Chapter I

Introduction

Hazard Analysis and Critical Control Point (HACCP) is a system that has been around since the late 1960's. Originally HACCP was designed for NASA and the space program to ensure a safe product by attempting to eliminate or reduce end point testing after processing. End point testing was very costly and could damage much of the fina product because some testing is destructive. As an alternative, HACCP is composed o several checks within the process to ensure a safe final product.

HACCP is composed of a number of necessary components. Each part of the HACCP plan must be completed before the HACCP system can run efficiently. A good HACCP system also requires teamwork and good communication within the plant. Commitment from upper management is essential for a system to function. Withou commitment there will be no support for the program to work effectively.

Also, a HACCP team must be formed to handle all of the HACCP related information. This team should be trained properly to understand the HACCP principles. HACCP training courses can be taken to educate those who might not be familiar with HACCP.

HACCP has been a requirement of the meat and poultry industry since 1998 when large plants were required to implement this preventive program. During the next two years, small and very small plants fell under the HACCP mandate. All of these plants are now required to maintain their HACCP plans and any new regulations that are mandated.

Two monitoring techniques used often in the food industry are the rapid bioluminescence method and the Standard Plate Count Method. The bioluminescence

method utilizes ATP within organic matter to provide results. The Standard Plate Count Method measures only microbial matter present and is mani fested through the actua colonies on a medium.

The purpose of this research was to evaluate the HACCP plans of all Virginia state inspected meat and poultry plants and to determine if they were functioning properly through the prevention of hazards. S nce HACCP assessment is an integral par of a successful HACCP system, these audits provided beneficial suggestions to the processing plant personnel, as well as prepared them for any regulatory assessments tha may follow. During the assessment of HACCP plans, microbial testing provided important baseline data on how well plants were maintaining their sanitation practices. In addition, comparison of the Standard Plate Count and Bioluminescence methods will provide information to identify which microbial determination method should be used with certain applications.

Literature Review

History

The Pillsbury Company first developed the concept of HACCP in the early 1960's. This firm worked cooperatively with NASA to develop this new system to ensure safety of the food consumed by the astronauts. At that time, most safety systems were based on end product testing. For this concept to be fully effective, companies must tes 100% of their product. Since most testing is destructive, this approach would no be feasible because the entire product would be required (Mortimore and Wallace, 2000).

At the 1971 National Conference on Food Protection, the HACCP system was first presented. This new approach to food safety gained interest among food processors

and was used as the basis for regulations regarding low-acid and acidified foods. Furthermore, the FDA even began using HACCP for investigation activities. However, after the initial excitement of the new system, interest in HACCP began to fade. According to Stevenson (1990), only a few large companies continued to apply HACCP.

During the 1980s, some of the government protection agencies asked NAS/NRC (National Academy of Sciences/National Research Council) to form a committee tha would generate some general principles for the application of microbial criteria in foods. This committee proposed the implementation of HACCP in food protection programs. In addition, they suggested that the food industry receive the proper training with regard to the HACCP concept (Stevenson, 1990).

Many food industries have implemented HACCP since its inception. Some have done so voluntarily, whereas others have been mandated. Industries currently mandated are Seafood (since 1997) and Juices (effective in 2002). The meat and poultry industr fell under the HACCP mandate in 1998(large plants). Small and very small plants followed in 1999 and 2000, respectively. The smaller plants were given more time to develop their HACCP plans due to fewer resources and personnel compared to larger plants (Bowers, 1998). The canned food industries do not have a mandatory HACCP requirement, but one is highly recommended. The major reason that some canning companies have implemented HACCP is to control *Clostridium botulinum* (Food Safety and Inspection Service, 2000).

Purpose

The HACCP program serves several purposes. The main objective of HACCP is to produce a safe product. HACCP is a safety program, not a quality program. Meta

fragments, microorganisms that cause illness, and harmful chemicals are examples o some of the hazards that HACCP will attempt to reduce or eliminate (Swanson and Anderson, 2000). There will never be a process that is absolutely safe, but there mus always be a constant effort to achieve zero defects (Snyder, 1991).

Another function of HACCP is to reduce or even eliminate the need for endpoin testing. Before the HACCP concept was developed, many processors depended on endpoint testing to determine if their product was satisfactory. This testing can be ver tedious and time consuming. Also, testing can lead to a loss of a portion of the produc since some types of testing are destructive (Bauman, 1990). HACCP attempts to reduce endpoint testing by conducting a series of checks throughout the process. At each step in the process, all possible hazards are considered in regards to how to prevent them and what actions will be taken if a significant hazard occurs (Mortimore and Wallace, 2000). By the time the product reaches the end of the process, HACCP attempts to reduce hazards to an acceptable level.

A third purpose of HACCP is to provide documentation to prove that the process is being conducted as written. Without documentation and records, there is not verification that anything has actually taken place.

According to the FDA (1999), the advantages of HACCP over other safety systems are that this preventative program:

- Focuses on identifying and preventing hazards from contaminating food
- Is based on sound science
- Permits more effective government oversight because record keeping allows investigators to determine how well a firm is complying with food safety laws over a period of time rather then how well it is doing on any given day
- Places responsibility for ensuring food safety appropriately on the food manufacturer or distributor

According to Mayes (1994), "Implementation of HACCP is not a quick 'back o the envelope' job done on a quiet afternoon, but it is instead a detailed technical evaluation of a product and process requiring time, commitment, scien ific and technica expertise to carry out hazard analyses and establish control and monitoring procedures, and the requisite knowledge, skills and attitude for successful implementation".

HACCP Training

HACCP training is a key ingredient in implementing and maintaining effective HACCP plans. Those involved in implementing a HACCP plan, teaching a HACCP course or assessing a HACCP plan all need to be well educated on the HACCP concept. Without training, the full benefits of HACCP are not likely to be obtained (Mayes, 1994). According to Mayes (1994), to be properly trained one must:

- Understand the practical implications of HACCP to food safety on a worldwide basis
- Gain practical skills and knowledge for HACCP implication
- Understand the continuous development and harmonization of HACCP.

FSIS identifies a HACCP trained individual as a person who successfully completed a recognized HACCP training course and who is employed by the establishment. This individual must also have "sufficient experience in the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question" (Food Safety and Inspection Service, 1996). FSIS (Food Safety and Inspection Service, 1996) recognizes a HACCP course as one that is available to mea and poultry industr employees that consists of:

- One day devoted to understanding the seven principles
- One day devoted to applying these concepts to this and other regulator requirements of FSIS
- One day devoted to beginning development of a HACCP plan for a specific process

Prerequisite Programs

Before HACCP implementation within the food industry, certain programs were already in place to provide for food safety. For the HACCP system to produce safe products, it must be built on a solid foundation of prerequisite programs. These programs provide the basic conditions that are necessary for the production of safe food. Some examples of common prerequisite programs are supplier control GMPs, SSOPs, letter of guarantee and pest control (NACMCF, 1999). Prerequisite programs ensure that HACCP plan(s) are functioning effectively (Stier, 1998). Consistent maintenance of these programs is important to the success of the HACCP plan (Bernard et al., 1997).

Understanding the difference between HACCP and prerequisite programs is accomplished through the recognition of two main points. First, prerequisite programs deal indirectly with food safety, whereas, HACCP focuses solely on food safety. Second, prerequisites tend to be more general and applicable across a processing plant. HACCP plans are only based on hazard analyses that are product or line specific. (Bernard and Parkinson, 1999). Also, there is often the misconception that HACCP replaces the need for prerequisite program. HACCP does not replace an prerequisites. It combines with the prerequisites to form a food safety system (Motarjemi, 1999).

Two of the most common prerequisite programs for HACCP are the Good Manufacturing Practices (GMPs) and the Sanitation Standard Operating Procedures (SSOPs). GMP's emphasize sanitary effectiveness and hygienic practices during food processing. An effective GMP program will help reduce the level of spoilage and pathogenic microorganisms (Eisel et al., 1997). Many companies require that their

supplier conduc regularly scheduled audits to assure that they are adhering to their GMPs (Stier 1998).

SSOPs are a widely used program to maintain proper sanitation within food processing plants even before HACCP was mandated (Gombas, 1998). SSOPs describe all daily procedures that will be conducted to maintain sanitation, specify the frequency of the procedures, and identify those responsible for implementing and monitoring the SSOP (Stier 1998). Both GMPs and SSOPs are signed and dated by a qualified officia and kept with all HACCP related documents (Adams, 1998).

Adams (1998) suggested that all SSOPs needed to be performed each morning before any processing begins and after processing is complete. Furthermore, records need to be provided for SSOPs, for example, monitoring records and any corrective actions taken due to improper sanitation. These procedures should be reviewed often to verify compliance with all regulatory requirements. One way to verify that these SSOPs are effective is by testing to ensure tha the guidelines are being followed. SSOPs should be updated often to accommodate changes within the individual operation and the food industry.

Some new regulations were established in 1996 for meat and poultry slaughter and processing plants to supplement HACCP. Those that operate under USD inspection and HACCP mandate must also test for *Escherichia coli* on carcasses to ensure that no fecal contamination is present, establish a "pathogen reduction step" for slaughter plants and those producing raw groun d products (based on reduction of *Salmonella* sp.), and develop a protocol for sanitation procedures (Eisel, et al, 1997). Plants were required to develop SSOPs and *Escherichia coli* testing procedures by Jan

27th, 1997, and Salmonella testing was initiated during 1998-2000 depending on size o the plant (Food Safety and Inspection Service, 2000). The processing plant is responsible for testing for *Escherichia coli* and FSIS will perform the *Salmonella* testing.

HACCP Components

Before developing the HACCP team, commitment from upper managemen should be obtained. Without commitment from the entire plant, HACCP will not function properly. The HACCP team is established of individuals who will execute the duties of implementing and maintaining the HACCP plan. It is important to have a tea with enough members to avoid too much work delegated to one person, but not too many members so that communication between them becomes difficult. A team consisting o four to six members is ideal, with one of them acting as team leader (Mortimore and Wallace, 2000).

It is recommended that the team consist of at least one expert from Quality Assurance, Operations or Production, and Engineering. The Quality Assurance exper will provide knowledge in what types of hazards can occur and the risks associated with these hazards. The expert from operations or production will have detailed knowledge o the day-to-day operational activity. The engineering representative will be capable o providing expertise on the processing equipment with respect to process capability.

Additional expertise will be needed and can be selected from within the compan or from outside consultants. It may be easier to keep the HACCP team internal for communication and availability purposes. These additional experts can be selected based on which will be more beneficial to that particular plant. Someone from research and development can be selected if new products and processes are being developed. Other

experts such as purchasing agents, microbiologists and statisticians can be beneficial to the team. Also, a HACCP expert might also be considered. One who is knowledgeable in setting up HACCP plans will help keep the team focused (Mortimore and Wallace, 2000).

Another requirement of a HACCP plan is to develop a product description and intended use of this product. According to Mortimore and Wallace (2000), the produc description should contain a brief description of the product with regards to storage temperature and shelf life. The description should also describe any hazards associated with the production of the product and how to control these hazards. Furthermore, it should give a description of target groups that may consume this product (Ababouch, 2000). The purpose of the product description is to help familiarize the HACCP tea with the products and technologies being utilized.

There must also be a list o ingredients at the front of the HACCP plan. This is usually a one-page summary of what meat ingredients and other adjuncts are present within the product.

Prior to conducting the hazard analysis, a process flow diagram must be created. This is a flow chart that represents the process starting with receiving of materials to shipping of the end product. All of those stages on the flow chart that are critical contro points must be labeled. The diagram should include time and temperature profiles for each stage of production. The flow diagram does not necessarily have to be an extensive drawing of the facility. A block type flow diagram is used most frequently (FDA, 2000). Once the flow diagram is completed it should be verified by the HACCP team to ensure completeness and thoroughness. The team should meet and review the diagram to ensure

that all stages are included and all other criteria are present. Modifications should be made as necessary (FDA, 2000).

After these preliminary steps, the HACCP team should develop the seven HACCP principles. Originally the HACCP protocol consisted of only three principles 1) Hazard analysis and risk assessment, 2) determine the critical control points (CCPs), and 3) monitor the CCPs. In 1989 the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) included four more principles to the HACCP syste (Sperber, 1991). According to Snyder (1991), the seven principles that now make up a HACCP plan are:

1. Conduct a Hazard Analysis and Risk Assessmen
2. Determine CCPs
3. Establish Critical Limits (CL) for each CCP
4. Establish Monitoring procedures for each CCP/CL
5. Establish Corrective Actions
6. Establish Verification Procedures
7. Establish a Record keeping Syste

HACCP Principles

Principle 1

The first principle involves conducting a hazard analysis, which involves assessing certain risks involved in production of a product. "Hazard Analysis is defined as 'the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan'" (Mayes, 1999). The firs part of conducting a hazard analysis involves identifying all possible hazards that could occur within the food product. The HACCP team should hold a brainstorming session to identify every possible hazard. During this session, the team should not cons der the significance of a

particular hazard. That will be dealt with during the risk assessment. Mayes (1999) states that "the Hazard Analysis is probably the key principle in the whole HACCP system and the one people find to be the most difficult."

The three types of hazards that must be considered during a hazard analysis are biological, chemical and physical (Tompkin, 1994). Biological hazards are normally those that involve microorganisms. *Escherichia coli* or *Listeria monocytogenes* in mea products are examples of biological hazards. Other pathogenic bacteria can also be considered a hazard (e.g. *Salmonella* and *Clostridium botulinum*). Further microbial concerns include viruses, parasites and mycotoxins. Biological hazards may also include macro organisms (Mortimore and Wallace, 2000).

Another type of hazard is a chemical hazard. These hazards involve specific chemicals that may be added to the product or chemicals that contaminate the food during processing. Cleaning compounds and pesticides are two examples of chemicals tha could contaminate the product. Other chemical hazards include several added which ma be an allergen to the consumer (eg. Peanuts, eggs or shellfish) (Mortimore and Wallace, 2000).

Other hazards are the physical hazards. As the previous two types, these also can occur during any stage in the process. Physical hazards are those that are sharp or hard that could cause injury or choking. Fragments of glass, metal or wood could all be considered physical hazards (Mortimore and Wallace, 2000). Bone fragments can also act has a physical hazard. Meat products do contain bones, so it is essential to remove a of the bone without leaving any fragments left in the product.

After all potential hazards are identified, the H CCP team must now conduct risk assessment. According to Sohrab (1999), "Risk assessment is a scientific evaluation of known or potential adverse health effects resulting from human exposure to food borne hazards". An example is where the team determines which identified hazards are significant. A significant hazard is one in which the likelihood of occurrence and severity of illness are high.

When determining the likelihood of a hazard, the HACCP team must research each hazard and identify any trends. If the literature indicates that this hazard does no occur often, the team can indicate that the likelihood of occurrence is low. The tea must also research a hazard to understand the severity if it is not properly controlled. Some hazards may be more severe then others. For example, microorganisms that can lead to chronic illnesses or death are considered very severe. Other microorganisms ma only cause small side effects. These are not very severe (Sohrab, 1999).

Principle 2

When the hazard ana ysis is complete, the HACCP team must go over the flow diagram and decide which steps are critical control points (CCPs). A CCP can be a poin in the process where a significant hazard can be eliminated or reduced to an acceptable level. A CCP is also a point where loss of control will lead to a significant hazard. I differs from a control point (CP) in that a loss of control at a CP will not lead to a significant hazard. Two examples of common CCPs are cooking and chilling, because these steps are designed to reduce the occurrence of a hazard. CCPs require a lot o careful development and extra documentation and that is why they should be limited to only those that are truly critical (Weddig, 1999). Table 1 illustrates the difference

between what hazards are controlled by CCPs and CPs (Sperber, 1991). When determining which steps are critical control points, some companies use what is called the shotgun approach. This is a method that is not based on any true reasoning; rather CCPs are chosen based on the opinions of the team. This may lead to an excessive number o CCPs resulting in problems for the plant. A more accurate and feasible method that can reduce the number of CCPs is use of the decision tree. This approach asks severa questions about each processing step where a hazard is significant (Tompkin, 1994). The questions are in "yes or no" format, and will eventually determine whether that step is a CCP. Figure 1 (in the appendix) illustrates a generic model for how the decision tree works (NACMCF, 1998).

Every HACCP plan must have at least one CCP, and it is recommended that the plant try to limit the CCPs to four or fewer. More then four CCPs increases the difficulty of maintaining the plan properly resulting in an excess of paperwork or the compan (Tompkin, 1994). Having too many CCPs is not advisable, but is not nearly as disastrous as too few CCPs which could lead to a food safety hazard and an unsafe produc (Mortimore and Wallace, 2000).

Principle 3

Once the CCPs are determined, critical limitsare required for each step that is a CCP. A critical limit is a maximum or minimum value to which a specific parameter must be controlled at each CCP. Common critical limits are temperature, time, moisture, pH and salt concentration. Critical limits are rarely a range of values. Each limit should have some sort of basis whether that is FSIS regulations, FDA action levels, or any other scientific literature (Food Safety and Inspection Service, 1996). An example is the

temperature within a freezer. If the critical limit is set at 0° C or below, the temperature must always remain at or below that temperature. The temperature must be watched ver closely and monitored to ensure that the limit is not exceeded (King, 1992). Critica limits can be slightly stricter than the regulations set by FSIS. This requirement w ensure that regulatory requirements are still met in the event of a slight deviation from the limit (Food Safety and Inspection Service, 1996).

Principle 4

The next step is to monitor each CCP and critical limit. Monitoring of each critical limit is very important because it helps to ensure that the CCPs are in compliance and the critical limits are not exceeded (Sohrab, 1999). Critical limits can be monitored continuously r non-continuously. If a critical limit were monitored continuously, a temperature monitoring system would be a good investment. A computer system will be devised for measurements at regular increments. For example, if a refrigeration stage has a critical limit of 4˚C, the monitoring system may take readings every minute and alert the company if a deviation occurs. Continuous monitoring is ideal when a particular parameter tends to have more variation then normal. This system will also need to be monitored by an individual to ensure the computer system is functioning properly (Tompkin, 1995).

If non-continuous monitoring is utilized, a member of the HACCP team mus conduct checks at regular increments (i.e. every 30 minutes or every hour). The individual must evaluate the refrigerated area with a thermometer and record the results. That individual is responsible for keeping an accurate record of each CCP and notifying the proper authority if a critical limit is exceeded. Because non -continuous monito ring is

being used, it is important that the frequency of monitoring be adequate to ensure contro of the CCP (Sohrab, 1999).

Principle 5

If there is a deviation from the set standards of a critical limit, corrective actions must be taken (Snyder, 1991). Corrective actions are procedures carried out when a loss of control has occurred at a particular CCP. Sperber (1991) suggested that all corrective actions as well as responsibilities should be clearly outlined before HACCP is implemented. All records and corrective actions should be documented to prove that corrective actions are being conducted (Sohrab, 1999).

The first step of a corrective action is to stop the processing line and isolate an possibly adulterated product (King, 1992). Once the non-compliant product is segregated, microbial testing will help assess the safety of the product (Kvenberg and Schwalm, 2000). If the product is deemed as unsafe, it will be discarded. However, if testing reveals minimal adulteration, the product can then be reprocessed (Food Safety and Inspection Service, 2000).

Before the processing continues, control must be reached at that CCP. Once the process is stopped, it is up to the individuals responsible to identify why a deviation has occurred and what can be done to bring the process back to conformance. Once this reason is determined, measures will be implemented to prevent the deviation from occurring again (King, 1992). If a deviation occurs too often at one CCP, the HACCP team will have to evaluate whether the HACCP plan is sufficient to control this hazard (Kvenberg and Schwalm, 2000). Corrective actions might even be considered if monitoring indicates a trend towards loss of control at that CCP (Sohrab, 1999).

Principle 6

The next principle that must be addressed is verification. Verification is the application of methods, procedures and tests to determine the company's compliance with the HACCP plan (Mayes, 1999). Verification covers all internal daily activities with regards to HACCP (Lupin, 2000). A few verification procedures include a review of the HACCP system and records, any deviations and product dispositions, and confirmation that the CCPs are kept under control (Mayes, 1999). The only way to be confident that a safe product is being produced is to verify that the personnel have contro at each step (Snyder, 1991).

Verification can be performed by plant audits with the use of microbial, physica and chemical tests. Government agencies will sometimes review HACCP plans to ensure compliance with standards (Snyder, 1991). The frequency of such audits should be sufficient to verify that the HACCP program is functioning properly (Mayes, 1999). There is often some confusion about how validation differs from verification. Verification determines compliance with the HACCP plan, where validation merely determines that the end results can be achieved (Sperber, 1999).

Principle 7

The seventh principle of HACCP is to establish adequate record keeping procedures. Without records, there is no proof that a plant is doing what their HACCP plan indicates. According to Sohrab (1999), the purpose of recording keeping is to show that the HACCP plan is compliant with the documented system. Records are useful in providing a basis for trends and for systemat c improvement of the process over time (Snyder, 1991).

All forms pertaining to monitoring results, corrective action logs, or training records must be kept on file for at least 1 year. Any modifications to, or audits of, the HACCP plan must be documented as well (Ababouch, 2000). USDA requires that the HACCP plan and records be filed together and be readily available when requested (King, 1992).

Pre-shipment Review

Although the pre-shipment review is not one of the seven components of HACCP, it must be executed each time product is shipped. The pre-shipment review is a method that allows the plant to keep track of when product was shipped and that all critica control points were monitored with appropriate corrective actions, if needed. A member of the HACCP team will verify that products are being shipped and will indicate the date and time. A signature is required from the employee for future. If there is ever an question on whether products were shipped, the plant can refer to their pre-shipment review.

HACCP Achievements

According to studies by Aramounii et. al. (1996) since HACCP implementation, there has been reduced microbial contamination on equipment surfaces tested in mea plants. Microbial results on meat grinders, knives and plastic lugs were all reduced a least 1 log CFU/cm^2.

HACCP has also improved the regulatory aspect of food safety by offering an opportunity for food control authorities to revisit their method of inspection. The HACCP system has increased the collaboration among scientists, which will essentially strengthen the abilities of food safety authorities in producing safe food (Motarjemi and

Kaferstein, 1999). According to Motarjemi and Kaferstein (1999) If a HACCP plan is based on sound science, it will prevent many outbreaks by improving hygienic quality of foods.

HACCP Assessment

Although HACCP assessment (auditing) can fall under verification, it is not one of the seven principles. Even though both regulators and processors have the same goa of producing safe products, their views differ on how effectiveness should be measured. The goals of a regulatory agency in terms of HACCP are to:

- Make the food supply safer through the prevention of food safety problems
- Enable regulatory agencies to more efficiently utilize their existing resources devoted to ensuring food safety
- Enhance the ability of the regulatory agency to provide consumers with the assurance that the food supply is safe
- Underscore the industry's role in continuous problem prevention and problem solving

(Kvenberg et. al., 2000).

The main purpose of HACCP assessment is to establish whether a processor is capable of producing or distributing safe products consistently, i.e. ensuring that the HACCP program is effective in maintaining product safety (Anon, 2000). Assessmen should include review of the HACCP manual and an on-site verification to establish whether the HACCP plan is properly implemented (Ababouch, 2000). According to Mortimore (2000), the outcome of any assessment should show that the manufacturer has:

1. Implemented a sound HACCP system
2. The knowledge and experience needed to maintain it
3. The necessary support (prerequisite) programs in plac

Check sheets can be used to make the assessment more effective. Check sheets have been proven to be an effective tool in assessing HACCP plans. However, check sheets alone will not suffice. It is important for the auditor to have adequate knowledge to identify any deficiencies and address them properly (Ababouch, 2000). It will be up to the discretion of the assessor on how to form their check sheets. Some may use a check sheet as an aide-memoire, but many separate questions must supplement the check sheet, since they are only a broad outline of criteria. There is no set formula for a HACCP plan; therefore check sheets will differ from plant to plant (Mortimore, 2000).

Assessments can be conducted either with an internal assessment team, or b outside consultants. An internal assessment should not be conducted by those individuals involved with the daily activities of the HACCP plan(s) (Lupin, 2000). One type o HACCP assessment is through the establishment of the effectiveness of in-house HACCP systems. Another assessment would include visiting the suppliers and ensuring their HACCP plan supplies safe incoming ingredients. Occasionally a third type of HACCP assessment may include customers' systems. This assessment will occur when the consumer is partly responsible for distribution of a product (Mortimore, 2000).

A regulatory HACCP audit m ay or may not consist of the following elements. Occasionally before the actual plant visit, a pre-assessment review can be conducted. This approach will give the auditor an opportunity to obtain a general idea of what type of operation is being conducte d and may help in formulating an initial check sheet (Anon, 2000).

Following a pre-assessment and arrival at a plant, the auditors should meet with representatives from the plant. Agreement should be obtained by both parties, so it is

important for the auditors to indicate their intent and what format will be used to conduct the audit (Anon, 2000). The auditors will also indicate what documentation will be needed to perform the audit (Mortimore, 2000).

Plant management may take the auditors on a tour of their facility. This w provide a first hand look to the actual process. The auditors should observe and determine deficiencies in the process. Any questions about the process that are no understood by the auditors should be asked during this tour (Mortimore, 2000).

The auditors should gather all of the HACCP related documentation and assess its competency. The auditors must review all of the SSOPs and the entire HACCP plan(s). Evaluation of the HACCP documentation will include verification that all seven principles are included and accurate, that a HACCP team is identified, and a description of the product with intended use is listed (Anon, 2000). The auditor is encouraged to take notes and ask questions during the actual review of the documen ation.

When the assessment is complete, the auditor will conduct a final meeting with the management. Here the auditor will present deficiencies found and suggestions for improvement. If a regulatory audit were being conducted, all non-compliances should be discussed with the management and it is the duty of the auditor to ensure that the management team clearly understands the deficiencies. If it is necessary, both parties may agree upon corrective actions and a follow-up may be scheduled (Mortimore, 2000). In a non-regulatory audit, suggestions will be provided to the management. The management may choose to accept these suggestions and make the necessary changes or they may choose to leave the plan if they feel it is sufficient.

A report may then be written by the auditors to indicate the results of the assessment; mostly what deficiencies were found with the HACCP documentation. The auditors may keep this report, so in the event of a follow up assessment, they have a record of their previous visit (Anon, 2000). In some cases the report may be sent to other authorities for review.

The frequency at which HACCP assessments are conducted depends on the risk category of the food and the level of commitment from the management. The frequenc will also depend on the reputation of the food processor (Ababouch, 2000). An assessment should be conducted any time there are changes to products or processes within a plant. It is a good idea to have audits scheduled throughout the year regardless of other factors that may arise (i.e. recalls, HACCP changes) (Anon, 2000). The curren regulation requires at least a yearly audit, but this is a minimum requirement (Lupin, 2000).

Microbial Testing

Purpose

"The purpose of microbial testing is to confirm that a ll possible avenues o contamination have been identified and that these avenues are being controlled" (Kvenberg & Schwalm, 2000). Categories which define the purpose of microbial testing are to determine safety, to adhere to GMPs and to predict product stability (Brown et. al., 2000). If a purpose for testing cannot be determined, the analysis should not be performed.

There are several areas where microbial testing has become very important and critical to food safety. Brown et. al. (2000) stated that testing can be used to survey the

microbial condition of a product or decide whether to accept or reject a batch of product. Testing can also act as part of a HACCP system. Furthermore, Kvenberg and Schwa (2000) indicated that testing could be used when conducting the hazard analysis, as a monitoring tool for corrective actions, and to verify that the HACCP plan is working. In the meat and poultry industry, it is important to test carcasses periodically to verify tha HACCP is working. Testing for generic E. Coli on meat carcasses is one method that is required in meat and poultry processing plants (Eisel et al., 1997). Microbial testing is also important to verify that prerequisite programs are effective; those such as GMPs and SSOPs. Testing before and after production will ensure proper sanitation (Kvenberg & Schwalm, 2000).

Standard Plate Count

Kvenberg and Schwalm (2000) suggested that processing equipment should be regularly tested to verify that sanitation practices are being followed,. One such method that is often incorporated is the Standard Plate Count Method (SPC). This met requires 48 hours to yield final results. It involves taking a swab of a specific area, and then plating out dilutions onto a growth medium (AACC, 1976). This procedure results in growth colonies, which are often referred to as colony forming units. This method i rather specific in that individual colonies can be recognized and counted.

After swabbing a surface, it is placed into sterilized buffered pep one water. This water acts as a suspension for the microorganism, but does not contain the proper nutrients for growth. Before inoculating the peptone tubes with the swabs, the tubes must be placed into an autoclave for 15 minutes at 15 psi (103.43 kpa (Akron, 2001)) and 121 degrees C (Acuff, 1992). The heat and pressure will destroy any microorganisms tha

may have contaminated the tubes. To cool down the tubes, they may be placed in a refrigerator.

The colonies that will be identified as colony forming units (CFUs) will be grown on Standard Plate count agar, which is a growth medium for microorganisms. When selecting a culture medium, the primary goal is to provide adequate nutrients a concentrations that will provide good growth for the target organisms (Stainer et. al., 1976). The premixed agar contains the following components: Agar-15g, Pancreatic digest of casein-5g, Yeast extrac -2.5g, and dextrose-1g. The dextrose can also be replaced with glucose (Atlas, 1995).

After the agar is prepared and mixed with sterile water, it will also be autoclaved to remove any contaminants. The agar should then be allowed to cool down to roo temperature. If samples are mixed with the agar before it is cooled down, some microorganisms may be destroyed due to the excessive heat.

After the agar has hardened and the plates are ready to be incubated, they should be inverted and placed into the incubator. Inverting the plates will help preven spreading. Moisture may build up on the lid of the plate; therefore inverting it will keep water from falling onto the agar. Spreading occurs when a colony becomes moistened and elongates across the agar. Plates should not be stacked too high and incubators should not be overly crowded; this will lead to a slower equilibration. If the incubator is properly ventilated and air is circulating plates should equilibrate to the incubation temperature within about 2 hours (Swanson et. al., 1992).

Bioluminescence

Another viable microbial method is a rapid bioluminescence technique, which involves the use of a bioluminometer to measure light. Bioluminescence methods have been readily available for a number of years. Their use may not be as widespread due to high cost and poor reagent stability. According to Kyriakides and Patel (1994), thi method can be effective due to its very rapid assessment of hygiene and sanitation efficacy.

As opposed to the SPC method, this technique measures all organic matter present on a surface, not just microbial contaminants (Illsley et al., 2000). It does no result in actual colonies, the results are displayed as relative light units (RLUs); therefore this method is less specific then the SPC.

In this bioluminescence reaction as in many others, ATP (adenosine triphosphate) provides t e energy for the reaction. ATP is a nucleotide present in all organic matter and contains three basic units: adenine, ribose and triphosphate. ATP is generated during cell metabolism, and disappears about 2 hours after cell death. The energy associated with ATP cannot be stored for long periods; it is converted to ADP (adenosine diphosphate) and AMP (adenosine monophosphate) soon after its formation (Chen, 2000).

The bioluminescence reaction that occurs is similar to activity in the tail of the North American firefly, *Photiinus pyralis* (Kyriakides & Patel, 1994). The tail of the firefly contains the chemical luciferase, which is an enzyme that catalyzes light emission. One way of measuring ATP is through the enzyme, luciferase. However, the reaction cannot take place utilizing only luciferase and ATP. Luciferan (a substrate of luciferase),

molecular oxygen and magnesium are also required for the reaction (Chen, 2000). Neufeld et. al. (1985) stated that the reaction cannot occur in the absence of ox gen. The first step in the reaction involves an adenyl group that is transferred from ATP to the carboxyl group of the luciferan to form luciferyl adenylate. This reaction also results in an elimination of inorganic pyrophosphate. The subsequent lucifer yl adenylate then reacts with molecular oxygen to produce light. Carbon dioxide is lost in the process (Chen, 2000). A diagram adapted from Kyriakides & Patel (1994) illustrates the reaction presented in figure 2 (in the appendix).

As a surface is swabbed, organic matter will be transferred to the swab. When placed into the luciferase solution, the ATP present will react and produce light. The amount of ATP present on the swab is proportional to the amount of light that will be generated (Chen, 2000). The reaction between ATP and luciferase solution will occur in seconds and results can be obtained in less then a minute (Illsley et al., 2000).

The bioluminescence technique provides an indication of cleanliness because it is capable of detecting meat residues that the SPC may not have detected (Chen, 2000). Readings on the bioluminometer can range from 0-500,000. Depending on the company's preference, they can identify certain values as acceptable or unacceptable (Biotrace, 1998).

There are several factors to consider when deciding whether to implement standard testing methods or rapid methods in a plant. The first would be the time in which it takes to obtain results. A rapid method is generally one that will yield results i less then 30 minutes. Results should be available in time to take action if specifications

were not met (Griffith et. al., 1997). Standard testing methods generally require days for results (Betts, 1999).

Some other factors to consider are cost of the assay and ease of use. The rapid methods generally cost more because of the technology involved and the reagen preparation. The increased cost of the assay allows for quicker results and a generally a much simpler assay (Griffith et. al., 1997).

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