

HACCP HISTORY AND CONCEPTUAL OVERVIEW

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ABSTRACT

HACCP is a system that enables the production of safe meat and poultry products through the thorough analysis of production processes, identification of all hazards that are likely to occur in the production establishment, the identification of critical points in the process at which these hazards may be introduced into product and therefore should be controlled, the establishment of critical limits for control at those points, the verification of these prescribed steps, and the methods by which the processing establishment and the regulatory authority can monitor how well process control through the HACCP plan is working. The history of the development of HACCP is reviewed, and examples of practical applications of HACCP are described.

KEYWORDS: HACCP, critical control points, CCPs, critical limits, beef slaughter

THE HISTORY OF MEAT INSPECTION

Federal meat inspection legislation dates from 1890, when a number of European countries began to raise questions about the safety of American beef. Congress gave the U.S. Department of Agriculture (USDA) the responsibility for ensuring that exports would meet European requirements and, in 1891, for conducting ante- and postmortem inspection of livestock slaughtered for meat intended for distribution in the United States. In 1906, the graphic picture of unsanitary conditions in meat-packing establishments described in Upton Sinclair's novel, *The Jungle*, outraged and galvanized the American public. Children's rhymes of the era mocked the meat industry with ditties such as:

Mary had a little lamb,

And when it starts to sicken,

She sends it off to packing town,

And it comes back as chicken.

Congress responded by passing the Federal Meat Inspection Act (FMIA), one of the first federal consumer protection measures. It established sanitary standards for slaughter and processing establishments, and mandated antemortem inspection of animals (cattle, hogs, sheep, and goats) and postmortem inspection of every carcass. Congress also required the continuous presence of government inspectors in all establishments that manufactured meat products for commerce. Because the program depended heavily on veterinary skills, it was implemented by USDA's Bureau of Animal Industry, which, during that first year, oversaw the inspection of nearly 50 million animals.

The meat inspection program that developed early in this century used organoleptic methods, based on sight, touch, and smell. The major public health concerns of the time were the potential for transmission of diseases from sick animals to humans and the lack of sanitary conditions for animal slaughter and production of processed products. The purpose of carcass inspection was to keep meat from diseased animals out of the food supply. Federal inspectors under the supervision of veterinarians checked every live animal and every carcass for signs of disease. They also watched for unsanitary practices and the use of dangerous preservatives. In addition to requiring carcass-by-carcass inspection in slaughter establishments, the 1906 meat inspection law provided for continuous USDA inspection of processing operations. Processing, which for the most part consisted of cutting and boning whole carcasses and the production of sausages, ham, and bacon, was usually done in or near the slaughterhouse. Processing was viewed as an extension of slaughter and was conducted by the same personnel. From the inception of the program, however, it was recognized that, in processing inspection, the inspector focuses on the operation of the overall production line, not on each production unit (in contrast to slaughter inspection, where inspectors focus on each carcass). The FMIA covered all meat and meat products moving in interstate commerce. It did not cover poultry as, at that time, chickens and turkeys were produced mainly on small farms for personal consumption or sale in the immediate area. They were inspected only by the purchaser. The growth of commerce after World War II had a major impact on the meat and poultry industry. New establishments opened and this growth surge continued well in to the 1960s. An increasing proportion of the total meat and poultry supply was being used for canned soups, frankfurters, and other processed foods, such as frozen dinners, pizza, and so forth. Between

1946 and 1976, the volume of such products nearly quadrupled. Along with these new products, of course, came new complexity—new technologies, new ingredients, new processes. These developments presented major challenges to the Food Safety and Inspection Services' (FSIS) inspection program. Additional skills were increasingly needed, such as food technology and microbiology. More personnel were needed to cover the expanding production and geographic distribution.

Meanwhile, better animal husbandry practices had improved animal health and reduced the public health risk from diseased carcasses. Extensive, statutorily mandated carcass-by-carcass inspection continued, however, with the important objective of eliminating from commerce meat from carcasses bearing the unpalatable signs of disease (such as tumors and lesions), meat from animals with diseases that could pose a human health risk (such as Salmonellosis or cysticercosis), fecal contamination of meat and poultry carcasses, and meat from carcasses bearing visible damage (such as bruises).

In the late 1950s, public concern grew about the potential for unseen health hazards in the food supply and various forms of adulteration that consumers could not, by themselves identify. This concern attracted the attention of Congress, which in 1958 passed the Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act, providing for pre-market approval of new food additives and their conditions and levels of use. Rachel Carson's *Silent Spring*, published in 1962, further stimulated concern, and in 1967, FSIS established the National Residue Program as the principal regulatory mechanism for determining and controlling the presence and level of pesticides and other chemical contaminants in meat and poultry.

Trends towards growth and increasing complexity in the meat and poultry industries continued, and FSIS continued to strain to keep up with an industry radically different in scale and scope from what it had been in 1906. These challenges stimulated FSIS to commission a number of studies to explore more efficient ways to inspect meat and poultry while maintaining consumer protections. The first of these, a 1976 study by the management consulting firm of Booz, Allen and Hamilton, Inc., recommended, among other things, that FSIS should put mechanisms in place that would shift responsibilities from inspectors to the establishment, giving inspectors a verification responsibility. The study also recommended the establishment of microbiological criteria for finished products. These recommendations elicited a generally negative response from consumer groups and some members of FSIS's workforce, who interpreted the recommended role changes as an abdication of FSIS responsibility. In the end, FSIS pursued only some of the recommendations. This trend continued through the 1980s and into the 1990s. During this period, numerous organizations, including the Government Accounting Office (GAO), the National Academy of Sciences (NAS), the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), and consumer groups, characterized the traditional inspection system as overwhelmed by the practical realities of modern meat and poultry slaughter and processing, and called for change.

The call for change was galvanized in the early 1990s with a tragic outbreak of *E. coli* O157:H7 foodborne illness in the Northwest of the United States. Hundreds of people were sickened in this outbreak, which resulted from the consumption of undercooked, contaminated ground beef, and four children died. In addition to significant structural changes to the agency's organization (especially the changes to remove from FSIS any responsibility for meat- and

poultry-promotional activities), FSIS developed the regulatory proposal that became the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (HACCP) Rule (published as a final rule in 1996). In this rule, FSIS established that its food safety goal was to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food-production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur. With respect to major enteric pathogens that contaminate meat and poultry products during the slaughter process, FSIS stated in this rulemaking that it believed that the risk of foodborne illness associated with these pathogens is largely avoidable and can be minimized by proper implementation of HACCP. The agency was clear that implementation of HACCP did not mean the absolute elimination of pathogens, but that it did mean preventing and reducing contamination with pathogenic microorganisms to a degree that very substantially reduces and minimizes the risk of foodborne illness.

HACCP CORE CONCEPTS

The central goal of the HACCP rulemaking was to stimulate improvement in food safety practices by setting public health-oriented targets or standards that all meat and poultry establishments must meet. A key feature of this concept is that by establishing targets or standards, innovation and changes will be stimulated to reduce the risk from all sources of foodborne hazards – biological, chemical, and physical – while simultaneously providing a tool

for holding establishments accountable for achieving acceptable levels of food safety performance.

This approach raised new and difficult scientific and policy questions, not the least of which was the basis upon which to set the targets or standards (which came to be called microbial limits or performance standards). The setting of specific quantitative limits for each significant pathogen was precluded because of inadequate scientific understanding of the link between specific levels of many pathogens and the risk of foodborne illness that would be needed to set standards on public health grounds. The approach that FSIS ultimately chose was to set targets for pathogen reduction based on what was judged achievable with available science and technology, and to require establishments to meet the limits on a consistent basis. In proposing the limits, FSIS acknowledged that, as knowledge and methods improve, additional pathogens could be targeted, and targets could be made more stringent.

In setting performance standards, FSIS emphasized that this approach was a way to achieve control – and assess the effectiveness of that control -- of meat and poultry production processes over time in relation to a specified target level of performance. It was not a means of evaluating and approving individual product lots.

RATIONALE FOR ADOPTING HACCP

FSIS concluded that the goal of improving meat and poultry safety could be best achieved by requiring all meat and poultry establishments adopt HACCP systems. HACCP is a systematic approach to the identification and control of hazards associated with food production that is widely recognized by authoritative scientific bodies, some of which had also commented on

FSIS' need to modernize its inspection system (i.e., the NAS, NACMCF, GAO, and international organizations such as the Codex Alimentarius Commission). HACCP provides assurances and documentation that processes used in manufacturing meat and poultry products are under control and are producing safe, wholesome, and unadulterated products.

OVERVIEW OF HACCP PRINCIPLES

HACCP was first developed by the Pillsbury Company as a means of assuring the safety of food produced for the U.S. space program. The National Aeronautics and Space Administration (NASA) wanted a “zero defect” program to guarantee safety in the foods astronauts would consume in space. HACCP, they recognized after surveying available control options, was the system that could provide the greatest assurance of safety while reducing dependence on finished product sampling and testing. HACCP, by virtue of identifying the hazards inherent in the product and process, and devising preventive measures that could be monitored, would control the process. Since Pillsbury presented the HACCP system at the 1971 U.S. National Conference of Food Protection, it has become gradually recognized as a valuable approach. For example, FDA had incorporated HACCP principles into its low-acid canned foods regulations in 1973 to address serious botulism problems in the canning industry. And in 1992, NACMCF endorsed HACCP as an effective and rational means of assuring food safety from harvest to consumption. (NACMCF was established in 1988 at the recommendation of the NAS to advise USDA and the Department of Health and Human Services, HHS, on food safety issues.) NACMCF formulated seven principles to be employed in the development of HACCP plans; the principles are detailed below. Under a HACCP system, if a deviation occurs indicating that control has been lost, appropriate steps are

taken to reestablish control in a timely manner to assure that potentially hazardous product does not reach to consumer.

Principle 1: Conduct a hazard analysis.

The first step in establishing a HACCP system is to identify all hazards – biological, physical, or chemical -- that can be associated with the product. The hazard must be such that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food.

Principle 2: Identify the CCPs in the process.

A critical control point (CCP) is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. All significant hazards identified during the hazard analysis must be addressed. CCPs include cooking, chilling, specific sanitation procedures, prevention of cross contamination, product formulation controls,, employee and environmental hygiene. All CCPs must be carefully developed and documented.

Principle 3: Establish critical limits for preventive measures associated with each identified CCP.

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. CCPs are most often based on process parameters, such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, acidity, salt concentration, etc. FSIS proposed that processors identify critical limits in their HACCP plans that must be met at each CCP to be certain that the hazard is controlled.

Principle 4: Establish CCP monitoring requirements and procedures for using monitoring results to adjust processes and maintain control.

Monitoring consists of observations or measurements taken to assess whether a CCP is under control. Monitoring is used to determine when a deviation occurs at a CCP and, if it is not continuous, needs to be conducted at a frequency sufficient to ensure that the CCP is under control.

Principle 5: Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit.

HACCP systems are designed to identify potential health hazards and to establish strategies to prevent their occurrence. However, ideal circumstances will not always prevail in a processing operation and deviations will occur. In such instances, NACMCF points out that corrective action plans must be in place to determine the disposition of the non-compliant product, and to identify and correct the cause of the deviation to regain control of the CCP. FSIS proposed that establishments describe in their HACCP plans the corrective actions that will be taken if a critical limit is not met.

Principle 6: Establish effective recordkeeping procedures that document the HACCP plan.

NACMCF states that an establishment's HACCP plan and all associated records must be maintained on file at the establishment. Examples include records on incoming ingredients, product processing, packaging, storage, and distribution, and deviations and corrective actions. Records generated during operation of the HACCP plan must be maintained and available for review, and FSIS specified that records must contain actual values, rather than general terms such as "satisfactory," or "unsatisfactory."

Principle 7: Establish procedures to verify that the HACCP system is working correctly.

NACMCF defines verification as the use of methods, procedures, or tests in addition to those used for monitoring, to determine if the HACCP system is in compliance with the plan, or whether the plan needs modification and revalidation. NACMCF identified four processes as steps in the establishment's verification of its HACCP system:

1. Scientific and technical processes to verify that all critical limits at CCPs are adequate and sufficient to control hazards that are likely to occur (also known as “validating the process”).
2. Assurance that the HACCP plan functions properly, through frequent review of the plan, verification, review of records, and determination that appropriate decisions and product dispositions occur when deviations occur.
3. Documentation through periodic review to ensure the accuracy of the HACCP plan, including an on-site review and verification of all flow diagrams, CCPs, critical limits, monitoring procedures, corrective actions, and records.
4. Regulatory verification that the plan is functioning satisfactorily through overall process validation (including any or all of the verification steps listed above) plus final product testing to demonstrate compliance with regulatory as well as other desired performance standards.

FSIS considered this verification principle a key element to link HACCP with the agency's regulatory strategy to establish public health-oriented standards that establishments must meet in order to do business. Without some objective measure of what constitutes an acceptable level of food safety performance with respect to pathogenic microorganisms, it would be impossible to determine whether an establishment's HACCP plan is acceptable and functioning effectively.

APPLYING HACCP TO BEEF SLAUGHTER: AN ILLUSTRATION

The goal of HACCP for slaughter operations is to prevent, eliminate, or reduce the incidence and levels of microorganisms pathogenic to humans. While beef slaughter operations do not include a treatment lethal to pathogens (such as cooking) that ensures the elimination of pathogenic microorganisms, a number of the processing steps can be controlled to minimize microbiological hazards.

A beef slaughter establishment's hazard analysis may identify several hazards, particularly enteric pathogens, such as *Salmonella*. CCPs where *Salmonella* contamination might occur can be identified and then controlled by establishing critical limits, monitoring those limits at an appropriate frequency, and taking corrective actions when deviations occur. Recordkeeping and verification procedures would also be identified for these CCPs in the establishment's HACCP plan.

For example, the intestinal tracts of animals can harbor large populations of enteric pathogens, such as *Salmonella*, even though the animals themselves are not sick. As the slaughtered animals are eviscerated, there is potential for spreading the *Salmonella* from the intestinal tract to the carcass, operator, or equipment, if the intestines are accidentally cut. Therefore, evisceration would be considered a CCP in a HACCP plan for beef slaughter. Critical limits for the evisceration CCP might be zero percent occurrence of the following defects for a single carcass: fecal material, ingesta, urine, or abscesses. The establishment employees working at evisceration would monitor by observing carcasses for contamination defects and would take

corrective actions if the critical limits were exceeded. Corrective actions might include: immediate trimming of defects from carcasses, addition of more establishment employees to the slaughter line, a reduction in line speed, sanitation of evisceration tools in 180°F water, etc. Records resulting from this CCP might include a random post-evisceration carcass examination log. Verification might consist of supervisory review of records and operations, and random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.

Removing the hide from cattle is a major source of microbial contamination during the slaughter process. Cattle entering the slaughter establishment carry with them microbial populations that reflect what occurred during pre-slaughter care and handling. *Salmonella* and other bacteria can be spread during the skinning process through contact with hide, hands, and various pieces of equipment. Therefore, skinning would be a CCP in a beef slaughter HACCP plan. Methods for control of contamination at skinning might include adequate training of the person doing the skinning to minimize contamination, including pulling the hide down and out from the carcass as opposed to upward and away, and proper cleaning and sanitation of equipment and carcass contact surfaces. Monitoring at this CCP might include observation of the effectiveness of the skinning process for each carcass, with a possible critical limits set so that 20 percent of carcasses or less have dressing defects. If this critical limit is exceeded, required corrective actions could include immediate trimming of defects on carcasses, additional establishment employees added to the slaughter line, and a reduction in line speed. Records from this CCP might include a random post-skinning carcass examination log. Verification might consist of a supervisory review of records, examination of random carcasses after skinning is complete using

a sampling plan sufficient to assure process control, and reviewing control charts to confirm that sampling frequency is sufficient to detect 20 percent defect criteria.