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HACCP: Present Status and Future in Contribution to Food Safety

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ABSTRACT

An implemented and maintained hazard analysis critical control point (HACCP) system offers high assurance of food safety. The HACCP system is rational because it is based on historical data about causes of illness and spoilage; it is comprehensive because it takes into consideration ingredients, processes and subsequent use of products and is applicable at all links of the food chain; it is continuous because problems are detected when they occur and action is taken then for correction; and it is systematic because it is a thorough plan covering step-by-step operations and procedures. It is presently the state of the art, and science, of food safety.

The HACCP approach is being used by some health and food regulatory agencies as well as progressive food industries. Internationally, it is (a) being incorporated into Codex documents (*17*); (b) endorsed and promoted by the International Commission on Microbiological Specifications for Foods (*25*); (c) developed into practical how-to-do-it manuals by the International Association of Milk, Food and Environmental Sanitarians (*13*), Campden Food and Drink Research Association (*23*), and International Life Sciences Institute Europe (*26*); and (d) being taught in training courses by the World Health Organization (*5,36*), other groups and consultants. In the United States of America, as an example of national activity, it is mandatory for use by processors of low-acid canned foods (*33*). It is promoted for use for fish and shellfish processing (*29,30*). Applications of it are also being used for processing meat and poultry (*18,28*). Some state and local regulatory agencies, but not all yet, are converting traditional inspections to HACCP promotion, consultation and/or verification activities for foodservice operations and markets (*16,22*). The State of Maryland has required its application for foodservice operations. The Food Marketing Institute (*3*), University of California, Davis and the National Food Processors (*31*), and the Education Foundation of the National Restaurant Association (*20*) have developed HACCP reference manuals. Several of these actions are well known by those in leadership of the food safety movement. This paper will address the present status and use of HACCP in retail food operations which is less well known than its use by food processors, and it will give predictions for the future.

PRESENT STATUS

HACCP Development in Retail Stores. Development of HACCP systems in retail stores is often more complex than it is for food processing plants in which only one food item is processed or only a few "straight" lines are used to process a number of foods in similar manner. Foodservice operations seldom have straight line conveying of foods. Development of HACCP systems for them involves coverage of all potentially hazardous foods which frequently totals between 50 and 500 foods. Because of this, HACCP systems are usually developed for groups of foods that have similar characteristics and/or processes. The process for development of HACCP systems is similar to that used by food processors, and the same principles are involved. It, however, may be done by one person rather than a team of company specialists.

Hazard analyses consider (a) reviewing epidemiological data about the food or food group in question; (b) testing pH and water activity of foods if these characteristics appear critical to its control or shelf stability; (c) reviewing formulations or recipes for anticipated hazards from ingredients and operations; (d) evaluating actual or potential contamination, survival and growth of microorganisms by observing each step of the operations; (e) making appropriate tests (e.g., analysis for microorganisms, chlorine concentrations) and measurements (e.g., measuring time-temperature exposures during cooking, hot holding, holding at room or outside ambient temperatures, cooling and reheating) to provide more information to evaluate microbial survival and growth; and (f) conducting challenge tests when necessary to gather data unidentified from the above activities and to confirm or refute hypotheses that are conceived during the analyses. Next, severity of potential outcomes (e.g., illness or spoilage) and risk of the hazards are assessed.

Flow diagrams, for example, foods in each category should list each ingredient and illustrate sequential operations for the preparation of the food. Each step of preparation is highlighted by a box surrounding a term that represents the step. Symbols for hazards are inserted (a) besides contaminated ingredients, (b) after preparation steps where observed, measured or anticipated contamination occurred or is likely to occur, (c) at processes in which microorganisms are likely to survive, and (d) when conditions prevail by which, and intervals within which, bacteria or molds multiply. Symbols

for critical control points are inserted adjacent to appropriate boxes to emphasize operations where the hazards could be controlled or prevented. Some preventive or control measures at critical control points (CCP) eliminate hazards resulting in nil risks. Others prevent further development, but they do not eliminate preexisting hazards. Others, however, only minimize, reduce or delay hazards, but they neither eliminate or prevent them. Still others either fail to prevent or control certain hazards or are not monitored, and thus it is unknown whether the preventive and control measures achieve their intended purpose. Hence, varying degrees of risks may remain.

The flow diagram is not the end product of a HACCP system, it's only a guideline for its development. HACCP systems consider each operation in relation to (a) hazards, (b) degree of concern (e.g., about the hazards' severity and risk) (c) type critical control point, (d) control measures and criteria (critical limits) at critical control points, (e) monitoring procedures, (f) monitoring record and responsibility, (g) corrective actions, and (h) verification activities. Monitoring forms are developed for use at various work stations and by managers. Verification forms are developed for use by quality control personnel.

Drafts of HACCP systems and supporting data should be reviewed by key members of quality control, production and product design staff whether or not they have been a part of a team that developed the systems. The HACCP systems should be revised, if necessary, following this consultation. Furthermore, the systems will require revision whenever (a) new foods are added to the menu, (b) different ingredients from those that were added at the time the systems were developed are used, (c) different or new equipment is employed during preparation or holding of the foods, (f) additional hazards are observed during verification visits, or (g) scientific or epidemiological studies identify previously undetected hazards.

At its completion each HACCP system must be critically reviewed by the developer(s) and summarized in what hazards it eliminates, prevents, minimizes, reduces or delays and what hazards remain and the relative risks of these outcomes. Such analyses are essential following development of HACCP systems to avoid misunderstanding or over confidence. Priority for attention, training and supervision must be at critical control points, which are operations where control can be attained and where monitoring is done to ensure food safety. Highlights abstracted from the systems (including listings of hazards, control procedures and monitoring procedures and responsibilities) can be used as (a) notices in stores, (b) in recipe books, cards or disks, and (c) in operational manuals. Steps for development of HACCP systems and suggestions for implementation are illustrated in Fig. 1.

Success of HACCP systems depends on management commitment. Executives must support the principles of the HACCP concept and supervisors of departments must give high priority to implementation of the systems. Store managers, supervisors and persons who are to monitor critical control points will need to be trained in (a) criteria for control, (b) monitoring procedures, (c) use of monitoring forms, and (d) corrective actions (*4*). Quality control personnel will have to be (a) oriented to the HACCP systems, (b) focused toward new priorities and (c) trained in procedures to verify the effectiveness of monitoring procedures. Store or corporate procedural manuals will have to be modified to incorporate appropriate aspects of the HACCP systems. Meanwhile supplemental sheets will have to be issued.

During verification visits, quality control staff should be alert for: (a) failures to monitor effectively a critical control point or to take appropriate corrective actions; (b) falsification of monitoring records; (c) lack of discipline in monitoring and verifying by store personnel; (d) improper corrective actions when monitoring detects that the critical limits are not attained; (e) modification of either recipes or procedures that circumvent control, monitoring or corrective actions; (f) previously unidentified hazards; (g) additional or omitted critical control points that can be effectively monitored; and (h) new ingredients, modified recipes, procedures or equipment that may affect food safety. Upon detection of the latter (h), procedures, or equipment, HACCP systems should be reviewed and revised as necessary. Regulatory agencies may observe further deficiencies in either the systems or its implementation during HACCP plan reviews, inspections or verification visits. If so, HACCP systems will require further adjustment.

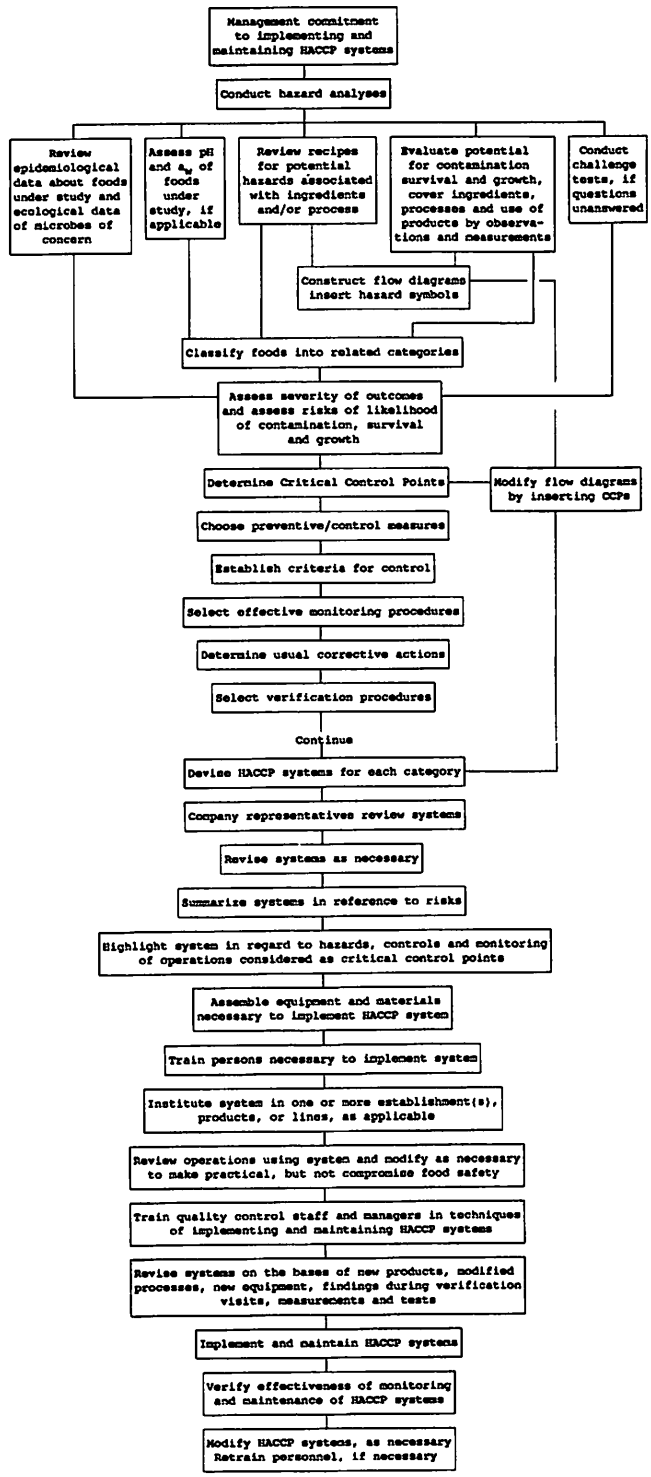
Regulatory Agency Actions. For approximately a decade, some state or local regulatory agencies have experimented with or utilized a HACCP approach (*16*). Several of them have switched from traditional sanitation inspections to critical item focused inspections. Some have conducted hazard analyses of foods of concern because of their frequent involvement as vehicles of foodborne diseases (*6,7,8,9,10*). Others (*22*) have conducted hazard analyses and focused on verification of critical control points based on factors that contribute to foodborne outbreaks (*1,2,19,32,34*). Furthermore, the Food and Drug Administration (FDA) in cooperation with some state and local jurisdictions have demonstrated by field trials that HACCP is a viable and practical option to improve food safety (*21*).

The Commissioner of the Food and Drug Administration has stated that "...application of hazard analysis critical control point (HACCP) principles at retail is the best available system for assuring food safety..." (*21*). The new FDA food code (*21*) for retail operations endorses it and recommends its implementation and allows variance from requirements if approved HACCP systems are implemented and maintained. For example, it states that..."FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to assure that food products are safe. A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies...A HACCP system allows regulatory agencies to more comprehensively determine an establishment's current and past conditions...Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventive compared to the HACCP approach for assuring food safety...FDA believes that HACCP concepts have matured to the point at which they can be formally implemented for all food products on an industry-wide basis. HACCP is a systematic approach to food safety which will dramatically improve the level of

food safety...An effective national food safety program from food production to consumer is enhanced by the implementation of HACCP. Implementation of HACCP programs by the establishments will profoundly enhance their role in the protection of public health beyond the traditional emphasis on facility and equipment design and maintenance and adherence to the principles of sanitation, good manufacturing and food preparation practices." These quotes show considerable progress of the FDA from past positions, and the need for training state and local health and regulatory agency and food industry personnel so that they reach the same conclusions.

Under the 1993 Food Code, food processing operations at retail food establishments (e.g., reduced oxygen packaging, curing and smoking) must be done according to an approved HACCP plan. Additionally, establishments can seek a variance from the requirements of the Code by submitting a HACCP plan for approval. Such plans must include flow diagrams, product formulations, training proposals, corrective actions that will be used, and verification activities. The plans must contain sufficient detail to allow the regulator to fully understand the operations and intended controls.

Figure 1. *Activities for developing HACCP systems for foodservice operations.*



Duties of the person in charge that are specified as HACCP-related include verifying: (a) employees' handwashing; (b) employees' evaluation of foods upon receipt; (c) employees' routine monitoring of food temperatures after cooking; (d) employees' routine monitoring of food temperatures during cooling; (e) that consumers are informed that raw or partially cooked foods of animal origin may cause foodborne illness; and (f) employees' monitoring of solution temperature and exposure time for hot water sanitizing and concentration, pH, temperature, and exposure time for chemical sanitizing of equipment and utensils during cleaning.

Based on the risks of foodborne illnesses inherent to the food operation, during inspections and upon request, the person in charge is required to demonstrate to the regulatory authority knowledge of foodborne disease prevention, application of the hazard analysis critical control point principles, and requirements of the Code. This dictates training in these subjects.

According to FDA guidelines which are annexed to the Food Code (FDA, 1993), the field orientation of sanitarians and inspectors should include at least one full HACCP inspection to acquaint them with sequential food operations. The inspector should be able to demonstrate proficiency with gathering information about the process, including accurate diagraming of food flows and determination of critical control points and their critical limits. The HACCP training exercise should include defining practical monitoring at critical control points, recordkeeping, actions to take when critical limits are not met, and preparation of a comprehensive report of the exercise. The training officer should critique this report.

According to FDA (1993) guidelines, "inspections" or official verifications of establishments operating under HACCP plans include a review of specifics of the plan. Foods that have been more frequently implicated in foodborne illness, those prepared in large volumes, and those requiring manual assembly prior to service should receive high priority for review. Critical limits to be measured or sampled during the visit include food temperatures, pH, water activity, and sanitizer concentrations in reference to temperatures and times at which pathogen are killed or their growth is limited. The verification should include whether critical control points are monitored at a frequency that ensures control.

FUTURE

To predict the future is speculative. Many seemingly unrelated and sometimes unpredictable events influence outcomes, particularly of actions that persons or companies take. It may take a long time for some of these predictions to become reality. A few generations of program administrators will probably pass before all of them will occur. Implementation of the HACCP approach to food safety has already endured a 25 to 30-year lag period since the concept evolved and was initially applied.

HACCP systems for at least potentially hazardous foods will become commonplace because of actions by that portion of the food industry that want to present high-quality products to their customers or want to minimize risks of their products causing foodborne illness or being subject to recalls and associated adverse publicity. In countries that demand or desire a high level of food safety, HACCP systems for potentially hazardous foods will become mandatory by law or regulation. Requirements of imports will demand statements that foods have been produced, processed and shipped under the protection of officially verified HACCP systems. If it is not a national policy, requirement for HACCP systems will be made by certain States or Provinces or even by certain progressive local jurisdictions. Recommendations to this effect have already been made by working groups and expert committees (*17,33*).

Hazard (e.g., microbiological) modeling will be an aid in hazard analysis. Computer software for this purpose is already available from the U.S. Department of Agriculture and the Institute of Food Research (U.K.). Computer programs will become available to guide those interested in developing HACCP systems. (At this time at least one such program is available from Campden Food and Drink Research Association.)

Hazard analyses will be conducted of ethnic foods in developing countries, and on these bases, priorities will be set for regulatory and educational activities. Food safety programs will shift from emphasis on aesthetics and items of minor sanitary significance to the operations foods undergo. Education will emphasize practical solutions to problems associated with contamination, survival and growth of foodborne pathogens in the foods processed in cottage industries, prepared and displayed by street and small shop vendors, and the public. Initial activities of this sort have already been done (*11,12,14,15,24,27,35,37*), but much more needs to be done. The findings should be used to change program focus and to implement applicable food safety activities.

Monitoring will become more technically sophisticated even at the retail level. For temperature monitoring, for example, thermocouple probes will be inserted into foods and information such as doneness or lack of compliance with the criteria set for critical control points will be signaled and/or recorded. In some cases the measurements will be recorded, saved and printed out on request at the site or at corporate headquarters. The data will become part of HACCP records available for verification. Technology to implement this is available and will become cheaper as its demand increases. Each establishment or chain will have verification forms for use at various work stations, by managers, and by quality control staff. As time goes by these will become automated and saved on computer disks for verification purposes. Training will be an essential element of implementation of HACCP systems. The training will need to be designed for (a) persons who will conduct HACCP evaluations and who will set-up the HACCP system, (b) persons who prepare and process foods at critical operations, (c) persons who monitor critical control points, (d) persons who supervise operations involving critical control points, (e) persons who verify critical control points, and (f) persons who administer food safety, food quality assurance and food regulatory activities (*4*). The training programs for persons who monitor critical control points will lead to certification, which will become mandatory in some jurisdictions. Such training will be sponsored by food industry associations, professional organizations and State/Provincial or national food regulatory or health promotional agencies.

Purchasers at the retail level will specify that processors have verified HACCP systems. Large retail companies or chains with quality control staff will verify processing operations with their staff; others will require evidence that critical control points are monitored effectively. This may not entirely replace end product specifications, but these will provide only partial evidence of verification and not be the primary food safety criterion; a HACCP plan will provide the focus. Actions of this sort by some food chains are already taking place.

These actions by purchasers and regulatory agencies will create a degree of confusion and non-uniformity of inspections and training. As frustration builds, action will be taken to put all available HACCP systems with identification of critical control points, monitoring procedures and verification approaches in computer networks. This may be done either by appropriate regulatory agencies at State/Provincial and national levels and/or by food industry associations or perhaps by an entrepreneur. This will allow a company to distribute elsewhere its HACCP systems to those who use and regulate it. This will result in the uniformity that the food industry has longed for. The networks will link all communities in which a food chain has stores. Approval will be done by either a centralized agency or at the community or State at which the company has its headquarters. In the later case, those giving approval will be trained and certified by a centralized agency. Systems for all food groups for any food chain or processor can be called up by the computer at any location linked to the network. Inspectors will be guided on what to look for and questions to ask to verify food safety for the item and place under investigation.

Such a network will expand nationwide if it does not start at that level. International agencies will sponsor working groups to standardize the networks. They may even establish computer networks of their own to distribute the systems to all countries having stores of food chains or receiving foods from a processor. This will at least be a recommendation of some working groups.

Such actions will make a dynamic impact on prevention of foodborne illness. "Safe foods for all through the HACCP approach," or words to that effect, will become an internationally used slogan.

Surveillance of foodborne disease will intensify and upon detection of outbreaks, HACCP systems will be established or modified. Other places processing or preparing the same foods or having similar operations, will be alerted and actions taken to ensure the implementation or readjustment of HACCP systems. Summary data will include incidence of foodborne disease cases and outbreaks, prevalence of vehicles, and relative risks of factors that contributed to the causation of the outbreaks. Regulatory, training and education activities will focus on epidemiological data and be revised based on contemporary events and food processing and preparation practices.

The HACCP concept has come out of the lag phase and is in a phase of rapid employment. The future will record that it replaced traditional approaches such as inspections, health examinations, and end product testing. HACCP is the future of food safety. The sooner that all involved with food production, processing, distribution, storage, marketing and preparation of foods learn this, the sooner that foodborne diseases will disappear and only become an interesting note in history books and a reminder that a HACCP system was either improperly designed, implemented or maintained.

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