HACCP: Hazard Analysis Critical Control Points

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The vast majority of people in the United States have no idea what HACCP is or what it is supposed to do for them. In fact a very large number of people in our own industry have no idea either. Therefore I feel it is important for the following statement to be made to set the stage and open all of our eyes!

> *HACCP is **easily** the most important concept/ system to affect the meat production and(or) processing industry since the inception of the meat inspection system back in 1906.*

Now if that statement doesn't spark your interest or make you begin to wonder what HACCP is you might as well stop reading this now. If it did get your interest then let me tell you more.

HACCP is a ***preventative*** program that is being utilized by the food manufacturing industry to increase the *safety* of the products that they make. Up until recently it was a voluntary program but now it is quickly becoming mandatory for most types of manufacturers. Seafood processors are now required by law to have approved HACCP programs in place to operate. Meat and poultry will be in the same situation by the middle of the year. FDA and USDA feel that HACCP based systems are the best way to insure food safety. Exactly how it should operate and how they will incorporate it into their existing inspection system remains to be seen.

The reason HACCP based-systems have become so popular in the food sector is twofold. First, it is *strictly* a food safety program and food safety is extremely important in the minds of today's consumers. Secondly, it is a *preventative* program, designed to prevent a food product from ever being a source or conduit of food-borne illness. Previous programs were designed to check products after they were manufactured to make sure they were safe! This type of system identifies key or *critical* points in the production of the product and puts *controls* at these points to assure that a food borne incident doesn't occur.

Many food manufacturers endorse HACCP not only because it makes their products safer, but because with a HACCP based-system they have better *control* of their entire operation and therefore operate more efficiently and productively.

Currently the major thrust of HACCP is in the "post-harvest" side of the industry. Their is talk of "pre-harvest" HACCP, which would go all the way back to the farm. At the present time this is only talk and nothing definitive is currently being done as far as proposed regulations. Numerous obstacles face any type of "pre-harvest" HACCP system; such as identification and trace back of animals, how to prevent much less eradicate certain human pathogens in animals, and how to implement or monitor such an enormous program. Currently this is not something for us to be concerned about because the science to support it is just not there, yet! However, it would behoove us to keep it in the back of our minds and to stay attuned to how the "post-harvest" HACCP systems and regulations proceed.

The remainder of this paper is a brief history of how HACCP came about in the food manufacturing sector and a fairly indepth discussion of the seven principles of HACCP and how they are applied. Whether you intend on having a HACCP program or not the history and purpose of HACCP may be interesting to you and may have some application to your particular operation.

HACCP History and Principles

History

The HACCP System for foods was originally developed in response to a request by NASA to insure that "space foods" used on manned space flights were ***safe!*** NASA's food safety concerns were twofold: (1) How would food particles (i.e., crumbs, etc.) behave in zero gravity and could they detrimentally affect intricate electrical equipment?; (2) how to guarantee absolute assurance that the "space foods" were not contaminated with pathogens (bacterial or viral), toxins, chemicals or physical hazards?

The first concern was easily dealt with using current technology, by developing bite-sized foods coated with a specially formulated coating which held the product together. However, the second concern was much more difficult. At that time, the current technology to assure 100% safety relied solely on end-product testing. With this method of quality control it was statistically impractical to assure a 100 % safe food product. In 1959, Dr. Howard Bauman with Pillsbury Company was the first contacted by NASA to reconcile the problem. He fairly quickly concluded the following:

> "We quickly found that by using standard methods of quality control there was absolutely no way we could be assured that there wouldn't be a problem. This brought into serious question the then prevailing system of quality control in our plants...If we had to do a great deal of destructive testing to come to a reasonable conclusion that the product was safe to eat, how much were we missing in the way of safety issues by principally testing only the end product and raw materials?
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> We concluded after extensive evaluation that the only way we could succeed would be to establish control over the entire process, the raw materials, the processing environment and the people involved."

Initially, Pillsbury and NASA tried to use NASA's "Zero Defects Program," which they used to test all hardware used in space flights. Although non-destructive, these tests (X-rays, ultrasound, etc.) were determined to not be appropriate for food products. This again was an end-product testing, what they needed was a ***preventative system***.

Next, they got the U.S. Army Natick Research Laboratories involved and evaluated one of their engineering systems; Failure, Mode and Effect Analysis (FEMA). This system, used for medical supplies, looked at what can go wrong at every step and(or) stage of a process and(or) operation along with possible causes and likely effects, *before* invoking effective control mechanisms. After close evaluation, Pillsbury and NASA adopted this technique as their model and began to make modifications to specifically apply this to food manufacturing. This technique allowed them to evaluate *each step* of a process for what might go wrong ("hazard"), then *select points* in this process where it could be determined if the process was in control ("critical control points"). Thus, Hazard Analysis Critical Control Point System for food products was born.

This original system consisted of three principles (unlike our current system, which has seven principles):

- Identification and assessment of hazards associated with growing/harvesting to marketing/preparation.
- Determination of the critical control points to control any identifiable hazard.
- Establishment of systems to monitor critical control points.

Along with these principles, critical control points were identified as points where loss of control would result in an unacceptable food safety risk.

Started in 1959 and used in Pillsbury plants for several years, the HACCP system wasn't publicly recognized until 1971. At the 1971 National Conference of Food Protection, Pillsbury presented their program and soon afterwards received a con-

tract by FDA to train FDA personnel on the HAACP system. There were several conferences and papers conducted and written in the 70s and early 80s concerning this "new" preventative system. During this time FDA issued the low-acid and acidified canned food regulations which were based on HACCP principles but did not recognize HAACP specifically. In fact, few companies really took the ball and ran with it until the mid 80s.

In 1985, the National Academy of Science published a report entitled "An Evaluation of the Microbiological Criteria for Foods and Food Ingredients." The NAS committee—actually the Subcommittee on Microbiological Criteria for Foods and Food Ingredients—stated that a preventative system (HAACP) was essential for controlling microbial hazards in food products.

From this committee recommendation sprang a flurry of interest in HACCP, not only in the United States but internationally (Codex Alimentarium Commission). NAS recommended that a National Advisory Committee on Microbiological Criteria for Foods be established. This committee has since embraced HACCP and more importantly further refined it to what we know it as today!

HACCP Principles

Principle #1: Conduct a Hazard Analysis

This a very important principle! Not only is it the first step in the process, but it requires more time and thought than any other step. The first thing to do is to completely describe the product you are making, how it is made and distributed. Also, the intended end-user should be identified (i.e., general public, infants, elderly, etc.) Next, the process in which the product is made must be described in detail. Every step in the process must be included, no matter how small or unimportant it may seem. This is commonly referred to as the "Flow Chart" for that specific *product* in your specific *operation*.

Next, you look at each step in the process and list the potential "hazards" that could come into play at this step. Hazards are grouped as Biological, Chemical and Physical. Initially, you should list every thing you can possibly think of that could be a hazard. Then you start "analyzing" these hazards for potential significance (i.e., risk and likely occurrence). Hazards that are of low risk and(or) not likely to occur are usually not considered further. After narrowing down the potential hazards to those of significance. You must then consider what preventative measures, if any, exist that can ***prevent***, ***eliminate***, or ***reduce*** the potential hazard to an acceptable level.

During the hazard analysis, the risk and severity of the hazard must come into consideration, as previously mentioned. These differ for each type of product and are confounded by your intended end-use consumer (e.g., hospital patient or healthy person) and method of distribution. Risk should be based to large part on experience, technical literature and supported by epidemiological data. Severity is the "seriousness" of the hazard. Note that these apply to *safety* and not to *quality*. HACCP is intended to be a "food safety" program, not a "food quality" program.

Upon completion of the hazard analysis, the hazards which you deem "significant" for your product, process and operation, should be listed for each step in the process. Secondly, preventative measures for these hazards should be described.

Example:

Step — Cooking

Identified Hazard — Pathogenic bacteria

Preventative Measure — Cook sufficiently to kill bacteria

Principle #2: Identifying CCPs in the Process

A critical control point is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, elim-

inated, or reduced to an acceptable level. With this in mind now you need to address each of the significant hazards you identified above to see if the step or procedure that they are associated with are CCPs.

The best and most accurate way to determine if a significant hazard is a CCP, is to use a tool called the decision tree. This is a fairly straightforward question and yes or no answer flow chart. There is room for debate on some of the "yes or no" answers, but it is as straightforward as possible.

Examples of CCPs could include cooking, cooling, reheating, sanitation, product formulation, cross-contamination, personal hygiene, receiving, etc. Depending on your product, process and particular operation, just about anything could be a CCP. Remember, *nothing is set in stone!* It varies.

The biggest mistake at this point in the HACCP process is to identify too many CCPs. This basically dilutes the effectiveness of the overall program. Follow the decision tree closely and take into account how your SOPs and GMPs would help in controlling the particular hazard at this step or procedure.

Principle #3: Establish Critical Limits

In the Hazard Analysis, we identified the significant hazards and then identified a *preventative measure* for each. Now we must develop criterion for each of these preventative measures associated with a CCP. Each CCP will have at least one—and maybe two or three—preventative measures that must be properly controlled in order to eliminate, prevent or reduce the hazard to an acceptable level.

These criteria can be a wide range of measurable attributes, such as temperature, pH, time, humidity, moisture level, physical dimensions, available choline, preservatives, viscosity, etc. These critical limits are usually measurable, objective attributes; however, in some cases, subjective measures such as color, smell, and general appearance can also be used.

Critical limits can be obtained from various sources, such as technical literature, regulatory standards and guidelines, epidemiological data, and personal experience of experts. Wherever you get your critical limits and what ever ones you use make sure of two things: (1) That they will control what you want controlled; (2) that you can live with them—in other words, that you can meet your own standards on a day-to-day basis.

Principle #4: Establish CCP Monitoring Requirements

The only way to know that you are operating you process within your critical limits, and thus in control of your process, is to monitor your critical limits. This doesn't have to be difficult although many people cringe when they think about having to do this. Get over it, because it is absolutely necessary!

There are basically two ways to monitor: continuously, and at pre-determined intervals. Continuous is always the best, but is not feasible in many situations. If you cannot continuously monitor, then the intervals between monitoring must be carefully determined so that you can accurately evaluate your process.

Examples of monitoring could include temperature, time, pH, moisture level, visual observation and, in some cases, microbial testing. When monitoring it is important to identify three things: (1) who is responsible to do the monitoring, (2) when is the monitoring to be done, (3) how is the criterion to be monitored?

Principle #5: Establish Corrective Actions

What do you do if while monitoring you realize that you have exceeded your critical limits and your process is, at least temporarily, out of control?

Well, if you didn't have a solid well thought out HAACP program, you would probably get excited and probably do something stupid in the heat of the moment. But with a HAACP program you have a written set of instructions that deal with this situation and they are known as ***corrective actions***.

Corrective actions are nothing more than procedures that are to be followed to the letter when your monitoring identifies that you have exceeded or not met your critical limits.

Examples: (1) You are cooking hotdogs and your cycle says they are ready (155°F) but your monitoring says they are only 145°F. Corrective action is simple: continue cooking until an internal temperature of 155°F is reached. (2) Your hot-holding line at a restaurant is supposed to maintain the food above 140°F; your monitoring finds that it is 134°F. Corrective action (twofold): if below 140°F for less than 2 hours, reheat to 165°F and serve once; if below 140°F for more than 2 hours, discard immediately.

Corrective actions can be singular and simple or multiple and complex: it depends on the product, your operation, and your end-user in many cases. Above all, remember that corrective actions ***must*** be specific and easily understood.

Principle #6: Establish Effective Record Keeping

Big problem for most operations!! This takes time and, many times, is a major pain in the butt. But it ***must*** be done. Without records how can you prove that your process is in control and how can you evaluate how well your HACCP program is working? Records are an absolute must. Try to make them as simple as possible while still getting all the information that you need to achieve the abovementioned goals.

Principle #7: Establish Procedures for Verification

Put simply, this principle is intended to make sure that what your are doing is working. It can involve periodic reviews of the entire system, primarily concentrating on the effectiveness critical limits. It can also be much broader and look at the entire system from end to end. Verification should be used to not only check the system but to continually update it and modify it to keep you in ***control***.

Verification can be done internally (and should be), or it can be done by outside audits. Verification will be the focal point for regulatory when they come to ensure that your establishments HACCP system is functioning satisfactorily.