WHITE PAPER

Integrating HACCP and SPC

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Most HACCP systems take an attribute approach to analyzing data, meaning that variable data collected to monitor a critical control point are typically categorized as either 'good' or 'bad.' Such an approach can limit the effective use of variable data by failing to detect process changes over time. This article discusses how combining traditional analysis of data with statistical quality techniques can increase the efficacy of a HACCP system.

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Integrating HACCP and SPC

Hazard Analysis Critical Control Point is a food safety management system designed to ensure the safe production and packaging of food. The HACCP process (Table 1) has both strengths and limitations. It provides a systematic and effective method to analyze a process, and identifies potential biological, chemical and physical hazards that can occur in food. In addition, HACCP requires the development of strategies to prevent the inclusion or reduction of these hazards to an acceptable level in the food.

The most effective way to avoid product hazard is to control the process properly rather than relying on final product inspection. For example, a good HACCP program cannot depend on microbiological tests as the means to prevent a hazard because they are too slow to provide the real-time information needed to maintain process control properly.

The problem, however, is that most HACCP monitoring systems take an attribute approach to analyzing data. Even if variable data are collected to monitor a critical control point, the data are typically categorized as either "good" (not exceeding the critical limit) or "bad" (exceeding the critical limit). This approach can limit the effective use of variable data by failing to detect process changes over time, where the process control may be deteriorating before a problem manifests itself.

One way to think about the role of process control is to consider the example of the canary in the mine shaft. The canary's untimely death indicates a dangerous situation in the mine shaft, much like HACCP alerts a plant manager of a potential hazard. Just as ventilating the mine shaft and monitoring the process ensures that dangerous conditions cannot arise, conducting statistical process control (SPC) in a food processing plant will prevent dangerous conditions from happening in the first place.

Statistical Thinking

Food processors can strengthen their HACCP programs by incorporating concepts of statistical thinking. Statistical thinking, a term first used by the American Society for Quality's Statistics Division in 1960, is based on the following assumptions: 1) All work occurs in a system of interconnected processes; 2) variation exists in all processes; and 3) understanding and reducing variation are the keys to success.

Recognizing the first assumption, conceptualizing all work in terms of interconnected processes, ensures a thorough and detailed understanding of the processing system. Next, understanding that every process displays variation as an accepted fact of life prompts analysis of variation. Quality professionals need to know the extent and predictability of process variation.

Variation can be divided into two types, common causes and special causes. If a process is controlled and influenced so that the process output measurements are predictable and vary within statistically defined upper and lower control chart limits, then the process is said to be stable and in statistical control. Thus, only common causes of variation are affecting the process. However, if the process variability is uncontrolled, and the process output measurements do not fall within the upper and lower control chart limits, the process is classified as unstable or out of statistical control. The process is affected by special causes of variation.

Table 1:
Preliminary Tasks in the Development of the HACCP Plan
and HACCP Principles

TASKS	PRINCIPLES
1. Assemble the HACCP team	1. Conduct a hazard analysis
2. Describe the food and its distribution	2. Determine the critical control points (CCPs)
3. Describe the intended use and consumers of the food	3. Establish critical limits
4. Develop a flow diagram that describes the process	4. Establish monitoring procedures
5. Verify the flow diagram	5. Establish corrective actions
	6. Establish verification procedures
	7. Establish record-keeping and documentation procedures

The National Advisory Committee on the Microbiological Criteria for Foods adopted this revised series of HACCP principles and application guidelines last year. The basic premises for these principles have not changed; however, the principles are now more concise and the definitions have been revised. In addition, the new document emphasizes the importance of prerequisite programs, education and training, and implementing and maintaining HACCP plans. There are also new guidelines to help professionals select appropriate critical control points.

The final aspect of statistical thinking is the realization that variation is the enemy. Variation must be reduced or eliminated if a company wants to increase productivity and decrease waste significantly. Quality improvement theory states that the first step of quality improvement is to remove the special causes of variation by determining and eliminating the root cause of the problem. If only common causes of variation are affecting the process, then the process is operating at the most efficient point for the currently defined system.

Control Charts

Control charts provide the primary tool to determine the extent and type of process variation. They are used to analyze two major groups of data: variable data, or measurement data, and attribute data, or count data. Table 2 describes different types of control charts and their uses. The most effective control chart that can be used to evaluate individual variable data that monitors control points is the individual moving range (x-mR) control chart. This chart allows the evaluation of individual data points rather than averages.

Table 2:
Types of Control Charts

TYPE OF DATA	TYPE OF CHART	USE OF CHART
Variable	Individual moving range (x-mR)	Each subsample is a data point
	Average - range (x-bar R)	The subsample consists of less than ten data points
	Average - standard deviation (x-bar s)	The subsample consists of ten or more data points
Attribute	p chart	Nonconforming units
	np chart	Portion of nonconforming units
	c chart	Nonconformities
	u chart	Portion of nonconformities
	Individual moving range (x-mR)	Any type of attribute data

Note: Some quality professionals suggest that most variable data can be analyzed using either the individual moving range control chart or the x-bar R control chart, and all attribute data can be analyzed using the individual moving range control chart.

An alternative method to analyze HACCP data is to use a two-step evaluation process. During the first step, data taken from the critical control point would be compared to the critical limits to determine whether a potential for a food safety hazard exists. Next, the data would be analyzed using an individual moving range control chart (see case study). The control chart allows for a graphical interpretation of the type and extent of variation that affects the process. If a process is capable of meeting critical limits, then it is or could be possible to make adjustments in the process prior to producing unsafe food. In addition, the analysis can provide the means to identify potential opportunities for improvements and increase the capability of the HACCP program, thus reducing the risk of making unsafe food.

Any HACCP program should be directed to food safety issues. The process is not designed to identify quality enhancement areas, even though well-designed HACCP programs can enhance the quality of products. Likewise, quality improvement processes can provide a HACCP benefit by reducing the risk of having a food safety hazard. For example, a process/product improvement project could center on reducing the amount of rework. This project may be implemented to increase the productivity and decrease the rework. Specific quality enhancement issues should be addressed through a quality management system such as described in the ISO 9000 standards.

A HACCP program must be linked to, rather than combined with, other quality systems. Each quality system is designed to accomplish specific objectives; it is important to keep those objectives separate. First and foremost, food processing companies must provide a safe supply of food. Still, a sound approach to increase the efficacy of the HACCP system is to combine the traditional analysis of data with the use of statistical quality techniques.

Case in Point

Butterball Turkey Company, Downers Grove, IL, has applied this statistical methodology to continually expand and improve its new Turkey Inspection System. As part of the control system, the company routinely analyzes data using control charts. Its process control charts and procedures are designed to identify trends and adjust the process to reduce the risks that defective products are generated. One example involves selecting carcasses and inspecting them for generic E. coli. This is done to

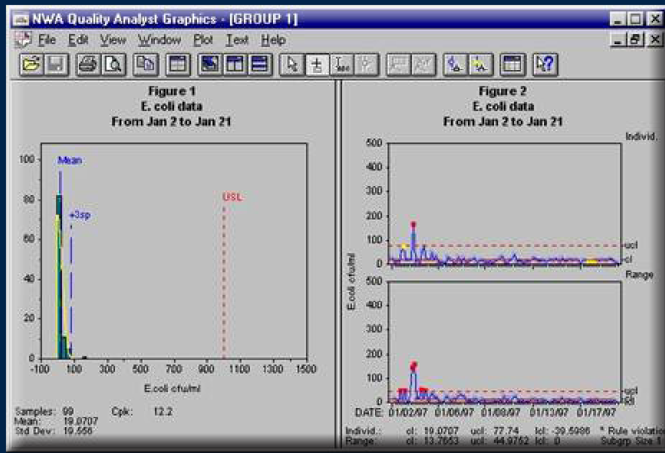

Figure 1 - E-coli data, January 2 to 21

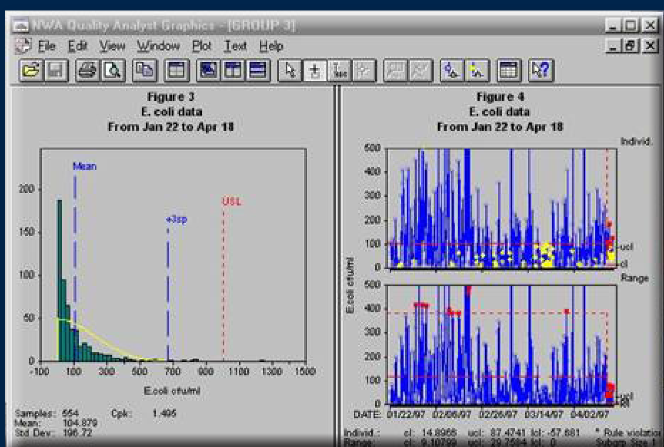

Figure 2 - E. coli data, January 22 to April 18

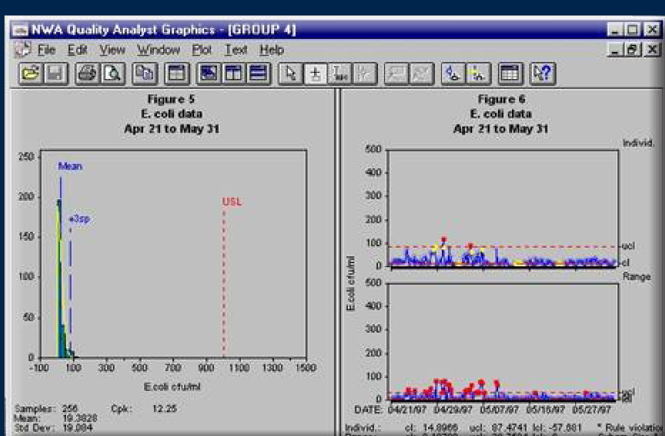

Figure 3 - E. coli data, April 21 to May 31

determine whether the birds contain unacceptable levels of E. coli or other bacteria.

Sampling and Bacterial Testing

Carcasses are aseptically sampled at the end of the chill system, after the drip line, using statistical sampling procedures. During the time these data were collected the whole-bird rinse technique was used. The carcasses were collected in a bag containing 600 mL of Butterfield's phosphate diluent. Next, they were rinsed inside and out by using a rocking motion of 30 cycles for approximately one minute. The rinse water was collected and plated using the AOAC 17.3.04 method. Results were reported as colony forming units per milliliter (CFU/mL). Data were statistically analyzed and control strategies were developed. This method of sampling has been replaced by a swab sampling procedure, but the concepts presented remain applicable for process control.

Process Analysis

Figures 1 through 3 demonstrate the analysis of this data using histograms and individual moving range control charts. During the first part of the sample year, statistical analysis revealed that the process was both stable and very capable (Figure 1).

Identifying Root Problems

At the end of January, a major manufacturing change was made in a Butterball plant that inadvertently resulted in a slight increase of the E. coli levels of the birds (Figure 2). The level was still below the critical level. Fortunately, because the process was very capable, the problems were identified and a corrective action team comprising plant operations, quality assurance, maintenance and procurement personnel was formed to identify and remove the problem's root cause. As part of the solution, procurement personnel worked closely with the producers to maintain and improve the conditions of the birds coming into the plant. In addition, new chlorinated spray cabinets were added to the processing line after the pickers. Also, the first and final wash cabinets were improved to include a new chlorinating system and higher water pressures. Checks were implemented to control and verify chlorine levels and water pressures. Additionally inspectors were added to the line after the final wash and before the birds entered the chill system.

Conclusions

Butterball has successfully linked the monitoring of control points to statistical process control, and the quality improvement processes. This linkage has permitted the development of a highly capable manufacturing process. As a result, if a change or other factor affects the system, a quality improvement team can identify the root cause of the problem and take corrective and preventive action. This strategy has additional benefits to the company: It increases employee involvement, awareness, attention to detail and motivation, while improving quality and productivity.

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