Guidelines for a Dynamic Quality Control Program in a Changing Market

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ABSTRACT

The importance of "Plant Quality Controls" have never been greater than they are today. Product Quality Assurance and consumer satisfaction are the two essential ingredients for success in today's competitive market place.

It is essential for plants in the Food Industry to establish the proper priorities in their operations for the development of a practical total Quality Control Program, in order to be assured of continued Quality Product production.

In this paper are presented a viewpoint analysis of Quality Control and guidelines for the development of a dynamic Quality Control Program in our changing market place.

My company, over the years, has always been quality minded, having installed an active Quality Control group many years ago, to assure that we produce uniform Quality products regardless of the production location. In this way, our consumers come to know that they will always receive the same uniform product regardless of where it may be purchased. Kraft has long realized that quality is a much sought after reality with the consumer, and thus long ago, instituted measures to maintain continuous and unvarying product quality through a standardization program. Our leadership in the food industry has been attained and maintained through constant and continuing emphasis on the importance of quality.

In times past, for many companies, the Quality Control function was considered to be a luxury — not absolutely necessary for successful business operations. But not so today! The story of company Quality Controls is different. The government and the consumer advocates are demanding safety and quality in food and other products through vastly increased governmental activities and numerous new regulations. Now it is recognized by most companies that Quality Controls are vital and represent, in many instances, the very life blood that is necessary to compete successfully in today's competitive and changing market. In one way or another, all of us must have experienced some effect from this new evaluation and change.

In this paper I want to re-emphasize the growing importance today of food quality as it relates to both the food and packaging industries. This phrase food quality has received notable and frequent press, radio, and television media coverage. There is no question that methods used in food processing, packaging, and in shipping and storage of products are coming under much closer surveillance, scrutiny, and inspection than at any time before. The time has well come for all food and packaging manufacturers to recognize that an important opportunity exists in today's competitive market place, where progressive companies can, through the continued production of high quality products, establish a stronger quality image and a more potent customer appeal for their products.

With the economy playing a major role in management decisions today, many company buyers have shown keen interest in "price-quality" relationships, and as such, it becomes a must to have superiority through Quality Controls built into products manufactured if companies expect to continue to market their products successfully. Now, in the succeeding paragraphs, let's look at today's Quality Controls involved in the processing of packaged food products. Perhaps first, it would be well to define Quality Assurance — Quality Control as we know it today. "Quality Assurance," as a departmental name, in place of "Quality Control," is fast becoming very popular in many companies to describe their staff-level activities. In others, for all practical purposes, the terms "Quality Assurance" and/or "Quality Control" are used interchangeably and are considered synonymous.

We use "Quality Assurance" in my company, as an overall departmental name at both the corporate and company staff levels. At operating levels of management, Quality Control titles continue to be used at both the general office staff and plant levels. Now for the term, "Quality Control", which may be more familiar to many of you. I wonder how many of us really understand the true meaning and function of Quality Control. Using a
little imagination, one could conceive that the idea of Quality Control might well have originated at the dawn of history, when a man pointed to an object and said, “I want another just exactly like it.” Needless to say, he failed to get it, and neither does anyone get it today. For it was true then, as it is now, that no one thing is precisely, exactly, like another. You’ve heard the common expression, “No two people are exactly alike”, so it is true with material things as well. Variation inevitably exists in natural composition, in packaging materials, and even in the precise manufacturing operations known today. Strive as we may for exact duplication, we really never quite obtain it.

As far as we are concerned in Quality Assurance or Controls, variation need not bother us until it reaches a degree, level, point, or an extent where it causes difficulty in a packaging operation or is otherwise harmful in any way to the product. In Quality Control work, the variables are pinpointed, highlighted, and eventually, we hope most of them are reduced or eliminated which really results in Quality product production.

So this is where a department such as Quality Control or Quality Assurance fits into a Company’s operation. This function must exist at both the top management and plant levels and the responsibilities, though relative, are necessarily different. Let’s first cover briefly the basic responsibilities of both levels of Quality Control or Assurance, and later go into more detail on each of the basic points mentioned.

RESPONSIBILITIES

Staff Quality Control or Assurance has the basic responsibilities for establishing:

1. Guiding principles for the quality control function.
2. Complete sanitation and product standard methods and procedures.
3. Procedures for handling activities associated with finished product standard quality and regulatory compliance.
4. Technical training aids for plant use.
5. A comprehensive plant quality control monitoring program.

Plant quality control or assurance basic responsibilities are to:

1. Set up an in-plant adequate quality control personnel training program.
2. Monitor product quality from start to finish — from the initial point of packaging and edible raw materials receipts — through processing, to the final packaging of product and the ultimate distribution.
3. Check for variance from standards.
4. Determine the extent of such variation.
5. Establish the significance and/or harm caused by the variations.
6. Scrutinize laboratory and production line control data.
7. Provide technical expertise to production operating departments.
8. Make decisions relative to acceptance or rejection of products manufactured.

GUIDELINES FOR PROGRAM DEVELOPMENT

Now that we have seen this background material, let’s go into the detail guidelines we should concern ourselves with in the development of a dynamic Quality Controls program. First of all, a total Quality Assurance or Quality Control program involves six principal categories. These are:

1. Guiding principles for the quality control function.
2. Product standard methods and procedures.
3. Sanitation standard methods and procedures.
4. Laboratory standard methods and procedures.
5. Product Quality standards and regulatory compliance.
6. Plant quality controls.

Now, let’s review these six categories one at a time.

Guiding principles for the quality control function.

1. A company philosophy and commitment to quality must be established, and the policies that guide the decisions and activities relating to Quality Control must be spelled out.
2. Quality Control jobs and their relationships to other plant management jobs must be understood.
3. It must be recognized that well qualified, trained, and dedicated people are a necessary pre-requisite to controlling product quality through manufacturing and distribution; further, that dedication to quality is a way of life that must be instilled in all who are involved in any of these activities.
4. Companies shall maintain quality control laboratories and personnel to assure compliance with the companies’ own standards and with government standards. Company products will at least meet, or exceed, the requirements of regulatory agencies.
5. Quality Control shall maintain a continual reporting system covering the reporting of “out of standards” results and other quality problems. To keep everyone informed, meetings shall be conducted as often as necessary on general product quality.
6. It is to be understood that high quality is essential to the best interests of the company management, employees, stock holders, and customers.

Product standard methods and procedures

1. We must have proper product formulations and detailed manufacturing procedures.
2. A positive program should be in effect on the pre-testing of incoming packaging supplies and incoming raw materials.
3. A good sound in-process control laboratory testing schedule must be in constant operation.
4. A concise but practical routine finished product laboratory testing schedule must be followed.
5. A statistical weight control program must be established.
6. Product package and shipper containers should be properly code dated.
7. Shipping and storage conditions should be spelled out.
Let's dwell more on this second principle category, as it easily warrants such further discussion.

Proper product formulations and detailed manufacturing procedures. Some of the basic details involved here are:

1. Research and development project. In most all cases, a Research Project is needed. In addition where engineering work is involved, a request for engineering project must also be made.

2. Kitchen acceptance test. All products must be first passed on by the new products committee before being shown in test kitchens. Samples are shown by R & D people with the kitchen personnel assisting in the preparation of formulations for showing.

3. Marketing and production approvals. Approvals must be obtained from the company operating departments (Production and Marketing).

4. Label processing. All labels must be approved by Quality Assurance or Control, Production, Marketing, the attorneys, and the management label committee before printing.

5. Plant production trials by R & D and Production.

6. R & D final formula and manufacturing procedure report. Final acceptance of product by Production Department.


Pretesting of incoming packaging supplies and raw materials.

1. Development of packaging and raw material standard specifications. Perhaps it might be of interest if I were to describe briefly what takes place in development of packaging specifications for a new product. Let's take, for an example, our package for caramel discs, better known as Kraft Wrapples. After the idea for this item was developed, R & D was apprised for the new product and was asked to develop packaging requirements for packing discs of caramel that would remain separated with no danger of spreading or flowing under various warehouse storage and store display conditions. This meant that the product in package really must be protected from outside conditions, that is, oxygen, moisture, etc., under conditions of sales promotion and use by the consumer.

R & D proposed treating paper sheets for separating the many layers of discs in package and using a multilayer outer flexible film for product package. Since a display carton was desirable, R. & D tested several types of material for this purpose, keeping in mind that product must be protected while in distribution and while displayed in the stores. All the while packages were meant for quality purposes, to stand upright in the display carton without the danger of collapsing, or destroying the display advertising and product quality characteristics. After many trials, B flute corrugated display carton was found to be acceptable by both Engineering and Production. Samples of the various proposed packaging materials were tested by R & D with Engineering's help and equipment. Only after all tests were completed and Marketing was satisfied with costs, overall appearance of the final package, and results obtained over long term storage conditions, were the tentative specifications issued. Only after plant trials were conducted and found to be satisfactory, were the permanent specifications issued.

When a new product is being launched, many of the specifications are issued as tentative so that quantities purchased can be held to a minimum. Too, if changes are made, the plant is not burdened with large inventories of materials to be worked off.

The packaging specifications cover all packaging items used in product, individual package container, cap, label, wrapper, shipping containers, etc. The code date area also is shown on specifications and pallet pattern specifications also are included. Pallet patterns are designed to show how the product should be palletized for best stacking in warehouses, and to give one a pallet modulus least susceptible to product damage.

2. No packaging supplies should be allowed to be used until they have been sampled, examined, or analyzed, and passed as satisfactory.

3. Approved suppliers are needed to assure manufacturers the least amount of supply problems, and to be in a position to work more closely with suppliers in solving mutual supply problems.

4. Physical inspections are to be made of incoming materials for infestation, using black lighting and visible inspection conducted for evidence of contamination or product damage. This is necessary for Quality Assurance and company self-protection, especially in view of the interest now being given to this area by regulatory officials.

In-process control laboratory testing schedule. This should be the most important single laboratory testing function. This really represents the key to successful processing operations. Laboratory control is exercised at various critical points along the processing operations. Samples are sent to the laboratory and results returned to the processing operator in time to allow him to make necessary corrections of batches based on laboratory data received. In Kraft processing operations, we use the pneumatic tube system to convey samples from the processing and receiving areas to the laboratory. It takes approximately 10 sec to send a sample from a processing area to the laboratory. Only “quickie” analytical tests should be employed to be of service to production department processing, as time is of essence.

Finished product laboratory testing schedule. Finished products should be analyzed on a regular basis (statistical if possible) for conformance to specifications. Each is checked for physical, chemical, microbiological, where necessary, and keeping quality characteristics.

Statistical weight control. In Quality Control, one should recognize that there are certain causes of process
Critical against industry accepted methods, to be assured that Laboratory standard methods and procedures standard methods for testing raw materials, in-process which produce comparable results when measured on over-all sanitation which should include:

Sanitation standard methods and procedures.

Each plant operation must have an organized program on over-all sanitation which should include:
1. Plant inspection program. Each plant must have a routine plant cleanliness inspection program. The building must be checked inside and out. Insect and rodent control must be in force. All in all, a regular housekeeping system must be employed.
2. Pest extermination method and procedures. These should include ready information on common pests found in and around plants, such as cockroaches, houseflies, beetles, weevils, night-flying insects, spiders, and rodents. Also, a list of approved chemicals and equipment to be used, as well as the amounts and conditions of use, shall be spelled out.
3. Plant and equipment cleanup. A scientific approach to sanitation control is required because of the many far-reaching technological changes made in packaging and food processing, in recent years. A documented program schedule for the actual equipment cleanup, using standard approved cleaners, should be available, and should point out specific areas, both inside and outside of the plant that are to be cleaned, and the persons designated who are responsible.

Laboratory standard methods and procedures

Laboratories must use standard methods or methods which produce comparable results when measured against industry accepted methods, to be assured that proper laboratory controls govern all product production. Whenever possible, it is advisable to use existing standard methods for testing raw materials, in-process product control samples, and finished products, compiling statistical data where needed, to establish testing reliability.

In those instances where more than one laboratory location is using the same method to control like finished products, it would be well to do collaborative samples among the different laboratories. Collaborative sample testing is considered a most effective tool to establish standard deviation method expectancy under conditions of use, as well as a means of detecting laboratory testing errors.

Product quality standards and regulatory compliance

1. Established methods and procedures should be set-up to develop information necessary to ensure compliance with, or secure approval of, regulatory agencies in matters affecting labeling, product formulae, and production procedures and equipment.
2. It is important to set up standard procedures governing the investigation of finished product defects or problems reported by consumers, plant and sales management, or resulting from company or governmental research findings. A person should be delegated the responsibility of investigating defective or damaged finished products to determine disposition in compliance with company quality standards and government regulations.

Plant Quality controls

The last principle category “Plant Quality Controls” completes the total Quality Control or Assurance program. This one should be regarded as the very heart — and a truly vital function in a plant operation.

We all probably know about the activities in Washington centering around the Consumer Food Act (Food Surveillance). Bill S641, which in short requires the food industry to adopt a more sophisticated Quality Control program. With such knowledge, it becomes an absolute necessity that all packaging and food companies embark on a program, if they haven’t already done so, to upgrade Quality Controls in their plants. In Kraft we began such a program in January, 1974.

Since the FDA’s food plant inspection approach mentioned in this legislative bill placed primary emphasis on the so called Hazard Analysis — Critical Control Point (HACCP) analysis program, we have adopted this new systematic HACCP concept method of evaluating food plant production operations as the basis for our program. To date, we have not regretted our decision as this approach has improved our controls considerably. Further, there should be no doubt under today’s climate of plant operations, that FDA expects packaging and food processors to adopt more comprehensive and better in-plant Quality Assurance systems to establish greater food safety and Quality Assurance. The HACCP system conceived by FDA represents an inspectional type approach where specially trained inspectors analyze and evaluate complex production operations, identifying deficiencies in manufacturers Quality Controls to prevent production and marketing of
THE HACCP SYSTEM

Hazard Analysis:
an element of process equipment or environment of
a process which, if not properly monitored, can result
in the introduction of hazardous foreign
materials into the product.

Critical Control Point:
an operation and given process which, if not
maintained within certain parameters, can result
in the production of food which may be unsafe
primarily from the microbiological standpoint.

The specific hazards involved in our HACCP program
using symbols to identify critical items are:

H — refers to those hazards relating to chemicals such as
chemical toxins, aflatoxin, heavy metals (mercury,
lead, etc.), PVCs, PCBs, pesticides, foreign matter
(such as stones, insects, glass metal, etc.).

C — refers to critical control points, hazards that are
microbiological in nature, such as bacteria and
molds, including *Salmonella*, *Shigella*, *Staphylo-
coccus*, *Clostridium*, *perfringens*, *Escherichia
coli*, etc.

K - represents all other critical control points over and
above the defined FDA hazard control and critical
control points (these need to be documented and
monitored, in addition to other control points to
meet required overall Kraft quality of finished
products and consumer acceptability.

SCOPE OF HACCP PROGRAM CONCEPT
AND COVERAGE

The program entails establishment and use of Good
Manufacturing and Quality Control procedures such as
were discussed earlier in this paper, together with the
following:

1. Establishment of a product flow diagram for each
different product line operation in the plant.

2. Pinpointing the defined critical and hazardous
control points on flow diagrams and separate form
charts representing potential hazards to consumer
safety.

3. Development of statistical methods covering labora-
ory sampling and testing.

4. Make OC (operational characteristic) curves using
statistical techniques to analyze laboratory data to
determine reliability effectiveness of established
controls from a safety and quality standpoint.

5. Monitor, on a continuous basis, all potentially
hazardous and critical control points in accordance
with established procedures and maintaining
adequate records.

Let’s review briefly in further detail, each of the points
just mentioned.

Establishment of a product flow diagram for each
different product line operation in plant

It becomes necessary to develop simple block-type
diagrams indicating the product-flow direction, by arrow,
of each finished product process. Starting with raw
material supplies at each point of use in process, the
diagrams must show each in-processing step identifying
the function performed and/or equipment, all the way
through to the ultimate shipping and distribution
records.

Pinpointing the defined critical and hazardous control
points on flow diagrams and separate form charts
representing potential hazards to consumer safety.

Using the abbreviated symbols for identifying each of
the critical items, flag the critical areas on the flow
diagrams and highlight these same critical areas in the
special analysis charts used for this purpose. Items
covered on the analysis chart are: product name, hazard
and/or activity, frequency of testing, control used,
responsibility, and location of records.

Development of statistical methods covering laboratory
sampling and testing.

What is involved here is to make a complete statistical
analysis of laboratory history test result data which are
available. These data should cover a period of at least 9
months, and preferably a year. In this manner, it
could be assumed that the standard deviations found are
realistic and representative of conditions.

Make OC (operational characteristic) curve

This curve is made using statistical techniques to
analyze laboratory data to determine reliability effective-
ness of established controls from a safety and quality
standpoint. In addition it becomes necessary to prepare
an OC curve representing the specifications. This
specification curve and the one representing actual
laboratory data are superimposed upon one another so
that a comparison can be made between: (a) what is
required by the specification, and (b) what is actually
encountered within the plant.

When the comparisons are made, and the process
laboratory data do not agree with the standard
specification data, one has but two alternatives —
change the specification, or change the process itself.
Changes are made so that specifications are realistic and
the processes are capable of producing products meeting
standard specifications. In this manner, we are assured,
at all times, that the plants should be following
attainable specification standard tolerances.

Monitor, on a continuous basis, all potentially hazardous
and critical points in accordance with established
procedures maintaining adequate records

1. Installation of program involves meetings with plant
managers and all of the supervisory staff, with staff
Quality Assurance and plant Quality Control per-
sonnel, so that all management personnel are fully
indoctrinated on program concepts and objectives.

2. Laboratory facilities need to be reviewed to see if any
adjustments or realignment of responsibilities are
necessary.
3. Training of technical personnel is required so that they are thoroughly familiar with all facets of the program.
4. Changes need to be made in plant procedures to bring them in compliance with HACCP company standards.
5. The Plant Quality Control manager is responsible for monitoring the HACCP Quality Analysis Control Program. Primary responsibility might be delegated to Quality Control supervisors to see to it that program procedures are being implemented on a daily basis in all plant areas.
6. Any plant changes in equipment use, product, flow, etc., affecting the validity of the flow diagrams and/or analysis charts shall be reported to the Plant Quality Control Manager, so that flow diagrams and analysis charts can be changed accordingly and continuously updated.
7. The program must be followed and any deviations reported to the Quality Control Manager and the Plant Manager.

SUMMARY

In summary it can be said, that once a formal Quality Control program has been established, it is important that the plant Quality Manager and his staff learn to:
1. Scrutinize quality data on all raw materials, in-process product mixes, finished products, product keeping-quality samples, and product complaints, to know the general quality characteristics of the operation.
2. Become involved in how to stay within procedures and specifications.
3. Identify major and minor product quality problems and learn how and why an undesirable situation occurred and how to rectify it.
4. Work out with the plant production management team, the means of providing remedies for plant quality problems.
5. Take immediate safeguard actions to prevent the same quality defect situations from recurring.
6. Consult with technical management, making the best use of their technical capabilities whenever conditions dictate.

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