Journal of Food Protection, Vol. 56, No. 6, Pages 548-554 (June 1993)

Implementation of HACCP in A Food Processing Plant

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(Received for publication November 19, 1992)

ABSTRACT

Hazard Analysis Critical Control Point (HACCP) systems can be used to assure the safety of food products. Management commitment is essential for a successful program. A team approach with worker involvement must be used to make the program work. Guidelines for implementation include developing a flow diagram, identifying hazards, controlling hazards at critical control points (CCP's), monitoring CCP's and recording information, and verifying the HACCP plan is working.

Food safety is of critical importance to the manufacturers of processed food products. No manufacturer wants to make or sell products which may be responsible for injury, illness, or death of a consumer. In addition, failure to assure the production and distribution of a safe food product can have disastrous economic consequences for a food manufacturer. An unsafe product which has harmed someone can result in legal actions by consumers and/or unwanted publicity that adversely affects a broad range of the company's products. Producing and selling an unsafe product may also result in regulatory actions and in the closure of the business. To avoid such possibilities and to fulfill their commitment to public welfare, food manufacturers devote significant resources to ensuring the production of safe food products. A tool which the food industry is adopting to aid in the production of safe foods is the Hazard Analysis Critical Control Point (HACCP) system.

The HACCP system was introduced to the food processing industry in the early 1970's. HACCP is a systematic approach to hazard identification, assessment and control. HACCP programs identify the potential hazards which may be associated with a food from growth, through harvesting, processing, storing, and distributing to the consumers' hands. A well-designed HACCP program will minimize the risk of developing food safety problems. Because producing safe foods is so important, HACCP programs must focus strictly on safety so that company management's clear message about food safety is not misunderstood by plant personnel and so that attention to safety does not become diluted by quality concerns.

Many manufacturers made attempts to implement HACCP in their facilities during the 1970's with the intent of assuring food safety. Almost all of those early programs were discontinued because they failed to achieve any quantifiable objective. This may be due to the fact that these programs often combined quality and regulatory programs with HACCP, diluting out the focus on safety. Such programs typically had many more "critical" control points (CCP's) than were needed to assure production of safe foods and were too cumbersome to be sustained over the long haul. Today, most manufacturers are faced with a multitude of safety, quality, and regulatory issues to monitor, but they may lack sufficient resources to monitor all points with the intensity warranted for safety assurance. Thus, unless the safety concerns are separated from quality and regulatory points and given the highest priority, they may not be given adequate attention, resulting in the potential production and release of hazardous food products.

HACCP is a management tool which focuses attention on food safety. A HACCP plan first identifies and assesses all the potential health risks that a particular food may present to the consumer. At this point expertise in food safety must be applied to discriminate between those risks which are significant and those which are so insignificant that they need not be included in the HACCP plan. This evaluation of potential risk must consider all risks associated with ingredients, production practices, and processes as well as storage, distribution, retailing, and consumer storage and use. The controls and monitoring necessary to minimize significant risks are then identified and implemented.

Criteria for selection of CCP's may differ depending on whether we are addressing a processed product, such as a precooked meat item, or a transformed/raw ingredient such as ground beef. In the case of cooked products, it is possible to eliminate pathogens during the cooking process. Thus, the goal in establishing CCP's for biological hazards for cooked products would be to eliminate contaminants and to prevent their reintroduction following cooking. But for a product such as raw ground beef, we cannot eliminate pathogens if present

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(unless the product is irradiated). The goal of our HACCP plan then is to minimize the possibility of contamination with pathogens and minimize their potential for growth. The individuality of each product and processing system must be considered in HACCP plan development. Thus, each product in a manufacturing plant will have its own HACCP plan tailored to its production system.

The purpose of this paper is to present a step-by-step approach to implementing a HACCP program in a food processing plant using a dry product as an example. Food manufacturers instituting a new HACCP program will benefit by reviewing and understanding this process. Food manufacturers who already have a HACCP program will benefit by assuring their program is focused on safety and comprehensively covers all presented areas.

STEPS IN IMPLEMENTING A HACCP PROGRAM

1. *Gain management commitment.* Senior management of a company needs to support food safety and implementation of HACCP in their processing facilities. They need to understand the benefits of HACCP as well as the commitment, costs, and implementation period for such a program. For effective HACCP implementation, visible management support and commitment are of paramount importance. Additional information is published on this area (*7*).

2. *Identify the HACCP team.* After obtaining commitment from senior management, a HACCP team responsible for implementing the program must be identified. The HACCP team should be multidisciplinary. The team should include, but not necessarily be limited to, members from manufacturing, sanitation, quality control, engineering, and research and development. Knowledge of ingredients, processing systems, potential hazards from operations, equipment, storage, and distribution rests with more than one individual or group. Evaluations of hazards, identification of controls and their limits, and developing the associated monitoring and documentation requires input from various disciplines. The HACCP team should be composed of members capable of providing this information.

   HACCP is a plant program from conception to implementation and use. A common misconception is that HACCP is a quality control (QC) program, and thus, a HACCP team should be staffed solely with QC personnel. With a team composed of QC personnel, the resultant HACCP program is generally less effective than one which recognizes the HACCP role and responsibilities of every person involved in food production. The intent of HACCP is not to increase inspections under the auspices of assuring safety; rather, the intent is to identify hazards and implement proper monitoring and control programs to assure safety of the finished product by minimizing or eliminating potential hazards during processing. The responsibility to monitor and control a particular safety point frequently rests with plant personnel other than QC; QC's role will be one of auditing and verification to assure compliance.

   For smaller food processors, where broad expertise may not be available, HACCP experts or process authorities familiar with implementation of HACCP should be consulted. Such experts may be able to assist in identifying the best composition for the HACCP team as well as providing needed expertise in deficient areas.

3. *Provide the HACCP team and line workers with training.* One or more team member(s) should be trained in the principles of HACCP and its application or implementation. This member can then serve as a resource to other team members.

   During the early stages of implementation, line workers must also be trained relative to their roles in HACCP application. Since these are the people who actually have control of an operation, they must be included in the process in order to make HACCP work. The training program should focus on the facility's products and be strongly applications-oriented. Participants should gain sufficient understanding to implement a HACCP program. The training program should focus on safety and should differentiate safety concerns from quality concerns and regulatory compliance.

   Training could be conducted by in-house HACCP experts, an outside HACCP course, or consultants brought in to aid in the implementation of the program.

4. *Utilize the following implementation guidelines.* The guidelines prescribed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) provide a general approach to implementation of a HACCP program (*6*). Other references also are available which discuss various aspects of HACCP implementation (*4,5,8,9*). Adherence to the seven principles of HACCP identified by the NACMCF (*6*) are recommended in developing the program (Table 1).

TABLE 1. *HACCP principles as defined by the National Advisory Committee on Microbiological Criteria for Food (6).*

Principle No. 1: Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.
Principle No. 2: Identify the CCP's in the process.
Principle No. 3: Establish the critical limits for preventive measures associated with each identified CCP.
Principle No. 4: Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.
Principle No. 5: Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.
Principle No. 6: Establish effective record-keeping procedures that document the HACCP system.
Principle No. 7: Establish procedures for verification that the HACCP system is working correctly.

It should be noted that the specifics of HACCP are continuing to evolve. Much of the basic HACCP information is being reviewed by such groups as the Codex Committee on Food Hygiene and the NACMCF to address difficulties and to simplify and clarify the tenets. This is encouraging, as the refinements now being made will ultimately serve to improve worldwide understanding and acceptance of HACCP as well as to make implementation easier. While descriptions and various components such as risk assessment techniques may change, the basic tenets will remain the same. The comments below highlight the current NACMCF guidelines while expanding on various areas of the process and providing recommendations that may aid in successful implementation of specific items.

a. *Describe the food and its intended use*

Information on the formulation of the food, ingredients used, intended consumer, and any special handling required during ingredient receipt, processing, product storage and distribution, retail display, and consumer use will be important to the HACCP team as it makes its evaluations. Potential hazards of a biological, chemical and physical nature that are associated with the food, its ingredients, and their processing may vary depending upon a product's handling and intended use. Sensitive ingredients historically associated with known hazards must be identified. All of this information is necessary for the team to do a comprehensive evaluation.

As an example, we have selected production of a dry product such as a cake mix. The mix is packaged dry into a retail-size box and is stored, distributed, and displayed at room temperature. The consumer will add liquid ingredients, mix, and bake. The primary hazards associated with the product are physical (foreign materials).

b. *Develop a flow diagram for the production of the food*

This flow diagram should follow the product from raw materials through finished product distribution to the ultimate consumer use. The diagram should include all points in the process from growth of raw materials, their harvest, storage, processing and distribution to manufacturers, manufacturing receipt, handling and storage, processing, packaging, storage, distribution, retail display, and consumer use. An example of such a diagram is shown in Fig. 1.

Hazards can be imparted to the food as early as the growth of the raw materials or may occur at other points up to consumption. To adequately assess the potential hazards for the product and determine proper controls, the HACCP team needs to have full knowledge of the system.

Upon completion of the flow diagram, the HACCP team should inspect the operation to verify the diagram's accuracy and completeness.

c. *Perform a hazard assessment (ingredient and finished product)*

The perceived safety hazards associated with any step, point, or procedure in the process (as detailed in the flow diagram) need to be identified. These would include biological, physical, or chemical hazards. The team should first list all perceived safety hazards without regard to the probability of occurrence or their severity. The location of these hazards should be noted on the flow diagram (Fig. 1) or on the HACCP worksheet (Table 2). As noted previously, the primary hazards in our example are physical - foreign material - although there may be chemical hazards such as fungicides applied in the field.

The team should then assess the risk associated with each hazard. The risk assessment should be directed at quantifying or qualifying the risk associated with each potential hazard, whether it be of a biological, chemical, or physical nature. Those hazards that would lead to a reasonable

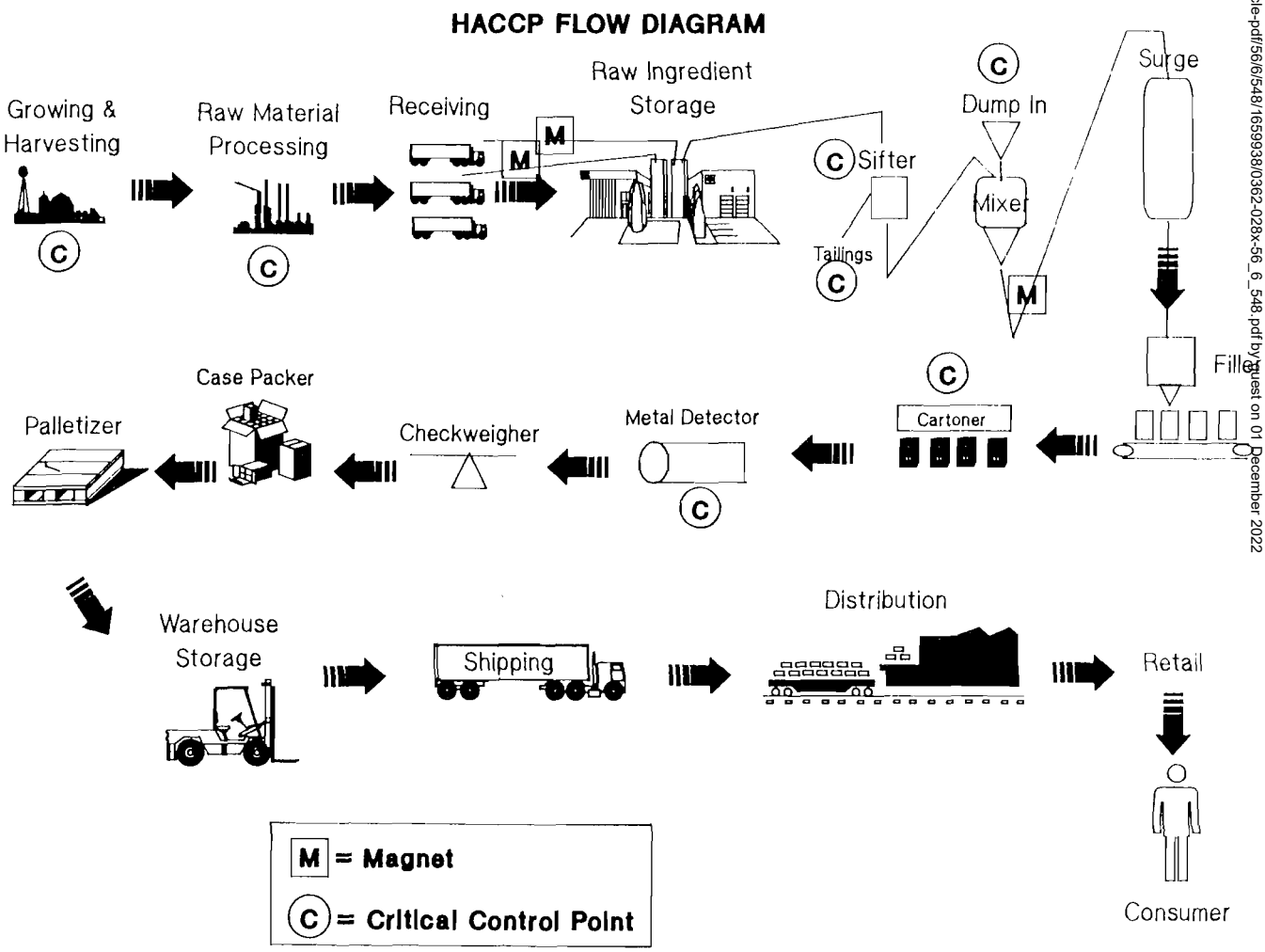
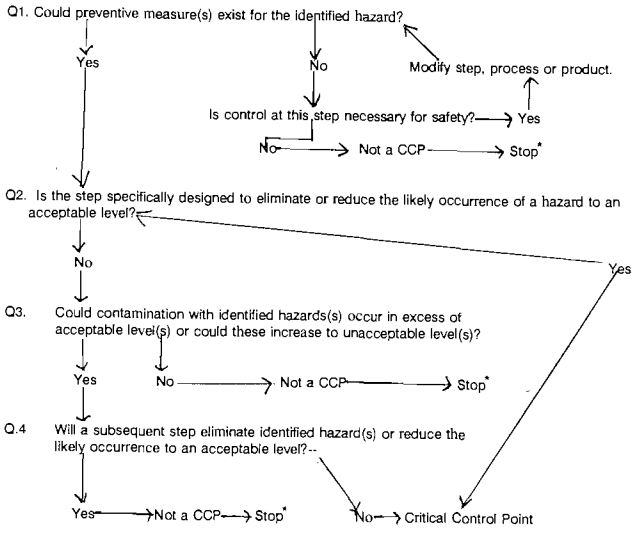


Figure 1. *HACCP flow diagram for a dry product.*

TABLE 2. *HACCP work sheet for critical control points.*

Item	Hazard	Control	Limit	Monitoring *Freq/Documentation*	Action *(for failure of CCP)*	Personnel responsible
1. Growing and harvesting	Improper chemical application	Grower records	EPA approved chemicals; specified tolerances	Certificate of guarantee for each lot; QC random audit of records and chemical assay	Reject ingredient lot baek to supplier. Inerease frequency of audit/record review	Shipment receiver QC = audit responsibility
2. Supplier HACCP programs	Chemical, physical and microbiological hazards specifieally identified	Supplier HACCP programs QC audits	No hazardous foreign material in lot	QC audits supplier HACCP program at least annually	Failure of supplier HACCP will result in delisting as supplier	QC has audit responsibility for supplier HACCP programs
3. Sifter	Hole in screen allowing physical hazards (i.e., wood, metal, glass, plastic, etc.) to pass through.	Routine monitoring of sifter screen	Intact screens	Operator check and record in processing log every shift	Defective screen will result in all product run since last check placed "on hold." System emptied and cleaned. Screen replaced. Lot rejected back to supplier.	Line operator Quality control notified and handles disposition of any product placed on hold, per standard operating procedures.
4. Tailings from sifter	Physical hazards (i.e., wood, metal, glass, plastic, etc.)	Tailings check from sifter	No hazardous material	Operator checks and records findings in Processing Log every 2 hours.	Any hazardous findings, supervisor and QC notified. All product produced since last OK check placed on hold. Ingredient lot rejected back to supplier.	Line operator. Quality control notified and handles disposition of held product and rejection.
5. Dump In	Physical hazards (i.e., wood, metal, glass, plastic, etc.)	Visual observation by mixer during dumping of bagged ingredients.	No hazardous material	Operator dumps each ingredient through 4 mesh screen and observes for hazards.	Any hazardous finding reported to supervisor. Current batch diverted and placed on hold. Mixer cleaned. Lot rejected back to supplier.	Mixer Quality control notified of hazardous findings and material placed on hold. Handles disposition of product and rejection.
6. Cartoner	Improper labeling which may cause health hazard (e.g., Yellow 5 and 6, *sulfites, etc.*)	Check off to ensure proper labels are used for product being *produced.*	Proper labels must be used.	Packaging operator reviews and records in packaging log that proper labels or cartons in use. Frequency = every 2 h and at each changeover.	Improper packages or labels must be reported to supervisor and QC. All product since last OK ehcck placed on hold.	Packaging operator QC notified of any improper packaging or labels being used. Dispositions held product.
7. Metal detector	Metal	Metal detector	No hazardous findings	Calibration checked every 2 h with appropriate test piece; recorded in metal detector log	All kick-outs checked by QC. Any hazardous findings investigated. Action to follow QC policy.	Line operator checks calibration, QC audits 2X/shift. QC handles metal detector rejections.

probability of an unacceptable consumer health risk need to be prevented, eliminated, or reduced to acceptable levels. Any point or procedure in the process where loss of control may result in an unacceptable health risk is defined as a critical control point (CCP). To determine if a point, step, or procedure in the process is a CCP, the NACMCF (*6*) as well as the Codex HACCP working group (*1*) are currently recommending use of a decision tree such as that contained in Fig. 2. When a point, step, or procedure has been associated with a significant hazard, then the decision tree (*6*) should be applied to determine if it should be designated a CCP. This procedure will help assure that the number of CCP's identified will be kept to the minimum needed to assure product safety. Minimizing the number of CCP's will help the HACCP plan stay "user friendly" and avoid the serious pitfall of being too cumbersome to function effectively. The cake mix line in our example requires only seven critical control points.



*Proceed to next step in the described process.

Figure 2. *CCP decision tree to be applied at each step of process with an identified hazard.*

Critical control points are differentiated from control points (CP's), which are points where loss of control will not result in an unacceptable health risk. Control points are generally nonsafety points related to product quality or regulatory compliance; while important, they are not regarded as part of a HACCP program.

If a CP is repeatedly violated or several related CP's are simultaneously violated, the situation may warrant placing the affected product on hold. Referring to our example of a cake mix, multiple failures of CP magnets or screens early in the system may indicate a potential safety problem. Careful review of the situation by quality assurance and food safety experts experienced in working with HACCP programs may be necessary to determine the proper disposition of this product.

The role of the HACCP team in assessing hazards is to

i. assess and recognize potential hazards in ingredients and products based on historical information;
ii. determine if the process contains a controllable step that

could eliminate or minimize the hazard;
iii. determine the risk of postprocess contamination or the hazard being reintroduced into the product;
iv. determine the risk of mishandling during storage, distribution, retail display, or by the consumer that may render the product harmful; and
v. determine the presence of a terminal heat treatment that may influence the risk to the consumer.

The above considerations allow the HACCP team to identify areas in which hazards in the food system can be reduced. This analysis may result in changing the form of an ingredient (e.g., fresh to canned), or changing a step in the manufacturing process (e.g., chilled to frozen) to reduce the risk. A modification of this model has been developed for risk assessment of chemical and physical hazards (*3*). The HACCP team should determine the method by which it wants to do a hazard analysis.

For ingredients, potential hazards need to be identified. Ideally, the ingredients as delivered to the manufacturer will be free of chemical, physical, and biological hazards. The suppliers of ingredients should be contacted to determine the existence and adequacy of their HACCP programs. To verify the acceptability of a supplier's HACCP program, it should be reviewed on paper, the plant may be visited, and the HACCP program audited. Collaborative studies on analytical tests to verify accuracy may also need to be performed.

If the above are acceptable, an occasional random audit of the supplier's program is suggested to verify continued acceptability. If the supplier lacks a HACCP program, control of the hazards associated with the ingredient relies on the following steps: ingredient specifications, letters of guarantee, vendor visits (if possible), vendor record review, and statistical lot acceptance testing for hazards. As the supplier develops a HACCP program, lot acceptance testing would be replaced by a reduced frequency audit program. If the supplier lacks an acceptable HACCP program, the manufacturer needs to establish sufficient controls within his own manufacturing program to assure product safety. If a significant hazard is determined to exist, a CCP with attendant controls and monitoring should be established.

d. *Select CCP's, enter on the flow diagram*

All identified safety hazards determined to be of significance must be controlled at some point in the food processing system. As noted previously, a critical control point is any point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. If a hazard is identified which cannot be controlled, then the process may need to be redesigned or the product reformulated. CCP's are related to safety and are established only at points where hazards exist which are not controlled at some other point. For example, the cake mix line (Fig. 1) contains several magnets to remove metal particles; however, a metal detector after packaging serves as the critical control point. Other examples of CCP's include cooking, retorting, chilling, thawing, sifting/scalping, pesticide application during growth of raw material, etc. CCP's are identified on the flow diagram (Fig. 1) and then entered on the HACCP work sheet (Table 2). As noted above, a decision tree approach (Fig. 2) should prove useful in determining whether to establish a CCP at a particular process step.

e. *Establish critical limits*

Critical limits on biological, chemical, and physical hazards represent the boundaries of safety and must be defined for each CCP. A CCP may have more than one critical limit. A critical limit is defined as one or more prescribed tolerances that must be met to insure that a CCP effectively controls a health hazard. A critical limit should never be violated. If any one of the critical limits is violated, then the CCP is out of control and the potential for an unacceptable health hazard exists. Examples of critical limits include minimum processing time and temperature, maximum refrigeration holding temperature, minimum hot holding temperature, maximum pesticide application level, maximum screen size on sifter, maximum pH, maximum fill weight, maximum viscosity, etc.

Violating or deviating from a critical limit at a CCP indicates the CCP is out of control. Deviating from the limit should indicate a health hazard could develop; that a product was not produced under conditions assuring safety; or that the safety of the product may be adversely affected by other factors such as raw materials (*2*).

Outside resources may be necessary to determine the limits of a CCP. These may include, but not be limited to, literature searches, supplier's records/data, regulatory guidelines, and various experts (thermal process authorities, consultants, microbiologists, equipment manufacturers, sanitarians, etc.). Experimental studies may be necessary to fully define the limiting parameters for a CCP.

The critical limits for each CCP should be documented. A column on the HACCP work sheet (Table 2) should note the acceptable critical limits for that CCP.

Documentation on how each of the critical limits were derived should be kept as part of the formal HACCP plan. This is particularly important if critical limits were derived from in-house experimental studies.

f. *Establish monitoring requirements*

The monitoring methods and procedures for each CCP need to be identified to ensure that the process is within the critical limits and that no safety hazard exists. The method or procedure, the frequency of monitoring, and the accountability for monitoring should be listed on the HACCP work sheet (Table 2).

Monitoring procedures must be effective to assure safety. Ideally, monitoring of CCP's should be done at the 100% level (i.e., continuously). When it is not possible to monitor the CCP on a continuous basis, the proper interval for monitoring should be established so that food safety is assured. Most monitoring procedures are automated for rapid on-line measurements; time for lengthy analytical testing is generally not available. Microbiological testing is seldom effective as a monitoring procedure for this reason. Chemical and physical measurements, correlated to microbiological results, are preferred due to their timeliness and potential for automation.

All supporting documentation on the monitoring methods, accountability, frequency, etc. should be part of the formal HACCP plan and retained by the manufacturer.

g. *Establish corrective action to be taken when there is a deviation identified by monitoring of a CCP*

Corrective action should be designed to bring the process back into control (i.e., correct the deviation). All product produced while the CCP was "out-of-control" should be placed "on hold." Generally, this would include all product produced since the last acceptable reading was taken at the monitoring point of the CCP and to the point where the records show the system to be back under control.

Disposition of the product involved in the deviation should be determined according to a pre-approved action plan. This pre-approved plan should be generated or approved by the HACCP team. Examination of any product "on hold" to determine its acceptability with regard to safety should follow an appropriate attributes sampling plan. This statistical sampling plan will assure sufficient sampling to verify safety or detect a potential hazard. Documentation of the event should be sufficient to identify the disposition of all product involved in the incident and all action taken to correct the incident and prevent reoccurrence. This documentation should be retained by the manufacturer.

The corrective action plan or reference where it can be obtained should be noted on the HACCP work sheet. This action plan should be part of the formal HACCP plan.

h. *Establish effective record keeping procedures that document the HACCP plan*

Each manufacturing facility should have a formal HACCP plan that effectively documents the HACCP program for each product. Each product should have its specific HACCP program tailored to its process. This program should include adequate documentation, as it relates to safety, on

- the ingredients, their specifications, sourcing, and compliance with specifications;
- the manufacturing process, including identification of CCP's, their limits, and controls;
- product safety records establishing adequacy of process or formulation, as well as product shelf life;
- packaging records as they relate to safety;
- action plans for deviations, product disposition;
- verification programs.

Each CCP should be documented. This documentation should include the identification of the CCP, its limits, frequency of monitoring, person accountable for monitoring, and a shift check-off sheet signed or initialed by the accountable party denoting each time the CCP monitoring procedure was checked. An appropriate verification program should also be in place to audit these sheets.

i. *Establish procedures for verification that the HACCP system is working properly*

The purpose of verification is to determine that the HACCP system is operating in accordance with the HACCP plan. Verification uses supplementary information to ensure that the HACCP program is working.

Examples of verification activities include

- checks on the proper functioning and accuracy of CCP monitoring equipment (routine calibration);
- spot checks of CCP records to verify the adequacy of monitoring and verify HACCP performance;
- environmental sampling for microbiological pathogens, swabbing of product contact surfaces, and finished product testing for bacteria indicative of insanitary conditions;
- random collection of ingredient or product samples to verify adequacy of CCP monitoring and control;
- review of all deviations and dispositions;
- review of the HACCP plan.

The results of all verification procedures should be documented. The report should include the verification of a functioning HACCP plan, intact and fully completed records and documents associated with CCP's, records verifying proper calibration and operation of all monitoring equipment, and proper handling and documentation of deviations.

The HACCP system should also occasionally be verified by an independent auditor (i.e., corporate office, process authority, etc.). This can be done on either a routine or an unannounced basis.

HACCP program review is recommended whenever there is an ingredient change, product reformulation, manufacturing process or procedure modification, or equipment change. The HACCP team should review the HACCP program during these events or on a yearly basis, whichever occurs more frequently.

CONCLUSION

The HACCP concept, which focuses on food safety, is a systematic approach to hazard identification, assessment, and control. The system offers a rational approach to the control of biological, chemical, and physical hazards in foods; it avoids many weaknesses inherent in the traditional, end-product inspection approach. The focus of the system is to direct attention to the control of key factors that affect the safety of the food. HACCP is applicable to all parts of the food chain from production through processing to use in the home.

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Harris and Cuppett, *cont. from p. 542*

effective inhibitor of lipase than its corresponding saturated fatty acid ester, stearic acid (C18:0).

It is interesting to note that although the divalent Ca^{2+} ion has been shown to activate lipolytic activity (*5,16,19*), CSL, at a 2% concentration, was an effective lipase inhibitor. Replacing the calcium ion (CSL) with a sodium ion (SSL) enhanced the inhibitory ability of the stearoyl-2-lactylate emulsifier at a 1% concentration approximately twofold (Table 1). These results, in combination with those of Dring and Fox (*7*) and Deeth and Fitz-Gerald (*6*), could implicate the sodium ion as being partially responsible for some of the observed lipase inhibition by SSL.

Esterification of the sodium stearate with two lactic acid groups resulting in the formation of sodium stearoyl-2-lactylate (SSL) did enhance its effectiveness as a lipase inhibitor to a small degree. In contrast to this effect, it is possible that the esterification of stearic acid to form calcium stearoyl-2-lactylate may have partially facilitated the effectiveness of CSL as a lipase inhibitor at the higher concentration (2%) by negating any stimulatory tendencies displayed by the divalent Ca^{2+} ion.

Based upon this study, emulsifiers such as sodium oleate, sodium stearate, and sodium and calcium stearoyl-2-lactylate can be effective inhibitors of lipases originating from *Pseudomonas* spp. in NFDM at concentrations $\geq$ 2%. Although not conclusive, there was limited evidence that the sodium ion and the unsaturated fatty acid, oleate, may have played a role in inhibiting lipase activity. Further research is needed to determine the effectiveness of these emulsifiers in inhibiting lipase activity on a long-term basis.

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