

CHAPTER SIX

HACCP: Industry versus Government

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BACKGROUND

Few initiatives in the recent history of food safety regulation have approached the significance of the Hazard Analysis and Critical Control Point (HACCP) system. The HACCP concept is simple; it is a systematic, proactive approach to preventing food safety hazards by focusing resources at those points at which food safety hazards can be controlled, an alternative to generally reactive end-product testing. By identifying the hazards associated with a product and determining the points in the process or practice where these hazards can be managed, the control, monitoring and verification of the process can assure that potential hazards are dealt with before a product enters distribution (NACMCF, 1993).

Industry and regulatory sectors alike have endorsed the use of HACCP by the food industry. Despite the simplicity of the HACCP concept, however, its application is complex. HACCP not only requires an analysis of every product and process, its implementation by a manufacturer involves a significant investment in education and training, record keeping and process verification. As regulators ponder the most effective application of the HACCP concept to their initiatives it is inevitable that the relationship between the regulators and the regulated industry will change, and questions have arisen as to what and how fundamental such changes will be. Reflecting on his own country's experience, an Australian government representative noted that Australia's application of HACCP has brought about a

massive culture change, making a communications strategy a necessity (USDA, 1994).

The history of HACCP dates back to the early 1960's, as a response to food safety requirements imposed by NASA for foods produced for manned space flights (FDA, 1994a; Stevenson, 1995). A case of foodborne illness in a space capsule would have been catastrophic, and so the agency was concerned that the foods used in such flights had an absolute assurance of the absence of pathogens and biological toxins. The Pillsbury company realized the limitations of end-product testing and its inability to assure that a product was free of pathogens. As an alternative approach Pillsbury adapted the "Modes of Failure" concept developed by the U.S. Army Natick Laboratories in the production of foods. The concept relied on the gathering of knowledge and experience about the food product or process and the use of this information to predict what problems might occur, and how and where they might occur in the process. It would then be possible to determine points in the process at which specific measurements or observations could be made to indicate whether the process was under control. If control was lost at these points, a food safety hazard might potentially occur. The system was termed the HACCP or Hazard Analysis and Critical Control Point system (Stevenson, 1995).

HACCP was first formally presented at the 1971 National Conference on Food Protection (APHA, 1972), and was established by the FDA, first as a strategy for the control of microbiological hazards in the mushroom can-

ning industry, and later for control in all low acid canned foods (FDA, 1973; NRC, 1985). In the FDA strategy, companies producing a given product would apply the HACCP system, identifying appropriate critical control points and monitoring procedures. Regulatory inspectors would review plant control protocols to determine the proper identification of critical control points and the establishment of appropriate monitoring systems. Once protocols were reviewed and the program implemented, the role of the regulator would shift to reviewing the results of monitoring to determine that the foods were being produced under conditions of adequate microbiological control (NRC, 1985).

During the 1970's many food processors attempted to implement HACCP programs in their facilities to assure product safety. Most of these programs were discontinued because they did not achieve a quantifiable objective (NFPA, 1993). Except for the use of HACCP for low-acid canned foods, its application to the regulatory control of foods fell into disuse in the United States. This was considered to be a result of the optional status of HACCP as well as a failure to train personnel (NRC, 1985).

In 1976, the use of the HACCP approach was emphasized at a meeting the World Health Organization (WHO) Expert Committee on Microbiological Aspects of Food Hygiene. As a result a joint meeting of the WHO and the International Commission on Microbiological Specifications for Foods (ICMSF) in 1980 evaluated the application of the HACCP system in food hygiene, endorsing the system as "an effective and economical approach to ensuring the safety and quality of foods produced in developed countries", and providing guidelines to promote the implementation of HACCP by developing countries (WHO/ICMSF, 1985). In 1985, the Subcommittee on Microbiological Criteria of the Committee on Food Protection of the National Research Council issued a report entitled "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients", which recommended the HACCP system as "a more specific and critical approach to the control of microbiological hazards in foods than that provided by traditional inspection and quality control approaches" (NRC, 1985). The report, commissioned by four government agencies involved in food safety, led to a renewed interest in the HACCP system in the United States (Stevenson, 1995).

In 1988, the ICMSF released a comprehensive examination of the HACCP system and its application (ICMSF, 1988). In that same year, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) held its first meetings. The Committee was appointed to serve as an expert scientific advisory panel to the Secretaries of Agriculture, Commerce, Defense, and Health and Human Services in the United States and, as part of its charge, was to encourage the adoption of the HACCP concept (Stevenson, 1995). In 1992 the NACMCF issued a document outlining the HACCP system and its

application. The document built upon an earlier NACMCF report, as well as a draft report by the HACCP Working Group of the Codex Committee on Food Hygiene. As presented, the HACCP system consisted of seven basic principles, including hazard analysis, the identification of critical control points, establishment of critical limits for the critical control points, monitoring procedures, corrective action, record-keeping and verification (NACMCF, 1992).

The HACCP process has been widely endorsed in the international community. At its seventh session meeting in Rome in March/April 1993 the Committee on Food Hygiene and Committee on Meat Hygiene of the Codex Alimentarius Commission endorsed HACCP as the process control system best able to address food product safety. The Commission restated the 7 principles of HACCP, forwarding a 12 step approach for practical implementation of the system (Codex, 1993; Garrett, 1995). The European Union (EU) has adopted the HACCP process and, by December 14, 1995, all food companies in the EU will be required to have in place an effective HACCP system (EEC, 1994; Grijspaardtink, 1994). EU member countries are at varying stages in adopting the HACCP system, with the efforts most advanced in the United Kingdom and Ireland (Grijspaardtink, 1994).

In Australia, Canada, New Zealand and the United States, regulatory agencies have endorsed the principles of HACCP, and HACCP based systems have become mandatory for the export of certain commodities. Australia began considering HACCP in 1984, and the system is currently being promoted as the "preferred way to control all hazards to ensure product quality whether they are of microbiological or chemical origin" (Codex, 1994). In Canada, planning began in 1991 on a food safety program which would encourage adoption of HACCP principles across all federally registered food establishments. This involved the formation of a partnership between the regulatory community and the food industry. The system utilizes the 12 steps/seven principles approach to HACCP application. The program is expected to be in place in 1996, and the government will soon meet with industry sectors to determine the form of regulatory HACCP in that country (USDA, 1994, 1995).

Recent initiatives by the USDA Food Safety and Inspection Service (FSIS) and the U.S. Food and Drug Administration (FDA) have brought HACCP to the forefront of attention in the United States. The FDA is currently evaluating comments on its proposed mandatory seafood HACCP regulation, released in 1994 and will soon be promulgating the final rule (FDA, 1994a). The agency is currently receiving comments on a pre-proposal to extend HACCP to all regulated foods (FDA, 1994b). In 1994 the USDA issued its proposed HACCP and pathogen reduction regulation, which would mandate HACCP for the U.S. meat and poultry industry (USDA, 1995).

The increasing use of the HACCP concept as a component of regulatory initiatives in the international community has brought to the forefront the ongoing debates about how the relationship between the regulators and the regulated industry should and will change, and how HACCP-based regulation will alter or coexist with currently existing food safety legislation. To address these issues, the NACMCF reviewed relevant information and issued a paper outlining the desirable role of both regulators and industry in the HACCP system (NACMCF, 1993). Several conferences, such as the World Congress on Meat and Poultry Inspection on October 11-14, 1993 (Biddle et al., 1993), the Quadrilateral Discussions on Food Safety (Quadrilateral Meeting, 1993) on October 18-21, 1991, and the FSIS HACCP round table held on March 30-31, 1994 (USDA, 1994), have served as forums for the discussion of these issues.

MANDATORY VS. VOLUNTARY HACCP

Central to the relationship between regulatory agencies and the food industry is the debate over whether HACCP should be mandated by regulators or should be voluntary, with the regulatory community providing an advisory role. In 1985, the National Research Council Subcommittee on Microbiological Criteria suggested that "for HACCP use to be broadly realized, it is likely that the utilization of this system relative to microbiological hazards of foods will have to be required by regulation" (NRC, 1985). This statement provoked some disagreement (Stevenson, 1995), and there have been differences of opinion as to whether regulatory agencies should mandate HACCP or play an advisory role. The argument for voluntary HACCP programs is based upon several assumptions: that a commitment to safety cannot be mandated by regulators, that industry will have greater ownership of the system if not compelled to use it, and that many small processors do not have the resources necessary to establish HACCP programs (Quadrilateral Meeting, 1993). Several approaches to voluntary HACCP have been outlined by the Quadrilateral HACCP working group (Quadrilateral Meeting, 1993). Those advocating mandatory HACCP programs have argued that public health considerations do not permit a voluntary program for several reasons; some manufacturers will not have adequate process control in the absence of HACCP requirements; the use of HACCP must be mandated to ensure a level playing field for all manufacturers; and in the absence of mandatory HACCP some in the food industry will not take advantage of the most current technologies for process control (Quadrilateral Meeting, 1993).

In New Zealand, a voluntary HACCP program has been recommended in lieu of a mandatory program. There it is felt that for a HACCP program to be successful industry should own the program, since compliance requires

industry commitment (USDA, 1994). In Australia, HACCP will be made mandatory for all processed foods, except processed meats, that are intended for export. For raw and processed meats, HACCP principles have been an optional component of quality assurance programs for hygienic slaughter and may eventually become mandatory (Biddle et al., 1993).

In the United States, FSIS has issued a proposed rule in which every inspected establishment would be required to develop, implement, and operate HACCP plans. The agency noted that the HACCP concept is not an inspection system, but a process control system which would provide opportunities to make inspection more effective. The proposed regulation states that "in addition to providing a greater quantity of information and in effect extending the scope of regulatory observations, the presence of functional HACCP plans for all products and processes will also produce more relevant data" (USDA, 1995).

In a recent presentation to the Food and Agriculture Organization of the United Nations, representatives of the FDA suggested that an advantage of mandatory HACCP is that "the regulatory agency will be able to focus its inspection resources on those critical aspects of a food establishments operations where food safety problems are most likely to occur" (Kvenberg et al., 1994). The same report mentioned that some in the food industry have stated that voluntary HACCP might be better suited for segments of the food industry lacking significant food safety risks (Kvenberg et al., 1994). The FDA is currently preparing a final rule for mandatory HACCP for seafood products and is proposing the expansion of mandatory HACCP to all foods. The possible expansion has drawn commentary from several industry groups.

They have argued that HACCP legislation and the resources of the FDA should be focused on those product categories that represent the greatest risk of food safety hazards and that HACCP should not be mandated for foods whose history has demonstrated a low risk for the occurrence of hazards.

FOCUS OF HACCP-BASED INSPECTION

Another issue central to the application of the HACCP system is whether it should be applied to quality as well as safety issues or should be focused solely on product safety. In 1985, the National Research Council endorsed the HACCP concept as an approach to "the assurance of safety and to the prevention or delay of spoilage in foods" (NRC, 1985). Other reports also suggested this approach, and a hazard was defined as "contamination of food with unacceptable levels of food-borne disease-causing microorganisms and/or contamination with spoilage organisms to the extent that hazards occur within the expected shelf-life or use of the product" (WHO/ICMSF,

1985). Australia has applied the HACCP concept as "the preferred way to control all hazards to ensure product quality" (Codex, 1994). Other countries, such as Canada and the United States, have focused HACCP-based regulatory initiatives on issues of safety only. The NACMCF has forwarded a definition of a hazard as "a biological, chemical, or physical property that may cause a food to be unsafe for consumption." (NACMCF, 1993).

Some have attributed the failure of many of the HACCP programs in the 1970's to their application to a combination of quality and regulatory programs. Such programs resulted in a cumbersome system with numerous critical control points, and diluted focus on product safety (NFPA, 1993). The Microbiology and Food Safety Committee of the National Food Processors Association has argued that "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 products" (NFPA, 1993).

REGULATORY APPROVAL OF HACCP PLANS

There is general agreement that an adherence to the seven principles of the HACCP system are necessary for HACCP-based programs to be truly effective. For the regulator, HACCP plan development represents a challenge; the development by a manufacturer of a HACCP plan for a product requires a great deal of expertise, which in many cases is specific to knowledge of a particular product, process, or food plant. The question arises as to whether plant-generated HACCP plans should be approved prior to implementation. If so, should the approving authority be different than the developer of the plan, such as a regulatory agency or a third party (Quadrilateral Meeting, 1993; USDA, 1994)? For some, the government should be involved in the acceptance and approval of industry plans, while others have suggested the use of third-party approval, drawing from the pool of experts in industry, professional associations and academia (USDA, 1994).

The Quadrilateral HACCP Working Group was unable to reach agreement on the issue, but provided questions for consideration. Among them: what is the potential conflict between regulatory approval of a HACCP plan and a subsequent regulatory decision to void that plan? Are a significant number of regulatory personnel available to approve HACCP plans in a timely manner? What is the relevance of a first-line regulatory involvement in the plan approval process, and what is the effect of an absence of plan approval? (Quadrilateral Meeting, 1993).

Regardless of whether independent approval of HACCP plans prior to implementation is required, development of acceptable plans will be facilitated by the formation of generic HACCP plans and process guidelines by

regulatory and other entities. Such plans could provide mandatory critical control points for plant-specific HACCP plans, serve as suggested guidelines, or set minimum standards for a particular process (Quadrilateral Meeting, 1993).

In considering the issue HACCP plan approval for its regulatory proposal, FSIS was given advice from colleagues at FDA that "any system of acceptance prior to operational validation was likely to be administratively complex and irrelevant to successful implementation" (USDA, 1995). As a result, FSIS concluded that successful process control, as indicated by the existence of a HACCP plan's complying to the seven principles, as well as the capacity of the plan to result in the production of complying products, would be indication that a plan is acceptable. FSIS concluded that the development, review and validation of establishment-specific HACCP plans would occur at the establishment level as a continuing process, with activities by both establishment and agency employees (USDA, 1995).

VERIFICATION OF HACCP PLANS

According to the NACMCF, the major role of regulatory agencies in HACCP programs is the verification that HACCP plans are effective and are being followed. The committee has suggested that the verification activities of regulatory agencies should focus on critical control points, and have presented a list of potential regulatory verification procedures (NACMCF, 1993). Verification procedures may include a review of records of critical control point monitoring, records of deviations and corrective actions and other records relevant to the HACCP plan (NACMCF, 1992).

Access to records is an important element of the regulatory agency's verification process; however, the need for access to records has prompted some concern (Food Chemical News, 1994; USDA, 1994). The debate lies in the degree of openness and accessibility of company records to the public. A delicate balance must be established between the public's "right to know" and the right of private companies to maintain proprietary and production records. Such records, if made public, could compromise a company's competitive position or be easily misinterpreted (USDA, 1994). The NACMCF has noted that HACCP plans are unique documents prepared to assure the control of a specific process or procedure and, as a result, may include proprietary information that must be protected by the regulatory agency (NACMCF, 1993).

While industry recognizes that records, such as those for monitoring of critical control points, are necessary for verification of food protection, there has been considerable disagreement between regulatory agencies and the food industry as to what records are relevant for regulator purposes (NRC, 1985). The NRC has asserted that

there is no need for access of regulatory agencies to proprietary information which has no relevance to food safety or quality (NRC, 1985). The council recommended that "the issue of access to records should be reviewed and resolved so that the food industry's apprehensions are allayed and regulatory agencies have the necessary assistance for effective execution of their responsibilities" (NRC, 1985).

While it is generally agreed that microbiological sampling can be a useful tool in the verification of HACCP systems, there is disagreement as to how microbiological sampling should be applied to be effective. The use of microbiological testing has been suggested for the evaluation of products before and after critical control points to verify that critical limits at these points are adequate (ICMSF, 1988; USDA, 1994).

Some have suggested that end-product testing should be utilized during the phase-in of HACCP and should remain part of the ongoing verification process (USDA, 1994). FSIS has proposed the use of interim targets for levels of *Salmonella* in raw meat and poultry to verify adequate process control. The process would use a moving sum verification scheme in which microbiological samples are taken daily and must not exceed an acceptable number of positives within an established "window" of days. If the acceptable limit within this window is exceeded, establishments would be required to take corrective action under Agency supervision (USDA, 1995). According to the agency, the establishment of such a testing program would reduce the level of human pathogens, and induce the process changes necessary in some establishments to achieve target levels of *Salmonella* as well as the reduction of the level and frequency of contamination by other pathogens (USDA, 1995).

Others have argued that the usefulness of microbiological sampling of end-product is limited by the problem of examining a sufficient number of sample units to obtain meaningful information (NRC, 1985; USDA, 1994). It has been suggested that the comparison of process controls would require a control for variability in the contamination rate of animals coming into slaughter, and that "the experimental logistics and costs of attempting such an evaluation would make the undertaking totally impractical" (Biddle et al., 1993). The limitations of attribute sampling to assure product safety originally led to the development of the HACCP system (ICMSF, 1988; Stevenson, 1995). The NACMCF has suggested that "a functioning HACCP system requires little end-product sampling, since appropriate safeguards are built in early in the process" (NACMCF, 1992).

RESPONSE TO DEVIATIONS FROM HACCP PLANS

The response of a regulatory agency to deviations will

vary depending upon many factors, including whether the application of HACCP is regulatory or advisory, or whether the program will involve quality as well as safety issues. Discussions at the 1994 FSIS HACCP roundtable revealed essentially two major perspectives. One perspective holds that a deviation from a HACCP requirement would not necessarily constitute a violation of law; however, the deviation may result in a regulatory remedy. Though a deviation from a critical control point would indicate the existence of a food safety concern, the degree of concern as well as the regulatory response to that concern must depend upon its severity. The other perspective asserts that, where HACCP is applied to safety issues only, critical control points are adopted to address potentially serious health hazards. Any deviation from the HACCP plan should constitute an adulteration, and therefore a violation of law, and be subject to enforcement action (USDA, 1994).

Several possible regulatory actions have been suggested, including an increase in inspection intensity or product testing, an increase in government audits, a suspension or termination of the inspected process, or a reversion to compliance requirements not based upon HACCP (Quadrilateral Meeting, 1993). In the FSIS proposed regulation, inspection service for a process covered by a HACCP plan would be suspended if that plan is found to be invalid. Invalid plans would be required to be corrected by the submission of a modified HACCP plan that corrects process deficiencies or, if adulterated product resulted from the invalid plan, evidence from product tested by an outside laboratory that the modified plan has corrected the deficiency (USDA, 1994).

PHASE-IN OF IMPLEMENTATION

The adoption and implementation of HACCP programs will require a culture change by industry and regulators alike. Considerable training of industry and regulatory personnel is necessary, and time is needed to develop HACCP plans for individual processes, and to implement them to assure that they are functioning properly. While it is generally agreed that a transition or phase-in period is necessary for the effective implementation of HACCP, there are variations in approaches to such phase-in. A certain date for implementation of HACCP could be set in all plants, or phase-in could be staggered based upon priorities such as the severity of risk, technical difficulties in implementation, training received, or a plant's compliance record (USDA, 1994). The Quadrilateral HACCP working group has outlined four considerations for the staggered approach to HACCP phase-in: Consider a time period of phase-in by industry sector; consider phasing in by high risk or low risk; consider seeking out plants that are willing to implement HACCP before others; and consider the degree of difficulty in implementing HACCP for various processes (Quadrilateral Meeting, 1993).

The NACMCF has advised that HACCP plans should be established based upon the risk and severity of the hazards associated with the process (NACMCF, 1993). Many have suggested that HACCP plans should first be implemented for those products with the greatest associated risk; however, it has been noted that starting with low risk situations could provide an opportunity to gain experience and improvements in HACCP application before moving on to high risk situations, where mistakes would be more serious. FSIS has proposed a phase-in plan that would begin with processes that constitute the greatest risk, combine some processes where the volume of production is lower, and phase-in implementation in all categories within one to three years after publication of the final regulation, with small establishments phased in last (USDA, 1994).

APPLICATION OF HACCP IN SMALL OPERATIONS

The establishment of product and process-specific HACCP plans requires access to expertise as well as a considerable investment in the training of product employees. Many small operations may lack the technical expertise and resources necessary for the development and implementation of HACCP programs. As a result, it has been suggested that technical assistance and a longer implementation period be provided to these manufacturers (Codex, 1994). FSIS has given small businesses the longest time period the implementation of HACCP. In Canada, a recent government initiative would establish an adaptation fund: A four-year program which would provide money for HACCP training and development in small businesses.

RELATION OF HACCP TO CURRENT INSPECTION

One of the most debated issues in the implementation of HACCP legislation by regulatory authorities concerns how these regulations will influence current inspection procedures. In Canada, the implementation of HACCP is expected to allow the regulators to focus inspection efforts on critical areas and production process controls (USDA, 1994). With a new focus on verification of process control rather than individual product-by-product inspection, change in the traditional role of the inspector is inevitable. Many have suggested that the implementation of HACCP will result in profound changes which will require less inspection presence in plants (USDA, 1994) in many smaller operations, which rely on their inspector for guidance, the role of the inspector would be likely to increase (Flickinger, 1994). The inspector may be called upon to take on the role of educator.

The NACMCF has suggested that regulatory agencies

could modify inspection procedures to take advantage of HACCP plants (NACMCF, 1993). They noted that "inspection for verification of HACCP plans could be in lieu of certain traditional inspection procedures rather than merely adding a new form of inspection onto existing procedures." A suggested option for such changes would be to take advantage of a phase-in of HACCP programs to allow a phased rather than abrupt withdrawal of direct regulatory supervision of operations (Biddle et al., 1993). In Canada, the implementation of HACCP is expected to allow the regulators to focus inspection efforts on critical areas and production process controls (USDA, 1994).

A prime example of the debate can be seen in issues involving meat and poultry slaughter inspection. Many have stated that, while live animal inspection should continue HACCP procedures should be a substitute for carcass-by-carcass/bird-by-bird line inspection procedures (Food Chemical News, 1995; Knutson et al., 1995; USDA, 1995). In the United States however, FSIS proposed regulations would establish a HACCP program in addition to continuing current carcass-by-carcass and continuous inspection in meat and poultry establishments. The Agency justified their decision by suggesting that current inspection procedures "play an important role in ensuring sanitation compliance is maintained, excluding diseased animals from the food supply and detecting and removing other defects, such as fecal contamination, which are directly related to food safety" (USDA, 1995). The Safe Food Coalition backed the decision, suggesting that the industry and FSIS needed time to make an orderly transition. The National Joint Council of Food Inspection Locals also supported the decision, stating that there would be no integrity without food inspectors to maintain oversight. The decision drew criticism from industry groups, who opposed a layering of new requirements on top of the old system (Food Chemical News, 1995).

The HACCP concept has been widely endorsed by both the food industry and regulatory community as an effective and rational approach to the assurance of safety and quality in foods. The increasing application of the HACCP system to food legislation in the international community has underscored the viability of HACCP as a proactive, science-based approach to process control. The adoption of the HACCP system will result in a massive cultural change in the relationship between the regulator and the regulated industry. Such a change will inevitably involve many disagreements and a considerable amount of anxiety.

In 1985, the NRC asserted that, in the past, the achievement of common goals of food quality and safety assurance were often hindered by adversarial attitudes and a lack of cooperation between regulatory agencies and the food industry. Cooperation will be essential for the resolution of issues of disagreement and the smooth and successful transition to HACCP-based inspection.

Success will require determination, perseverance, and plenty of communication.

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