FOOD SAFETY AND SANITATION

Quality Control

Learning Objectives

- Differentiate between quality assurance and quality control
- Identify documentation that is pertinent to supplier approval
- Monitor and verify suppliers and their associated materials to ensure they conform to expectations
- Identify key controls for formulas and associated batch sheets/work orders/computer controls
- Monitor process settings and process outputs to ensure compliance to process specifications
- Identify non-conforming product and establish hold mechanisms
- Determine disposition criteria for non-conforming product

Table of Contents

The goal of a quality program is to consistently conform to specifications or meet expectations to provide a product that the customer wants. This chapter focuses on activities associated with quality control.

Quality Assurance vs. Quality Control

Quality assurance involves a variety of programs and associated activities designed to ensure that products are manufactured, stored, and shipped in a way that ensures a safe and consistent product. Basically, quality assurance ensures the product is made right the first time.

Quality control is one area of quality assurance defined as monitoring against process settings, process output, and finished product samples to ensure finished products meet customers' expectations. Monitoring conformance to specification includes, but is not limited to:

- monitoring the material (raw material, work-in-progress, and finished product)
- monitoring the processing parameters and environment
- tracking and trending positive and adverse findings
- ensuring appropriate corrective actions for out-of-specification findings

Approved Suppliers

Although the cost of goods is a key factor in selecting a raw material supplier, cost should never be the determining factor. There are hidden costs with poor suppliers. You may have to add costs to "clean up" the purchased material. The material may function poorly, resulting in decreased productivity or yield. You may need to purchase emergency supplies or substitute materials if delivery is poor. Or, out-of-specification finished product may result in customer dissatisfaction or loss.

Multiple departments or positions may be involved with the initial approval of a supplier, including research and development, quality, production, finance, sales, etc. At a minimum, the following information is essential from the supplier to determine approval.

- Contact information, including corporate and manufacturing contacts, for business hours and emergency situations

- Ability to ensure that the supplier's policies, programs, and procedures minimize product safety concerns; this can be via third-party inspection/audit, an on-site inspection by a knowledgeable internal auditor, or by providing essential documentation
- Ability to consistently meet the material specifications
- An agreement that the supplier will call you as soon as possible during a recall situation, whether the material being recalled was supplied to you or not
- An insurance policy for the level of coverage that would cover your costs if the supplier's recall adversely affected your product

Supplier Monitoring and Verification

Supplier compliance should be periodically checked against the specifications. The frequency of checks will depend on your history with the supplier, the microbiological sensitivity of the material, and the essential functionality of the material to your operation or finished product.

Each lot-specific certificate of analysis (COA) should be checked against the specifications. Checks include that required tests are being conducted/reported and that the results are within the specifications. Verification of COA test results should be periodically conducted. This involves collecting a sample of the incoming raw material and testing it for some or all of the characteristics outlined in the supplier's COA. For materials being tested for pathogens, all containers of the lot should be placed on hold and not used until negative test results have been received. Some raw materials may not have COA requirements; however key characteristics should be periodically checked.

The frequency of collecting and testing samples of incoming materials depends on multiple factors, including:

- Supplier/raw material status - For a new supplier or new raw material, the first several shipments/lots should be tested for the key characteristics. If the initial shipments are shown to meet specifications, this frequency can be reduced.
- Functionality - Testing for the granulation/sieve size for salt or sugar may not be needed if it is being dissolved in a liquid (granulation size may not be critical), however the same check may be needed frequently if the salt is sprinkled on chips.

- Amount of material being received - Simple organoleptic (visual, aroma, taste) analysis should be considered for bulk materials to make certain it is acceptable before being mixed in silos. For example, it is typical to test for color and flavor on each shipment of high fructose corn syrup.

Use other supporting information to determine supplier compliance, including:

- History of identified issues - Keep a running track of issues identified by receiving, production, and packaging.
- Supplier response - How the supplier responds to any identified issues or requested changes.
- Shipments - Are they on time; do the materials and amounts received match what was ordered; is billing is timely and accurate?

Periodically communicate your findings to the supplier. Do not limit this communication to negative feedback (i.e., identified concerns), but also let them know when your monitoring and verification confirms that they are meeting your specifications and expectations.

Raw Material Specifications

After the team has discussed and agreed upon the key characteristics for the raw material, it is essential to document these expectations. This can be as simple as the supplier's dated technical data sheet or as complex as developing your own specifications. There are advantages to developing company-specific material specifications. Special requirements, such as narrowing key parameters or proprietary materials can be outlined and agreed upon between the supplier and purchaser. Certificates of analysis and other unique requirements can be specified and understood. Your company-specific specifications can be readily shared with other suppliers (e.g., secondary suppliers or when price shopping). A uniform format for all specifications eases retrieval of key information.

At a minimum, each raw material should have clearly documented technical and food safety information, including:

- The name of the product and the item number
- Components or composition of the material (an ingredient declaration)
- The presence of regulated or customer-recognized food allergens
- Organoleptic information (appearance, flavor, and aroma)
- Pertinent physical, chemical, and microbiological information
- Shipping and storage information
- Shelf life
- Handling directions (such as temperature or humidity)
- Revision date

Certificate of Analysis (COA) Requirements

Certificate of Analysis

Product Code: AC-ROS-001 B **Issue Date:** 23/07/2009
Product Name:
Batch No: 09070
Quantity: 100 Kg
Manufacturing Date: 02/07/09

Physical Properties

	Observed	Standard
1. Refractive Index	1.433	1.403 - 1.463
2. Specific Gravity	1.030	1.001 - 1.063
3. Bulk Density	-	Not Established
4. Appearance	Matches Standard	Clear Liquid
5. Colour	Matches Standard	Colourless to pale yellow
6. Flash Point	Matches Standard	> 100

Sensory Data

1. Aroma	Matches Standard	Floral, Rose like
2. Taste	Matches Standard	Sweet Rose

COA requirements are based on the tests you determine are needed for a raw material. The supplier then conducts the tests on the specific lots being sent to you and reports the results (the certificate of their analysis). You may not need lot-specific testing for some materials (e.g., corrugated cases). Other materials may have an extensive list of parameters to be tested and reported. COA requirements are based on your identified need for assurance that the product meets the key specifications.

If a COA is required, the test results should clearly identify the lot number the tests were conducted on, the sample size, and the test methodology used (e.g., BAM, AOAC, etc.)
Also determine the procedures associated with a COA review, such as:

- The department responsible for ensuring that a COA is available for each lot received and actions to take if the COA was not provided
- The department (receiving, quality, purchasing, etc.) responsible for comparing the results against the specifications to determine if the material meets your requirements

- The person approved to determine if the material can be accepted and used if the results do not meet your specifications (typically quality)

Formula and Batch Sheet Controls

Formulas are typically developed by research and development. Formula information should include the use of in-process or finished product that was left over from a previous product time or did not meet the desired quality characteristics (rework). Rework directions should include the quantity of rework that can be used per subsequent batch to ensure that the batches containing rework can meet the quality characteristics of product that does not contain rework. Rework directions should also ensure that food safety concerns (e.g., undeclared allergens) do not occur.

One role of the quality department is to transfer key information from the formula to a format that is useable for the production/packaging team. The production team uses this batch sheet or similar document to know the specific ingredients, allergen content of the materials, quantities of materials to add, and production directions (sequence of ingredient addition, mix time, etc.). Production then uses the batch sheets to document the production activities of the product being made.

Batch sheets must include sufficient space and directions to allow operators to document the following information:

- number of batches made
- lot numbers of the raw materials used and methods for identifying when a lot is changed
- the actual amount of material used (e.g., fluctuating amounts of water)
- rework used (formula number, amount, and traceability information)
- amount of rework generated
- amount of materials destroyed

Computer-controlled material addition is a very common method of communicating batch directions or for automatically adding materials. The essential controls should include:

- Who is authorized to change the information within the system
- Who verifies that the information is correct
- The key formulation/directions for sequence, mix time, etc. is password protected so that it cannot be accidentally changed

- Periodic verification that the computer controls are following the directions as entered
- How changes are documented (date of change, what the change was, why the change was made, etc.)
- A safe backup system and storage requirements for the resulting computerized records

In-Process Specifications, Monitoring, and Verification

Process step standards are typically identified during product development and plant trials. Checks against these standards are necessary to ensure the process is functioning as designed and will result in a finished product that meets specifications. These checks range from taking the temperature of the incoming raw materials through to the final pallet stack configuration. Essential checks (e.g., sequence of adding materials, mix speed/time, pasteurizer or fryer time/temperature, pressure requirements, seal strength, fill levels, oxygen levels, etc.) are product and process dependent. Quality works closely with different departments to identify where the product or process is to be monitored, the acceptable parameters/range of acceptable results, the appropriate corrective actions, and the method for documenting results.

The person that actually performs the checks is dependent upon where the check is made, the complexity of the check, and access to the needed tools/instruments. For example, the incoming receiving temperature may be conducted by the receiver. The finished pallet configuration may be checked by the packer.

Once an in-process step has been identifi ed, an in-depth review of the requirements to accurately do the check then needs to be developed and provided.

Finished Product Specifications and Monitoring

Every food company's goal is to provide products that are safe, legal, and high quality. Finished product specifications should not be limited to just the organoleptic, analytical, and microbiological characteristics of the product. Finished product specifications should also include the packaging (primary and shipping), labeling (retail and shipping label), and stacking/shipping configuration and materials (such as use of slip sheets, type of pallet). Both the product and the finished packaged product (as presented to the customer) need routine, scheduled, documented checks. As with in-process specifications, the first step is to identify the key characteristics to be checked. This ranges widely, based on the product and the purpose of the check.

Legal Requirements

Various checks are conducted to ensure legal requirements are being met. Two of the most widely used are checks for labeling requirements and for weight/fill requirements.

Labeling requirements are regulated and are different in each country. These checks often include: what is required to be on a label, where it is to be placed, size of the print, nutritional statements, what is essential for the plant is to ensure that only approved labels are used, and that correct labels are attached to the finished product. When a new lot of labels is received a check should be conducted to ensure the label manufacturer did not accidentally change them when they did a print change and that the colors are correct. Labeling checks are also key during actual use; changeover checks verify that the product is going into the correct package/label.

Weight/fill requirements help ensure the legal requirements for meeting the label declaration are being met. Finished product should pass over a check weigher, fill level measurer, or be periodically weighed. If the standard is by liquid fill (to the top of the jar, etc.), then each lot of a new packaging material should be checked to ensure the containers will actually contain the desired quantity. Regulators are concerned with underweight products (economic fraud), as well as overweight products (accurate nutrition statement).

If the finished product does not pass over a check weigher, a sample plan is necessary to ensure a representative sample is collected and that each filler head is being sampled. The results would then not just be for the average (the amount of each sample divided by the number of samples), but also individual containers to ensure each are within an acceptable range.

Product Safety

Quality assurance typically identifies if the finished product is to have additional microbiological analysis, such as for indicator

organisms (e.g., total plate count, yeast, mold) and/or pathogenic organisms (e.g., *Salmonella*). Some locations have laboratories that can test for indicator organisms, though very few have a laboratory that is appropriate for testing pathogens. If pathogen testing is conducted, the samples are typically sent to an approved laboratory.

There can be other unique characteristics of a product to ensure finished product safety, such as salt content or acidity. Since some of these characteristics can be corrected immediately, these parameters are typically tested before the product is released to the next step of the process.

Based on the product and your process, the Hazard Analysis Critical Control Point (HACCP) team may have identified additional key processes that are to be checked to ensure they are working properly. Some of these checks may be product-specific (e.g., internal temperature) or associated with checking the equipment (e.g., a filterormetaldetector).

Product Quality
Determine the characteristics that make your product different from other manufacturers' products and check them against specifications.

Types of Monitoring/Checks

Organoleptic analysis is for characteristics you can measure with your senses (e.g., appearance, flavor, aroma). Entire books and studies have been devoted to the skill and training for this type of analysis. For this type of testing, determine how the individuals are chosen (can they actually detect the desired/undesired characteristics), how they are trained, if there is a standard to compare the product against (e.g., color standards, flavor standards, photos of what the finished product should look like).

Don't focus solely on the product itself, but also how the product is presented to the customer. Finished product checks should also include accuracy of the label, appearance of the closure, (is it straight), excess glue, legibility and placement of the lot code, stacking of the material within the container, etc.

Another type of check is use-of-product testing. Products that need further processing (e.g., a dry blend), a bake-off, or following similar steps as used by the customer may be essential to determine if the finished product performs as desired.

Analytical tests require instruments to measure the characteristics. This can be as elaborate as a mass spectrometer to test the volatile oil content to as simple as ensuring the finished product meets the weight requirements.

There are two primary purposes for microbiological testing of finished product: ongoing monitoring that the desired characteristics are consistently being met and to assess if the product is acceptable for shipping. The microbiological analyses commonly used with ongoing monitoring include total plate count /aerobic plate count (TPC/APC), yeast, and mold. Based on the product and process, some locations include coliform as a

monitoring tool. Recognizing that the results of the tests will not be known for a number of days, determine if the product can be shipped while awaiting the results.

Microbiological testing is also used to assess if the product is acceptable for shipping (food safety or customer requirements). If the purpose of the microbiological analysis is to assess that the process worked as designed and resulted in a pathogen-free product, the product should NOT be shipped until the test results have been received because otherwise if the results are positive for a pathogen you would then potentially have a recall situation. If the purpose of the microbiological analysis is to meet customer COA requirements (testing indicator organisms and not pathogens), determine if the product can be shipped before the results are known (the results are known before the product reaches the customer).

Frequency of Checks or Tests of In-process and Finished Products

The operators who actually see the product as it is made should be provided with standards for ongoing comparison. If taste testing is conducted, ensure that there are facilities for washing hands after tasting.

Tools to measure color, size, weight, and other easy-to-monitor parameters should be available to line employees since they are the first person to identify if issues are developing. It is desirable that three or more people conduct organoleptic analysis. A common practice is to conduct the organoleptic analysis just before the end of a shift or at shift change and have a team that includes production, quality, etc. review the products made during the shift. Additional samples may be collected by the quality department for their review and tests. These additional tests are used to calibrate the line operators' findings with the official standards to determine if the operators' results are the same as the quality department's results.

A common practice is to keep a small amount of the finished product as a retention sample. These are typically kept for the product's stated shelf-life and used as a reference for customer complaints.

Non-Conforming Material Controls

Many processing checks are used to simply monitor and document the product's history (e.g., oven settings, blower pressure, etc.). Other checks are preventive to note potential issues before they actually impact the product or process (e.g., weight control at a depositor) or before the operator can make immediate corrections (e.g., testing the acidity at a mixing tank). Preventive checks must have approved corrective actions, such as how to adjust the depositor and how much more acid to add. After corrective action is taken, a second check should be conducted to ensure the actions taken actually corrected the issue.

Another type of check identifies if the material or product has the potential of being significantly changed or has undesirable characteristics. These out-of-specification materials must be assessed by management to determine the appropriate disposition steps. The range of potentially out-of-specification findings can be vast and as simple as the receiver noticing that the incoming material packaging has changed color (which is an indication that the material itself may have been changed or the incorrect material was shipped) to underweight finished product.

Until the material or product can be assessed, the suspect or non-conforming product must be effectively segregated to ensure it is not used or shipped until appropriate disposition has been determined. The hold-and-release program is typically used for segregating and assessing non-conforming materials.

Typically anyone can place a product on hold and communicate the hold to the quality manager. Assessment and determination of the appropriate final disposition of the held material is then the quality department's responsibility. While quality is determining the appropriate disposition of held product, the material should be effectively segregated and measures should be taken to prevent accidental use or shipment. These measures can include physical separation such as a hold cage or area, visual tags or stickers, and/or computer controls.

Proprietary Information Controls

Proprietary information (e.g., product formulation, batch sheets, work instructions, and in-process standards) need strong controls to ensure that information is not released outside the company, that information can only be changed by approved individuals/positions, and that changes are clearly identified.

Document Retention

There are very few documents or information that should be kept indefinitely, however product formulation history is typically kept forever so that there is a running history of the changes to the product.

All records that document the product's history should be kept for the legally required amount of time. For a short shelf-life product (e.g., fresh fish), records are to be kept for a minimum of one year. Records for products with a shelf-life longer than 6 months should be kept for a minimum of two years or the shelf-life of the product, whichever is longer. Check the regulations for the document retention requirements.

Product history includes a large amount of documentation, including:

- Facility programs at the time the product was made
- Formula and associated batch sheets
- In-process standards and associated monitoring results (encompassing the majority of the plant programs, including sanitation, allergen control, integrated pest management, chemical control, label control, etc.)
- Corrective actions for out-of-specification results

Computer records of the product history have the same retention requirements as hard copies of production documents.

Quality Reference Card

Use this Quality Reference Card as you contribute to your company's quality program. When you are ready, proceed to the workshops to apply what you have learned to real-life situations.

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Quality
Reference Card

Quality Assurance
- A variety of programs and related activities designed to ensure that products are manufactured, stored, and shipped in a way that ensures a safe and consistent product

Quality Control
- An area of quality assurance
- Monitoring against process settings, process output, and finished product samples to ensure finished products meet customers' expectations

Approved Suppliers
- Provide corporate and local contact information for business and emergency hours
- Minimize product safety concerns through policies, programs, and procedures
- Consistently meet material specifications
- In the case of a recall situation, agree to contact immediately
- Obtain an insurance policy

Supplier Monitoring and Verification
- Periodically check supplier compliance against the specifications
- Check that required tests are being conducted and that the results are within specifications

Raw Material Specifications
- Name of the product and item number
- Ingredient declaration
- Identified food allergens
- Organoleptic information
- Physical, chemical, and microbiological information
- Shipping and storage information
- Shelf life
- Handling directions
- Revision date

Batch Sheets
- Number of batches made
- Lot numbers of raw materials used
- Actual amount of material used
- Rework used
- Amount of rework generated
- Amount of materials destroyed

Finished Product Checks
- Legal –Labeling requirement checks; weight and fill checks
- Product safety – microbiological analysis; HACCP-related checks; other unique product characteristics
- Product quality – Determine characteristics that make your product different from other manufacturers' and check them against specifications

Types of Monitoring/Checks
- Organoleptic analysis – appearance, flavor, aroma, etc.
- Label accuracy
- Use-of-product testing
- Analytical tests
- Microbiological tests

Document Retention
- Product formulation – keep forever
- Product history records
  - Short shelf-life product – keep records at least 1 year
  - Shelf-life longer than 6 months – two years or the shelf-life of the product, whichever is longer

AIB INTERNATIONAL - Reference Cards

1. Which of the following certificates of analysis is in compliance with the given specification?

SPECIFICATION

Cracked Black Pepper: 23455

Particle Size: 1.2-2 mm

Moisture: 13% Max

Piperine: 7% minimum

Salmonella: Non-detected

E. Coli: Non-detected

Certificate of Analysis

Product: Black Pepper, Cracked

Lot: 4-099

Piperine: 7.2%

Particle Size: 1.2-2.8 mm

Pathogens: None detected

Certificate of Analysis

Product: Black Pepper, Cracked

Lot: TR3113

Particle Size: 1-2 mm

Moisture: 11.5%

% Piperine: 8%

Salmonella: <3/g

E.Coli: < 3/g

Certificate of Analysis

Product: Black Pepper, Cracked

Lot: 58712

Moisture: 13.1%

Piperine: 7.7%

Particle Size: 1.2-2.0mm

Salmonella: < 3/g

E. Coli: <3/g

2. Which of the following certificates of analysis is in compliance with the given specification?

SPECIFICATION

Tomato Paste 28/30%

Ingredients: Tomato (salt)

Optical Residue: 28-30%

pH: 4.2-4.4

Bostwick: < 10 cm

Certificate of Analysis

Tomato Paste

Lot: 76514

pH: 4.2

Optical Residue:30%

Sugar Ratio: 43

Color a/b: 2.2

Certificate of Analysis

Tomato Paste

Lot: 14-132

pH: 4.2

Optical Residue: 30%

Bostwick: 10.4 cm

Certificate of Analysis

Tomato Paste

Lot: MD1477

pH: 4.5

Optical Residue: 28%

Bostwick: 9 cm

This batch sheet is used for chocolate chip cookie dough. Some of the actual amounts of flour fluctuate and the operators are periodically asked to make half batches.

1. What corrections would you make or what additional information would you include on this batch sheet?

Ingredient name	Allergen	Standard size	1	2	3	4	5
Chocolate chip or sugar cookie dough rework can be added.							
Place following ingredients in mixer and blend on speed #1 until all lumps are broken down							
Sugar, Brown	None	185.75					
Sugar, White, Superfine	None	212.69					
Add the following and mix until the mixture is smooth							
Butter, Unsalted	None	320.45					
Add the following while the mixer is on Speed #1 (do not go faster!) for one minute.							
Eggs, Whole, Liquid	Eggs	141.79					
Vanilla Extract	None	14.18					
Scrap the sides of the bowl (from the top of the blender to the bottom) Add the following while the mixer is on Speed #1 (do not go faster!) until blended.							
Flour, Pastry	Wheat	540.94					
Baking soda	None	8.51					
Salt	None	8.51					
Add the following while the mixer is on Speed #1 (do not go faster!) until blended, then increase to Speed #2 for 5 minutes							
Chocolate chips	Don't know	567.17					

Which of the following checks indicate non-conforming product based on these specifications?

Raw Material Specification	
Protein %	8.0 +/-1.0
Ash %	0.4 +/- .04
Vomitoxin	<1 ppm1001

Process Specification	
Dough Temperature	90°F Maximum
Piston PSI	20-25 bars
Oven Temperature	250°F- 300°F
Cooling Time	3 minutes minimum

Finished Product Specification	
Moisture %	12.5-14.5 %
pH	5.2-6.2
Diameter	5.5 -6.5″
Label Weight	322 grams

Check Type	Result
Ash %	0.5%
Cooling Time	200 seconds
Diameter	6.6″
Dough Temperature	88°F
Moisture	14%
Oven Temperature	288°F
pH	5.2
Piston PSI	26 bars
Protein %	10.80%
Vomitoxin	1 ppb
Weight	340 grams