part of food-safety concerns.
- Significantly higher number of recalls or withdrawals are associated with mislabeled or harmful food products for allergenic reasons than with any other cause.
- Key components of a food allergen management program:
 - Supplier control
 - Ingredient receiving and storage (separation between non-allergenic and allergenic materials)
 - Process design strategies (including sanitation schedules for preventing cross-contamination)

Big-8 Allergens



The fourth program I would like to highlight is the allergen control program. Part of the reason I want to highlight this one is because it has been one of the fastest growing areas of concern within the food industry. We have seen a significantly higher number of recalls or withdrawals being associated with mislabeled or harmful food products for allergenic reasons. Key components of a food allergen program include supplier control and asking suppliers to provide a quality guarantee letter or a certificate of analysis. Another important component is ingredient receiving and storage, making sure allergen-containing ingredients are stored in separated areas. The last one is process design so that no cross-contamination will happen during processing. For example, manufacturing the non-allergen-containing products first in the morning and then allergen-containing products later in the day. This can minimize the chance of introducing allergens to your allergen-free products.

Required QA/QC programs

HACCP

- Hazard analysis critical control point (HACCP)



- Preventive control for human foods (Food Safety Plan)

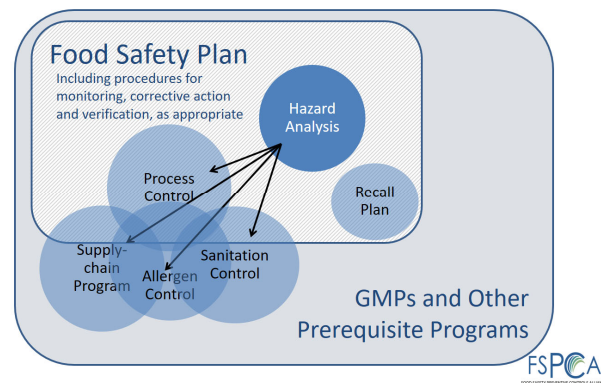
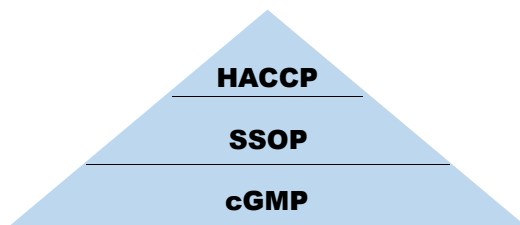
Products except low acid canned products and products under the regulation of space programs

- ☐ Both food safety programs are based on hazard analyses.
- ☐ While HACCP focuses on critical control points (CCPs), PC focuses on preventive controls including CCPs, allergen control, sanitation, supplier chain management, and more.
- ☐ A recall plan is now also a part of the Food Safety Plan.
- ☐ Verification and recordkeeping are important for both programs.

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

The last required program is the food safety program. Two important ones listed here are HACCP and PC. Products that need to have a HACCP program include meat, poultry, fish, juice, milk, and egg products. All other products except low-acid canned products and products under the regulation of space programs are under the regulation of PC. Both food safety programs are based on hazard analyses. While HACCP focuses on critical control points during processing, PC focuses on CCPs, allergen control, sanitation, supplier chain management and other areas to ensure product safety. A recall plan is part of a Food Safety Plan. Verification and recordkeeping are important for both programs.

Required QA/QC programs



These two figures are from the Food Safety Preventive Controls Alliance preventive control training manual, highlighting the connections between good manufacturing practices, sanitation programs, and food safety programs.

QA/QC Programs

- Required QA/QC programs
- Optional QA/QC programs

Kosher certification program
Organic certification program
Outside audit program
Contract laboratory testing program



In addition to required programs, there are also optional QA programs. Examples include the kosher certification program, organic certification program, outside audit program, and contract laboratory testing program. The reason we call it optional is because they are not applicable to all processing plants. However if you are producing kosher food and would like to use some of the kosher labels, then a kosher certification program becomes a required program for your company, and your certificate needs to be renewed following the certifying agency's requirements.

Summary

- **Quality is of great importance to the food industry**
- **Food safety is part of your food quality**
- **The definition of quality can be manufacturing-based, user-based, or value-based**
- **Performance and conformance are important dimensions of food quality**
- **Quality assurance is the management system that guarantees the successful execution of food quality and safety programs**
- **Management plays a profound role in the successful implementation of QA/QC systems**
- **QA/QC programs**
 - Required programs
 - Optional programs



Quality Assurance and Quality Control

In summary, the goal of this lecture is to provide you with an overview of quality assurance and the connections between quality assurance and food safety programs. After this lecture, we hope that you understand safety is part of your product quality. Quality is the foundation of your company's success and development. The definition of quality varies, and depends on who is evaluating the quality. Such evaluation can be objective or subjective. Quality can have different dimensions. Performance and conformance are two important dimensions of quality. Conformance, in particular, represents the precision with which the product meets specific standards (typically regulatory standards). A successful QA system starts with management. Upper management needs to acknowledge the importance of quality and quality assurance and needs to provide time and effort to train employees. An organization chart, a required QA program, facilitates efficient management and communication. There are many QA programs. In general, we group them into required programs and optional programs. Regardless of which type of program we use, one of the most important key components to ensure their success is verification - verifying that you are doing what you say in your programs.

Thank you very much



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