

HACCP (Hazard Analysis Critical Control Points): Is It Coming to the Dairy?

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ABSTRACT

The risks and consequences of foodborne and waterborne pathogens are coming to the forefront of public health concerns, and strong pressure is being applied on agriculture for immediate implementation of on-farm controls. The FDA is considering HACCP (Hazard Analysis Critical Control Points) as the new foundation for revision of the US Food Safety Assurance Program because HACCP is considered to be a science-based, systematic approach to the prevention of food safety problems. In addition, the implementation of HACCP principles permits more government oversight through requirements for standard operating procedures and additional systems for keeping records, places primary responsibility for ensuring food safety on the food manufacturer or distributor, and may assist US food companies in competing more effectively in the world market. With the HACCP-based program in place, a government investigator should be able to determine and evaluate both current and past conditions that are critical to ensuring the safety of the food produced by the facility. When this policy is brought to the production unit, the impact for producers and veterinarians will be substantial.

(**Key words:** Hazard Analysis Critical Control Points, HACCP, food safety)

INTRODUCTION

The safety of the food supply remains a high priority for consumers, producers, veterinarians, and regulatory agencies. This concern is often justified. A task force of the Council for Agricultural Science and Technology has published a general consensus document stating that foodborne illness in the US affects 6.5 to 33 million people/yr; foodborne illness causes approximately 9000 deaths annually (4, 12). The recommendation for on-farm programs [p. 14 in (4)] includes the following statement:

We recommend that control practices be applied from food source to consumption, including the incorporation of Hazard Analysis Critical Control Points (HACCP) principles. New scientific advances should be incorporated into control practices.

In focusing on this endeavor, the USDA regulates meat and poultry, and the FDA is responsible for regulating all other foods. In addition, food safety on the farm is the responsibility of the producer and can be a collaborative effort with veterinarians. Food processors, manufacturers, wholesalers, retail outlets, and restaurants also play a key role in maintaining the safety of food products and food ingredients (1, 8, 9, 10). Finally, the consumer has a pivotal role in food safety by ensuring that the food is not mishandled after purchase but is prepared and served in a proper manner.

On July 6, 1996, President Clinton announced a significant reform of federal food safety rules for meat and poultry. [The final rule and a request for comments was published 25 July, 1996 in the Federal Register (Volume 61, number 144, 38805). The federal agency involved is the Department of Agriculture, and the title is "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems".] In providing this rule, the Food Safety Inspection Service established requirements that apply to meat and poultry establishments. These requirements are designed to reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products, to reduce the incidence of foodborne illness associated with the consumption of those products, and to provide a framework to modernize the current system of meat and poultry inspection.

The four pillars of this reform are listed:

1. Establishment of a HACCP Plan. Every processing plant must adopt its own HACCP plan to address all of the significant hazards associated with its products. The effectiveness of the HACCP plan will be continuously verified by inspectors from the USDA Food Safety Inspection Service.

Received September 18, 1996.
Accepted June 5, 1997.

2. Mandatory testing for *Escherichia coli* in all slaughter plants. Carcasses must be routinely tested for the presence of generic *E. coli* contamination in order to verify the effectiveness of the plant in preventing or reducing fecal contamination.
3. Pathogen reduction performance standards for *Salmonella* spp. Every slaughter plant and meat processing facility that produces raw ground products must ensure that their contamination rate from *Salmonella* spp. is below the current national baseline incidence rate.
4. Sanitation standard operating procedures. Every plant must adopt and carry out a written plan for meeting its daily sanitation responsibilities.

The HACCP system was initiated during summer 1996 with USDA implementation of its testing program for *Salmonella* spp. Next follows the activation of the program for standard operating procedures program and the requirements for testing for *E. coli*. Dates by which the rules will be effective are January 26, 1998 for large establishments (≥ 500 employees) and January 25, 1999 for smaller establishments (all establishments with >10 employees, but <500).

What does this regulation have to do with the dairy? Slaughter plants for culled cows will test their equipment for contamination by *Salmonella* spp., and, if such contamination occurs, the animals entering the plant will be the prime suspects (i.e., HACCP step 1 is to review incoming material), and inspection of the dairy or beef production unit of origin will occur. The ability to trace back to the dairy or beef production unit will not be far behind. Local fluid milk and cheese processing plants should be developing a HACCP program if one is not already in place, and the HACCP plan requires closer scrutiny of the primary raw ingredient: milk from the dairy.

HACCP—The New Approach In Food Safety

After the development and implementation of good manufacturing practices, industry personnel and regulators have been depending upon periodic checks of manufacturing plants and random testing of final products to ensure food safety. When foodborne illnesses occur, local, state, and federal agencies react with teams of investigators to track down the problem. In an attempt to modernize food safety efforts, the USDA and FDA are mandating the HACCP system. In essence, HACCP has seven principles (Table 1) and 12 steps for its implementation (Table 2). The specific aim of a HACCP program is to identify problems before they occur and then to establish con-

trol measures that are critical to maximizing food safety at each stage in production (6, 7), including the farm. The HACCP system has been endorsed by various scientific groups, including the National Academy of Sciences, the National Advisory Committee on Microbiological Criteria for Foods, and Codex Alimentarius Commission, a body that sets standards.

In January 1994, the FDA proposed regulations that would establish HACCP for the US seafood industry, and these regulations were finalized in December 1995. However, HACCP principles have been investigated for the fish processing industry in Europe for several years (6). Several portions of HACCP are already in place in FDA-regulated plants canning foods that are low in acid; these regulations have been incorporated into the recently revised FDA Food Code. The Food Code functions as prototype legislation for state and territorial agencies that license and inspect food establishments in the US. In short, the FDA is considering HACCP as the new foundation for revision of the US Food Safety Assurance Program because HACCP is deemed a science-based, systematic approach to the prevention of food safety problems. In addition, the implementation of HACCP permits more government oversight in food production, places primary responsibility for ensuring food safety on the food manufacturer or distributor, and may assist US food companies in competing more effectively in the world market. With a HACCP-based program in place, a government investigator can determine and evaluate both current and past conditions that are critical to ensuring the safety of the food produced by the facility.

HACCP and the Live Animal Production Unit

Considerations for on-farm control of foodborne and waterborne illness in humans are being justified by

TABLE 1. The seven principles of contemporary HACCP (Hazard Analysis Critical Control Points).

1. Conduct analysis of potential hazards (e.g. chemical, microbial, and physical).
2. Determine critical control points for the targeted hazard or hazards.
3. Establish critical limits.
4. Establish routine monitoring procedures to assess these critical limits.
5. Establish corrective actions to be implemented if critical limits are exceeded.
6. Establish an effective record-keeping system for the program.
7. Establish a system of verification to document that the HACCP program is being followed.

TABLE 2. The twelve steps of modern HACCP (Hazard Analysis Critical Control Points) in food processing.

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1. Assemble a multidisciplinary, facility-based HACCP team.
 2. Describe the final product and the method of its distribution (e.g., formulation and processing requirements).
 3. Identify the intended use of the food and the targeted consumer group or groups.
 4. Develop a flow diagram that describes the production and distribution process.
 5. Verify the flow diagram.
 6. Implement principle 1. Conduct a hazard analysis by preparing a list of steps in the production process where significant chemical and microbial hazards occur and begin to describe preventive measures.
 7. Apply principle 2. Identify the Critical Control Points (CCP) in the production process, usually via decision-tree analysis.
 8. Employ principle 3. Establish critical limits for triggering the implementation of preventive measures associated with each CCP that has been identified.
 9. Implement principle 4. Establish CCP monitoring requirements and organize the procedures for using the results of the monitoring program. Goal: use results of the monitoring program to adjust the procedures and maintain control of the production process.
 10. Organize principle 5. Create corrective actions to be initiated when the monitoring program indicates a deviation from an established critical limit.
 11. Maintain principle 6. Establish effective procedures for record keeping that document implementation of the HACCP system (e.g., the HACCP plan, records obtained during production, etc.).
 12. Institute principle 7. Establish procedures for verification that the HACCP system is working correctly (e.g., internal and external verification, periodic revalidations of the system).
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consumer groups and regulatory agencies in that one or more livestock species are the reservoirs for some important disease agents. However, many species of pets and wildlife (and even humans) may also serve as reservoirs for these and other pathogens. There are a number of foodborne and waterborne hazards that potentially can originate during animal production. Biological hazards include *Salmonella* spp., *Cryptosporidium parvum*, *Campylobacter jejuni*, *Listeria monocytogenes*, *Escherichia coli* O157:H7, other enterotoxigenic *E. coli*, *Yersinia enterocolitica*, and *Trichinella* spp. Chemical hazards include antibiotics, herbicides, and pesticides. Physical hazards include needles.

A key question is how HACCP plans will be implemented on the farm. The theories of HACCP have not been applied to live animal production units (3, 11), which may become problematic for animal and plant agriculture if various groups begin demanding that such programs be implemented on the farm. An important definition is that of a critical control point—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. Correct implementation of the HACCP principle requires that scientifically documented steps and preventive measures exist that can be effectively applied at known critical control points. At present, determination of critical control points may be possible for on-farm implementation for chemical or physical hazards. These areas currently are essentially addressed by current livestock quality assurance programs (e.g., poultry, swine, beef, and dairy). However, potential biological hazards that may exist

on the dairy or other production units do not have well-known critical control points. It may be easy to outlaw the presence of bacteria, viruses, and parasites on the farm, but this rule will be hard to enforce. An interesting peek into what pathogens are of interest to the FDA can be found on the Internet: *Bad Bug Book* (<http://vm.cfsan.fda.gov>). In addition, USDA news releases and media advisories are available on the Internet (<http://www.usda.gov>).

DISCUSSION

Food safety is a pressing issue for government, consumers, food retailers, and processors. This sense of urgency must be recognized by dairy producers and veterinarians. Although the burden of microbial foodborne disease is not known with a high degree of certainty, the estimated number of clinical cases and deaths annually (2, 12) is disturbing, especially because the US is among the leaders in providing a safe food supply for the nation. On-farm HACCP programs for chemical or physical hazards are possible to develop and implement. However, it is currently difficult to improve food safety substantially using HACCP on the farm. For instance, no current scientific evidence supports any of the control points available on the farm for implementation to reduce or eliminate the hazard of *E. coli* O157:H7 (ECO157:H7). The key features that are necessary to eradicate a pathogen (e.g., a single host, no wildlife reservoir, production of identifiable clinical disease, and availability of a cost efficient diagnostic assay) do not exist for *E. coli* O157:H7.

There are opportunities at present to develop HACCP plans to address concerns about chemical

residues (e.g., antibiotics, herbicides, or pesticides in milk or cull cows). Until critical control points for zoonotic diseases are known, the dairy industry can adapt and implement good dairy practices to aid in managing animal health problems and to begin addressing pathogens of concern for foodborne and waterborne illness. On-farm procedures to monitor the presence of emerging and reemerging human pathogens will need to be established in the near future. Probable critical control points on the farm for many of these human pathogens will be housing and bedding, water and waste management areas, hospital pens, calving pens, treatment areas, bulk tank milk, and young stock and cull animals. By adapting a national standard of good dairy practices for the production of milk and dairy beef, many worries surrounding potential chemical and microbial residues leaving the production unit can be alleviated through documentation and education.

ACKNOWLEDGMENTS

The University of California, Davis School of Veterinary Medicine is a charter member of the Food Animal Production Medicine Consortium. The University of California, Davis Livestock Disease Research Laboratory and the California Dairy Food

Research Center are thanked for their generous support of the Dairy Food Safety Laboratory.

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