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Ensuring Food Safety and Quality:

A Review of HACCP and ISO 9000 Systems

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Ensuring Food Safety and Quality:

A Review of HACCP and ISO 9000 Systems

Including a Section on the Newly Proposed U.S. FDA Seafood HACCP Program

by

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TABLE OF CONTENTS

	Page
INTRODUCTION	1
THE HACCP SYSTEM	1
The History of HACCP	2
The Seven Principles of HACCP	3
The HACCP System	3
THE ISO 9000 SYSTEM	8
ISO Program Elements	9
ISO Quality System Requirements	9
ISO Costs	13
INTERNATIONAL TRENDS IN ISO 9000 AND HACCP	14
THE SEAFOOD HACCP PROGRAM	15
The FDA Proposal	15
Importer Obligations	17
Estimated Costs	18
Applying Seafood HACCP	19
REFERENCES	21

LIST OF FIGURES

Figure		
1	Customizing the HACCP System	4

INTRODUCTION

Ensuring the safety of food products is mandatory no matter where they are produced or processed, or where they are consumed. Ensuring product quality is, similarly, an essential element of the food trade, both domestic and international.

Increasingly in today's international economy, the ability of both government officials and industry representatives to regulate many food processing establishments is diminishing. At the same time, manufacturing processes are becoming increasingly complex, often making more difficult the task of assessing and controlling the manufacturing process. These two elements, combined with consumer demand for safe and high-quality food products, are moving the international food industry and its regulators toward a new systems approach to ensuring both product safety and quality. Two distinctly separate but related programs that promote this systems approach are seeing increasing use in today's food industry. The first is the Hazard Analysis and Critical Control Point (HACCP) program. The second is the International Organizations for Standardization (ISO) 9000 quality management standards series, or ISO 9000.

The focus of HACCP is food safety. The focus of ISO 9000 is overall quality, which, for foods, necessarily incorporates safety. HACCP has its origin within the U.S. food industry whereas ISO 9000 has its origins within the European Union, modeled after an analogous British standards series. HACCP is a foods-based system; ISO 9000 relates generally to all manufactured goods and services, of which food is but one.

This paper addresses the functional and structural aspects of HACCP and ISO 9000 within the food industry. Additionally, because the U.S. Food and Drug Administration (FDA) has proposed the use of HACCP as the regulatory control mechanism of choice for both U.S.-produced and imported seafood products, this paper includes an overview of the new FDA *Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products*, referred to as the seafood HACCP program.

This paper is not intended to be a thorough review of either HACCP or ISO 9000, but a general overview to provide a background on the two systems. References at the end of this paper provide a guide to additional reading on both systems.

THE HACCP SYSTEM

What is HACCP? What are its elements and history, and how is it applied to food to ensure product safety?

HACCP is a systems approach used within the food industry to ensure product safety. HACCP involves a systematic study of food products and their ingredients, handling, storage, packaging, and distribution, and consumer use to determine the following:

- Potential hazards that could lead to an unsafe product;
- Points that must be controlled to prevent a problem from occurring (these are the critical control points, or CCPs);

- The critical limits for CCPs; and
- The monitoring, documentation, and follow-up that must be done to keep the system working properly.

HACCP is designed to control both the actual processing of the product as well as the general sanitation of the food production establishment. Additionally, depending on the product and the extent of a firm's involvement with it, HACCP can control hazards associated with the growing of a crop (pesticide applications) or the storage, distribution, and retail sale of the product (time and temperature conditions regarding product storage).

The History of HACCP

The history of HACCP (Corlett and Pierson, 1992) is interesting. HACCP had its origins in the U.S. space program when, in 1959, the Pillsbury Company was asked to produce a zero-defect food for the U.S. National Aeronautics and Space Administration (NASA). Apart from the technical problem of creating bite-sized foods that would not crumble in space and contaminate the environment, there was the need to make absolutely sure the food would not cause illness leading to an incapacitated crew or aborted mission. Working in conjunction with the U.S. Army Natick Laboratory, the U.S. Air Force Space Laboratory Project Group and NASA, Pillsbury examined existing zero-defect programs and found they were designed for durable manufactured goods and used nondestructive testing procedures (such as X ray and ultrasound) that were inappropriate for the food industry. Because the testing of food products to detect safety problems such as hazardous chemicals or bacterial pathogens necessarily involves destruction of the sample, 100 percent testing would obviously be unacceptable.

The Pillsbury team, led by Howard Bauman, thought that if they could develop a preventive system, one that could control and monitor raw ingredients, processing, the environment, personnel, and storage and distribution, they could be reasonably certain that the end product would not fail. Pillsbury found that the Natick Laboratory had developed such a system of analysis called "modes of failure" for use with medical supplies. This model was adopted and modified, becoming the prototype for the HACCP system.

The HACCP system was first presented to the public at the 1971 National Conference on Food Protection. Pillsbury subsequently conducted classes for FDA personnel in the HACCP system and, in 1973, published the first comprehensive document on HACCP. The FDA's acidified and low-acid canned food regulations, also established in 1973, use the HACCP system as the approach to regulatory control although without using the term HACCP or its nomenclature.

Serious consideration of HACCP's broad application to the food industry began in 1985, when the U.S. National Academy of Sciences, in its publication "An Evaluation of the Role of Microbiological Criteria for Food and Food Ingredients" (NAS, 1985), recommended the use of the HACCP system in controlling microbiological hazards in foods. The subsequent U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) developed a pamphlet titled "HACCP Principles for Food Production" (NACMCF, 1989), which was later revised and retitled "Hazard Analysis and Critical Control Point System, National Advisory Committee on Microbiological Criteria for Foods" (NACMCF, 1992).

In 1987, the U.S. National Oceanic and Atmospheric Administration (NOAA) was given a U.S. congressional mandate to design a program of certification and surveillance to improve the inspection of

fish and seafood consistent with HACCP. This effort has been carried out by the National Marine Fisheries Service (NMFS) with implementation of a program centered around *The Report of the Model Surveillance Project: A Report to Congress* (NMFS, 1991). At the same time, the U.S. Department of Agriculture also began a study of HACCP for use in meat and poultry production establishments.

The Codex Alimentarius Commission has also recognized HACCP. At its June 1991 meeting, the Codex Committee on Food Hygiene accepted from its HACCP Drafting Group a draft document on HACCP, which the committee has circulated for comment (Codex, 1991).

Most recently, in January 1994, the FDA announced its *Proposal To Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products* (Federal Register, January 28, 1994). This proposal, if adopted, would use the HACCP system to establish mandatory controls to ensure the safety of seafood products sold commercially in the United States and exported.

The Seven Principles of HACCP

The HACCP system is constructed around seven principles recognized as the heart of HACCP by industry, regulatory agencies, and Codex (Corlett and Pierson, 1992). These principles are as follows:

- Conduct a hazard analysis. Prepare a list of steps in the food production and handling process during which significant hazards occur and describe appropriate preventive measures to adopt.
- Identify the critical control points (CCPs).
- Establish critical limits for preventive measures associated with each identified CCP.
- Establish CCP monitoring requirements and procedures for using the results of monitoring to adjust the process and maintain control.
- Establish corrective action to be taken when monitoring indicates a deviation from an established critical limit.
- Establish effective record-keeping procedures that document the HACCP system.
- Establish procedures for verifying that the HACCP system is working correctly.

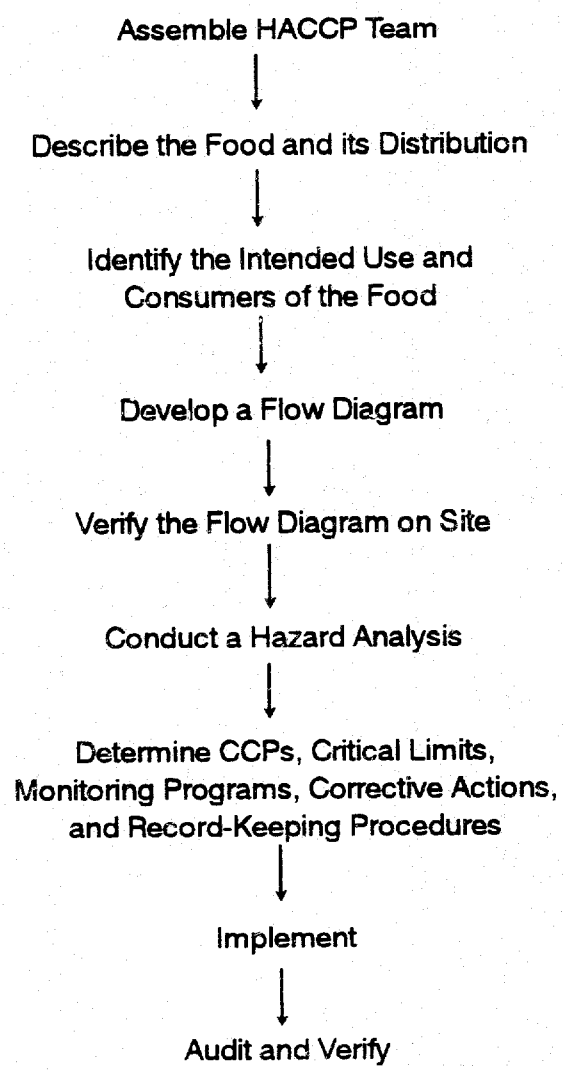
The HACCP System

HACCP is a step-by-step approach incorporating the principles above to determine (1) the potential hazards associated with product, (2) the CCPs that must be controlled to prevent the hazards from actually occurring, (3) the critical limits that must be imposed at the CCPs that cannot be exceeded if the product is to be safe, and (4) the documentation, monitoring, and verification needed to ensure that the system is working and that it continues to provide the means by which product safety can be ensured (Corlett and Pierson, 1992).

Food processors customize HACCP to their specific plants and products using the process summarized in Figure 1.

FIGURE 1

CUSTOMIZING THE HACCP SYSTEM



The first step in the process is to assemble the HACCP team. This team must be expert in the product and its processing. The team should include experts in production, sanitation, engineering, quality assurance, and food microbiology and include both local individuals knowledgeable in the daily operations of processing plants and corporate management — and, if necessary, consultants expert in HACCP.

The team first describes the food and its method of distribution. This description details the product, its recipe or formulation, whether it is shelf stable or distributed refrigerated or frozen, how the distribution channel will work, and the potential for abuse in the system. The customer type also should be specified — that is, whether the food will be consumed by the general public or by special groups such as infants, the elderly, or immuno-compromised individuals such as those with AIDS or cancer. Foods consumed by special groups will likely require additional controls and more stringent critical limits.

A complete and detailed flow diagram must be prepared that represents all steps in the process, from sourcing of ingredients to processing, packaging, and distribution. The flow diagram for a firm that actually produces the raw agricultural commodity should go all the way back through the actual crop production practices. Similarly, the flow diagram for a firm involved with the distribution and sale of the product should incorporate these elements. The flow diagram should be verified in an on-site visit and analysis.

The next steps encompass the actual HACCP principles.

Conduct a Hazard Analysis (Principle No. 1)

This is a step-by-step analysis of the entire process to identify the potential hazards associated with the product. A potential hazard might include a pesticide application to food in the field or in a storage bin. It might be an ingredient that allows illness-causing bacteria to grow, the design of a piece of equipment, the ability to monitor a cooking or chilling process, or a personnel hygiene practice. For inclusion in the list, the hazards must be serious enough that their prevention, elimination, or reduction to acceptable levels is considered essential to the production of safe food.

Hazard analysis is done by asking a series of questions about the product. Examples include: Does the food contain any ingredients that may present microbiological hazards? Are pesticides applied and, if so, when — before or after processing? Does the process include a controllable processing step that destroys microbial pathogens? Does the layout of the processing facility provide adequate separation of raw from ready-to-eat foods if this is important to food safety? Is the package clearly labeled *Keep Refrigerated* if this is important for safety?

The NACMCF uses a risk categorization approach to rank foods. Foods are first described based on their number and the types of hazards they pose. Six main hazard classes are described:

- Nonsterile foods designated and intended for consumption by at-risk populations such as infants or the elderly;
- Products that contain sensitive ingredients in terms of microbiological hazards;
- Products whose processing does not entail a controlled step that effectively destroys harmful microorganisms;

- Products that are subject to recontamination after processing and before packaging;
- Products that have substantial potential for abusive handling by distributors or consumers that could render the products harmful upon consumption; and
- Products for which no terminal heat process is used after packaging or during cooking in the home.

After the foods are described, they are categorized according to risk, Category 6 representing nonsterile foods intended for consumption by at-risk groups, Category 5 representing foods subject to five general hazards, Category 4 representing foods subject to four general hazards, and so on down to Category 0 for foods representing no hazard.

Accompanying the hazard analysis is a consideration of what preventive measures, if any, can be applied to control the hazard. These can be physical, chemical, or other measures used to control a specific hazard.

The hazard analysis and identification of associated preventive measures accomplishes three purposes. First, the hazard is identified. Second, the analysis can be used to modify a process or product to further ensure or improve safety. Third, the analysis provides a basis for determining the CCPs.

Identify the Critical Control Points (Principle No. 2)

A CCP is a point, a step, or a procedure at or during which control can be applied and a food safety hazard prevented, eliminated, or reduced to an acceptable level. The information developed in the hazard analysis steps should enable the HACCP team to identify the CCPs.

Critical control points can be located at any point in the process at which an identified hazard must be prevented, eliminated, or reduced. A CCP can be, for example, a pesticide application carried out during the growing of a crop or its storage. A CCP might be a specified cooking process, a chilling process, a packaging process, the length of time a product is stored (as well as, perhaps, the storage temperature), or a critical employee practice such as hand washing.

Because HACCP is plant and product specific, separate facilities preparing the same food can differ in their risk of hazards and those of their points, steps, or procedures that are CCPs. Differences in layout, equipment, selection of ingredients, or the process employed account for different risks.

Establish Critical Limits for Preventive Measures Associated with each CCP (Principle No. 3)

A critical limit is the maximum level or criterion associated with each preventive measure. A preventive measure might, for example, be a pesticide application, an acidity level in a product, a heating process, or employee hand washing. Corresponding critical limits for these steps would be a specific pesticide residue tolerance that the ingredient or finished product cannot exceed, the pH value of an ingredient or of an intermediate or finished product, the time and temperature requirements of the heating process, or the number of times or situations in which an employee must wash his or her hands.

Establish CCP Monitoring Requirements and Procedures for Using the Results of Monitoring to Adjust the Process and Maintain Control (Principle No. 4)

Monitoring is done through a planned schedule of examinations of the CCPs to ensure that all CCPs are operating within their critical limits. Monitoring is critical for several reasons. First, it indicates when a process is tending toward a loss of control, at which time action can be taken to bring it back into control. Monitoring also identifies when a process is out of control and corrective action must be taken. Finally, monitoring provides the documentation needed to verify the HACCP plan.

Monitoring usually entails an examination of records such as test results, automatic temperature records, processing time and temperature records, pH records, package sealing records, or storage and inventory records for ingredients or finished products. Most monitoring procedures have to be done rapidly. Physical and chemical procedures such as those involving precise physical observations including temperature, time, moisture levels, or pH are therefore preferred.

Ideally, monitoring should be done continuously. This is often possible in time and temperature monitoring, which occur in processing and storage situations, or in pH monitoring. When it is not possible to monitor a critical limit continuously, it is important to establish the monitoring interval on a statistical basis so that the process stays under control.

If the process begins to exceed the critical limits, procedures must be in place to reestablish control rapidly. These procedures can involve activities such as adjusting line flow rates, adjusting the amount of specific ingredients added to the processing stream, or adjusting overall production volumes to control inventory and shelf-life limits.

Establish Corrective Action to be Taken When Monitoring Indicates a Deviation from an Established Critical Limit (Principle No. 5)

The HACCP system is designed to identify potential problems before they occur and to prevent failures. However, deviations from critical limits will occur, and corrective action plans must exist to handle these situations. The HACCP plan must include action to be taken when one or more CCP critical limits are exceeded. This action can include holding and retesting the product or disposing of the product. A long- term action may include changing suppliers if incoming ingredients are persistently the source of problems. The plan must include documentation to show the disposition of all products that are out of compliance.

Establish Effective Record-Keeping Procedures that Document the HACCP System (Principle No. 6)

This step includes not only the obvious, such as maintaining documentation relating to incoming ingredients, processing, finished products, storage and distribution, but also the HACCP plan itself and the documentation used to establish it, including items describing the HACCP team and their responsibilities, flow diagrams, and verification procedures.

Establish Procedures for Verifying that the HACCP System is Working Correctly (Principle No. 7)

This is actually a fairly complex process that is essential to the long-term operational success of HACCP for a processing establishment. Verification involves four different levels of activity:

- Routine audits of CCP records and a review of risk management decisions and product dispositions when process deviations occur. (This is the regular, ongoing review of the system to ensure it is operating effectively.)

- Regulatory agency review of an establishment's HACCP plan when regulatory programs mandate HACCP systems. This may be similar to the above level of activity but is done in conjunction with the regulatory agency.

- Revalidation of the HACCP plan. This is normally done whenever significant product, process, or packaging changes occur. Revalidation includes a documented on-site review and verification of all flow diagrams and CCPs in the plan, with changes made to the plan as necessary.

- A periodic review to ensure that the critical limits at the CCPs are satisfactory. This normally requires professional experts to review and update the limits based on changing science and technology.

In summary, HACCP is a preventive, safety-focused system used to identify the potential hazards associated with the production, distribution, and consumption of food; identify the critical points needed to control hazards and the critical limits for those points for individual products and processing establishments; and establish and monitor corrective action and auditing or verification programs that will ensure the production of safe and wholesome food products.

THE ISO 9000 SYSTEM

Whereas HACCP has a safety focus, ISO 9000 has a quality focus and is perhaps best viewed as a Total Quality Management System. ISO 9000 encompasses safety as a component of quality but extends beyond HACCP. HACCP fits within ISO 9000.

ISO is located in Geneva, Switzerland, and is a federation of national standard bodies representing 91 countries. ISO promotes the development of international standards and related activities to facilitate the international trade of goods and services. ISO standards cover a wide variety of products and processes but focus primarily on the hard goods area.

In 1976 ISO started developing the ISO 9000 standards to describe a quality management system (Surak, 1992). The standards, published in 1987, were modeled after British Standard 5750. They were originally intended to be advisory in nature and aid in the development of contracts between customers and suppliers. Recently the standards have been used as a basis for third-party audits and registration of quality systems. Increasingly, enforcement of ISO 9000 standards is a prerequisite for goods traded internationally. By 1992, 55 countries had adopted the ISO 9000 series (Surak, 1992). In the United States, the standards are published as American National Standards Institute/American Society for Quality Control (ANSI/ASQC) Q90 series.

The ISO 9000 quality assurance standards consist of five separate and distinct standards: ISO 9000, 9001, 9002, 9003, and 9004. ISO 9000 and 9004 provide guidelines for selection and use of the standards, whereas ISO 9001, 9002, and 9003 are implementing standards (ISO, 1992).

ISO Program Elements

ISO 9001, 9002, and 9003 programs incorporate some or all of the following 20 elements (ISO, 1992):

- Management Responsibility
- Quality System
- Contract Review
- Design Control
- Document Control
- Purchasing
- Purchaser-Supplied Product
- Product Identification and Traceability
- Process Control
- Inspection and Testing
- Inspection Measuring and Test Equip.
- Inspection and Test Status
- Control of Nonconforming Product
- Corrective Action
- Handling, Storage, Packaging and Delivery
- Quality Records
- Internal Quality Audits
- Training
- Servicing
- Statistical Techniques

ISO 9001 is the most comprehensive standard and includes all of the 20 elements. It is the model for quality assurance in design and development, production, installation, and servicing.

ISO 9002 is the model for quality assurance in production and installation. This standard includes all elements but two: design control and servicing.

ISO 9003 is the least comprehensive standard. This standard is designed for quality assurance in final inspection and testing and encompasses only 12 of the 20 elements.

ISO Quality System Requirements

To obtain a clearer picture of the ISO 9000 system, it is helpful to review the ISO Quality System Requirements in detail (ISO, 1992; AQUIS, 1992).

Management Responsibility

There must be a total commitment by management to the ISO 9000 program. Management must prepare a policy statement that reflects its policy and objectives relating to quality and its commitment to the ISO 9000 system. There must be a procedure to ensure that the policy is known, understood, and implemented throughout the organization. Additionally, management must nominate one person who will ensure that the quality objectives and ISO standards are being complied with. There must be adequate personnel and resources to implement the program, and the duties and lines of communication of all personnel with responsibility for quality must be documented. Finally, the quality system must be reviewed regularly by management, and consideration given to findings of internal and external audits.

Quality System

The company must have a documented quality system to ensure that all product specifications and regulatory requirements are met. The system must include a **quality manual**, which describes the quality system in place, and a **procedures manual** explaining how processes are carried out. The company must be able to demonstrate that the quality system is in place, that it does not exist only on paper.

Contract Review

The contract should be reviewed to ensure that the client's requirements are documented and understood, and that differences of opinion are resolved. Consideration must be given to food safety as well as to product quality, including any assumptions the client may make concerning the stability or shelf life of the product and compliance with regulatory requirements.

Design Review

This element is used only with ISO 9001 and often does not apply to food processing establishments.

There must be procedures for translating the client's specifications and requirements into technical specifications for raw materials, processing, packaging, storage, and the like. The design review element ensures that individual responsibility and a planned approach to each activity. The element is also intended to identify and resolve potential conflicts between technical design requirements, marketing requirements, and regulatory requirements.

Document Control

Procedures must be developed for approving, reviewing, amending, and controlling the issue of all documentation relating to the quality system — including manuals, procedures, and forms — to ensure that they are adequate, up-to-date, and available to the people who need them.

Purchasing

The procurement of goods and services — including items such as ingredients, processing equipment, packaging materials, laboratory services, cold storage, and pest control services — must be planned and controlled. Purchase requirements must be defined clearly in specifications and purchase orders. Suppliers must have the capacity to meet all requirements, and appropriate means must be established to ensure that incoming raw materials, packaging, and the like are controlled, checked, and documented.

Purchaser-Supplied Product

This element relates to materials supplied by a client, for example in a contract processing situation, and requires the purchaser to ensure that product supplied for incorporation into manufactured goods delivered to the client is subject to verification, proper storage, and accountability.

Product Identification and Traceability

All product must be permanently marked for identification. Lot identification is preferred. There must also be a documented procedure for tracing product in the event of a product recall. Product recall procedures must include an appropriate list of contacts that must be updated regularly.

Process Control

In many ways this is the heart of all quality and safety control programs. Within the ISO 9000 system, this is the point at which HACCP most clearly is involved and where it is logically referenced.

In process control, the company must identify and plan the production and storage processes that directly affect quality, and ensure that the processes are carried out in a controlled fashion. Procedures and work instructions cover every aspect of these operations, including buildings and equipment, sanitation, process control, and product handling and distribution. The reader should refer to the HACCP section of this paper for the level of detail this section covers.

Inspection and Testing

Inspection and testing are key parts of the ISO 9000 standards and of HACCP. The procedures are applied throughout processing; there is inspection and testing of incoming materials, in-process testing of intermediate ingredients and products, and inspection and testing of the final product. The quality system must ensure that incoming ingredients and packaging are not used until they have been verified as conforming to specifications. Any incoming material used prior to clearance must be linked to procedures to detain or reject final product should the raw materials show nonconformance. Procedures must also be in place to prevent the distribution of product until final inspection and testing have taken place. Here, as with raw materials, the necessary shipment of final product prior to final inspection and testing must be linked to recall procedures if the final product does not conform to standards.

Inspection, Measuring, and Testing Equipment

Because the inspection and test measures used to ensure product quality are only as good as the equipment used in the testing, period checks must be made to ensure that all inspection, measuring, and testing equipment is operating properly. All calibrated equipment must be identifiable and its calibration status clearly apparent to the user. The equipment must be handled and stored in a manner that will not adversely affect its accuracy. Regular service of the equipment must be carried out. Records of calibration and servicing must be kept.

Inspection and Test Status

All product must be clearly identified by labels, stickers, tags, placement in a specific physical location, or some other means to indicate its inspection and test status and the name of the person responsible for its release.

Control of Nonconforming Product

Procedures must be in place to prevent the inadvertent use or release of nonconforming product, including ingredients, packaging, intermediate, or final product. Procedures must also be in place to handle the disposition of nonconforming product; these procedures include reworking, regrading, and retesting (as appropriate) of all levels of initial, intermediate, and final product. The procedures also include recall procedures for the final product.

Corrective Action

The company or organization must have in place a procedure for investigating incidents of nonconforming product and customer complaints, and for reviewing quality reports and routine test results to detect and correct real or potential problems. The emphasis on corrective action must be on correcting the system and not just fixing the product.

Handling, Storage, Packaging, and Delivery

Procedures must be in place to make sure that damage to or deterioration of the final product does not occur subsequent to its manufacture. In some cases the company may want to have procedures in place to verify the handling of the product even after the company no longer has actual control of it if liability to the company can occur in the distribution chain. The company should verify that control procedures are implemented, particularly when the company may not have direct control over the product.

Quality Records

The collection, collation, archiving, and ultimate disposal of all records that form a part of the quality system, including computerized records, are critical. Procedures must be in place to ensure that all quality records are legible and retrievable up to the time of disposal. The length of time that specific records must be kept and how they are to be disposed of must be spelled out clearly.

Internal Quality Audits

Regular, scheduled audits of the quality system must be carried out. These audits must cover every element of the quality system. The results must be conveyed to the appropriate management level and action taken to correct any deficiencies found to occur in the quality system.

Training

There must be programs in place to train staff in new procedures and technology related to their responsibilities. Training is especially important for staff with quality-related responsibilities. Certain staff, such as retort operators or laboratory technicians, may already have specific training necessary and be licensed to carry out their jobs. Records must be kept of all training.

Servicing

This section applies to ISO 9001 only.

Where follow-up action is specified in a contract, or servicing is an expected part of the manufacturer's responsibility, procedures must be in place to ensure that the servicing is conducted properly by appropriately trained personnel in an approved manner using appropriate equipment and materials. The effectiveness of the servicing must also be incorporated into these quality assurance procedures.

Statistical Techniques

Many of the elements necessary for properly constructed quality assurance programs require statistical techniques to ensure their adequacy. Whenever statistical techniques are used, the company must establish procedures to ensure that the techniques are sound and capable of being shown to be valid.

The ISO *International Standards for Quality Management* provide a comprehensive system to ensure product quality. The system, when used in conjunction with an independent, third-party registrar, can be an important means to enhance purchaser confidence in a product.

The normal process for obtaining ISO registration involves several steps. The first is a clear commitment by top management to quality management and to the ISO 9000 system. Next is the formation of an ISO steering committee, analogous to the HACCP team. After that, training in the ISO 9000 system begins, followed by development of a quality manual and the start of internal audits. Next is the selection of a registrar. A registrar is an ISO-approved private, independent organization that is competent in the audit process and, in this instance, competent in the food field. The registrar normally carries out a pre-assessment, then the formal assessment. Improvement in the company's quality assurance system may be necessary between these steps. Registration is obtained upon successful completion of the assessment audit and the correction of any minor discrepancies. Once the initial registration is received, a company must carry out regular internal audits and periodic (at least twice a year) third-party surveillance.

ISO Costs

Costs for implementing ISO 9000 are difficult to estimate because situations vary dramatically among companies and among individual plants within companies. Costs depend on the product type, the manufacturing establishment, and the state of readiness of the firm and the plant. An estimate provided by the U.S. National Institute of Science and Technology of the average cost for obtaining ISO approval is $21,000 per plant. Much of the cost of ISO 9000 approval is internal, associated with assessment, training, documentation, and auditing; the cost of registration with the approved registrar is frequently less than the sum of internal costs.

INTERNATIONAL TRENDS IN ISO 9000 AND HACCP

Internationally, a clear trend appears to be developing toward the use of the systems approach to ensure food quality and safety, whether through ISO 9000 or HACCP or a combination of the two. The reasons for this trend are several:

- The systems approach does a better job at ensuring product quality and safety than does spot-checking. This is particularly true as technology increases and high product throughput levels and complex equipment make spot-checking more difficult.

- A systems approach is often more cost-effective and more efficient in ensuring quality and safety.

- A systems approach using ISO 9000 or HACCP enhances the creditability of the product, permitting a greater market access in the international community. This factor is becoming increasingly important as recognition of ISO 9000 and HACCP grows in the international marketplace.

Both ISO 9000 and HACCP are, in fact, becoming important factors in the international food trade. The European Union system rests on the use of ISO standards (as implemented through the EN 29000 Standard Series) to ensure product quality through a third-party certification and auditing system (Surak, 1992). Very simply, ISO 9000 is becoming mandatory for doing business in the European Union. Additionally, both HACCP and the ISO quality standards system are receiving recognition within Codex. The Codex Committee on Food Hygiene has developed a draft report on HACCP (Codex, 1991). Additionally, the Codex Committee on Food Import/Export Food Inspection and Certification Systems has authorized the drafting of a document relating ISO 9000 to HACCP (Codex, 1993). Also, many countries outside the European Union — including Australia (AQUIS), Thailand (Codex, 1993), and Indonesia — are recognizing ISO 9000 as a valuable means to enhance the quality of their goods and services and using it as a mechanism to enhance their competitiveness in the international marketplace. Finally, the FDA, in adopting HACCP as a proposed regulatory approach to the seafood industry, is planning to require that international seafood importers meet the stated HACCP system requirements (Federal Register, 1994).

These developments will, over time, reduce reliance on the testing of individual finished products at the port of entry and increase dependence on both internationally accepted product safety and quality assurance systems such as HACCP and ISO 9000 and bilateral or multilateral agreements among governmental health authorities recognizing the equivalency of one another's systems for ensuring product safety and quality. Multilateral harmonization of export and import documentation will follow.

As the development of international quality and safety assurance programs such as ISO 9000 and HACCP proceeds, however, care must be taken to avoid the inadvertent use of these systems as technical barriers to trade. Programs must be implemented in such a way that product safety and appropriate quality are ensured without restricting trade and market access.

THE SEAFOOD HACCP PROGRAM

The HACCP program being proposed by the FDA (Federal Register, 1994) is particularly important internationally because FDA is mandating HACCP use for both imported and domestic fish and fishery products. At this time, the FDA seafood HACCP program is a proposal only. The announcement was made in the January 28, 1994, issue of the Federal Register, with the open comment period extending to at least March 29, 1994. The open comment period is likely to be extended. The FDA is proposing that any final rule that may be issued based on the proposal take effect one year following the rule's publication.

According to the proposal, FDA has proposed the HACCP approach for several reasons:

- First, adoption of HACCP controls by the seafood industry, coupled with inspections by FDA based on the HACCP system, will produce a more effective and efficient system for ensuring the safety of seafood products. The current inspection system, as stated by FDA, places too great a burden on government inspectors to uncover problems and take regulatory action to address those problems. HACCP places primary responsibility on the industry to demonstrate that hazards are understood and are being prevented.

- Second, a nationally mandated HACCP system will provide a basis for enhanced confidence in the safety of seafood products. The seafood industry presents a number of food safety challenges — including microbial issues, natural toxicant issues, and chemical issues including heavy metals, drug residues, and pesticide residues. There is a need to enhance the safety of seafood and to do so in a cost-effective manner.

- Third, the know-how for applying HACCP to seafood is in an advanced state of development. The system has matured and progressed enough, at least for seafood, to permit its use in a regulatory system.

- Fourth, a nationally mandated HACCP-type system of controls appears to be a prerequisite for continued access to world markets.

FDA also noted that seafood industry representatives have urged the federal government to institute a mandatory HACCP-type inspection system for their products.

The FDA Proposal

What does the FDA Seafood HACCP proposal consist of?

The proposal will require that every processor and importer have and implement a written HACCP plan that is specific to each location where fish and fishery products are processed by that processor, and each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together if the products' hazard, critical control points, critical limits, and HACCP procedures are identical.

The HACCP plan will require each processor and importer to carry out five different activities.

- Identify the safety hazards that are reasonably likely to occur and thus have to be controlled. These hazards will include the following:

  — Natural toxins
  — Microbial contamination
  — Chemical contamination
  — Pesticides
  — Drug residues
  — Decomposition associated with human illness
  — Parasites
  — Physical hazards
  — Unapproved direct and indirect food and color additives.

- Identify the CCPs for each of the identified hazards.

- Identify the critical limits that must be met at each of the CCPs.

- Identify the procedures that will be used to control and monitor each of the CCPs to ensure compliance with the critical limits, and state the frequency of the monitoring. Monitoring procedures should include the monitoring of consumer complaints. Procedures should also include calibration of process control instruments and validation of software for computer control systems if they are used.

- Provide for a record-keeping system that will document the monitoring of the CCPs. The records should contain the actual values obtained during monitoring. The records should also include consumer complaints that relate to the operation of CCPs or possible critical limit deviations.

The proposal requires that any critical limit deviation trigger segregation and holding of the affected product, immediate review by an individual who has been trained in the HACCP seafood program, corrective action with respect to the product and the CCP, timely assessment by a trained individual to determine whether the process or HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modification of the HACCP plan if necessary. The proposal also stipulates that the processor and importer shall employ at least one individual who has successfully completed a prescribed course of instruction in seafood HACCP.

The proposal also recommends that the HACCP plan identify consumer hazards that may not be directly related to safety. These hazards include decomposition and spoilage not related to illness, economic adulteration such as added water, and the potential for species misidentification.

The proposal indicates that the failure of a processor or importer to have and implement a HACCP plan that complies with the proposal shall result in products that are considered to be adulterated under Section 402(a)(4) of the U.S. Federal Food, Drug and Cosmetic Act.

The approach of the FDA is not to design HACCP plans for individual processors, although several model plans will be prepared by FDA for various species and process types. Rather, the proposal will require that processors and importers themselves develop and implement HACCP plans. The FDA will verify during inspection that processors and importers have developed and implemented proper and appropriate plans.

FDA notes there are special concerns about raw molluscan shellfish, potential scromboid-toxin-forming species such as tuna and mackerel, and smoked fishery products. The proposal deals in-depth with HACCP plans and procedures associated with each of these kinds of products.

Importer Obligations

The stated policy of the FDA is to have equivalence between domestic processors and importers. Consequently, the requirements of the seafood HACCP proposal will apply to importers. The obligations of the importer under the proposal are described below.

- To have and implement a HACCP plan that describes how the fish or fishery product will be prepared, packed, and held while in the control of the importer.

- To have on file the HACCP plan of the foreign processor. The HACCP plan must meet the requirements of the FDA proposal.

- To take affirmative steps to assure themselves that their imported product was produced under this HACCP plan. The FDA proposal indicates that these steps can include (but are not necessarily limited to) the following:

  — Obtaining from the foreign processor the HACCP records for the specific lot(s) of product being imported.
  — Obtaining a certificate from a foreign government authority certifying that firm is operating under a valid HACCP plan or certification on a lot-by-lot basis.
  — Regularly inspecting the supplier's facilities to ensure that they are being operated in compliance with the applicable HACCP plan.
  — Periodic testing of the final product by the importer or a private laboratory hired by the importer.

The proposal says that the importers' obligations to have product produced under a valid HACCP plan will be met if a memorandum of understanding has been signed between the FDA and a government authority from the product's country of origin stating that the FDA's and the foreign government's regulatory systems are equivalent with respect to fish and fishery products.

The proposal will require that the seafood, upon importation, comply with the HACCP regulations. The proposal indicates that compliance can be met in at least four different ways:

- An examination by FDA at the importer's place of business of the importer's and foreign processor's HACCP plan and associated records that show that the specific lots of imported seafood were, in fact, produced under the plans;

- The existence of an active memorandum of understanding between FDA and the exporting country that stipulates the country will impose regulatory controls equivalent to those established in the FDA proposal;

- Evidence that an exporting country has in place and is enforcing a HACCP-based regulatory system; and

- The inspection of the foreign processor by FDA or some other organization designated by FDA.

The proposal indicates that without assurances that imported product has been produced under a HACCP plan and that sanitation controls meet the specifications in the FDA proposal, the product will be considered adulterated and will be denied entry.

Because the FDA seafood HACCP program is only at the initial proposal stage, authoritative information on implementation is not yet available. However, for imported product, implementation will focus initially on the importer to ensure that the exporting firm has an appropriate HACCP plan in place and that imported product is, in fact, produced under this plan. Implementation may also begin with more frequent on-site inspections of international production facilities by the FDA. The FDA is likely to consider establishing equivalency agreements with foreign governments; these agreements will recognize the existence of seafood HACCP programs that are the equivalent of the FDA program and will probably permit the entry of product into the United States with less frequent inspections.

Estimated Costs

In its seafood HACCP proposal (Federal Register, 1994) the FDA notes that no single source of data was found to be entirely satisfactory for developing a preliminary estimate of costs for the proposed regulations. Cost estimates for implementing and operating a seafood HACCP program are based on three sources: industry data, costs obtained from the Model Seafood Surveillance Project mandated by the U.S. Congress, and FDA data. Although the range of costs in the studies was considerable, the average annual cost of the proposed rule for each domestic manufacturing plant is estimated to be $24,000 for the first year, irrespective of the size of the plant, and $15,000 for subsequent years. The FDA further estimates that each importer will have start-up costs of $9,000, and that repackers and warehouse operations will have annual recurring costs of $9,000. No estimates of the annual cost for foreign-operated establishments are available. More detailed information can be found in the FDA Seafood HACCP Proposal (Federal Register, 1994).

At this point, the FDA proposal is open for comment. Staff of the FDA Office of Seafood have clearly indicated their responsiveness to comments relating to the import area. The policy of equivalence between domestic and imported seafood products is likely to be retained, however.

Applying Seafood HACCP

SITUATION: CHEMICAL CONTAMINATION FROM HARVEST WATERS

- The **hazard** is the fish or shellfish that may be harvested from contaminated waters. The seafood will or is very likely to contain residues above the legal limit of mercury or pesticides.

- The **critical control point** or CCP in this situation is the harvest area itself.

- The **control measure** is threefold:

  — First, identify the harvest area.

  — Second, find out whether the area is open or closed to harvest, or whether there is a likely occurrence of above-tolerance seafood.

  — Third, reject fish from closed areas or from areas where test results show above-tolerance residue results for the contaminant(s).

- The **critical limit** is zero for a closed area (that is, no fish can be accepted); otherwise, the limit is the tolerance for the contaminant.

- The **frequency of monitoring** varies.

  — For finding out the location, each lot or batch is monitored.

  — For finding out whether the harvest area is closed, monitoring takes place before accepting the fish and at least quarterly thereafter.

  — For rejecting fish, each batch that does not meet the critical limit is monitored.

- The **records** are the documents specifying the harvest area for each batch and the test records that document contaminant levels.

- The **corrective action** is to destroy or recall product that fails to meet the critical limit.

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Previous Page Blank