

meat and poultry products. In slaughter establishments, PQC programs are designed to control economic, quality, and some product wholesomeness aspects of production. Such programs include finished product standards, preoperational sanitation and carcass presentation. All slaughter PQC programs are voluntary.

Preventive systems of process control have been formally employed in the slaughter of broilers and Cornish game hens since 1983, and in the slaughter of turkeys since 1984. These process control approaches are integral features of inspection systems known as the New Line Speed (NELS) inspection system for broilers and cornish game hens, and the New Turkey Inspection System (NTIS) for turkeys (9 CFR 381.76). Forty-five establishments operate under NELs today, and 27 establishments operate under NTIS.

Under these slaughter process control systems, the establishment demonstrates compliance with regulatory requirements by identifying the points in the slaughter process that are important to regulatory compliance. The establishment then sets realistic standards for these points, and observes them often enough to detect deviation from a standard before non-compliance occurs. The establishment also identifies action it will take if a standard is not met. The written program and the generated records of observations and actions are evidence of the degree of process control and regulatory compliance. By reviewing and evaluating establishment records and verifying them with process observations as necessary, FSIS inspection personnel ensure an establishment is meeting its responsibility to produce safe and wholesome product.

The principal difference between slaughter process control systems in place in NELs and NTIS establishments today, and the proposed HACCP system is the focus of the systems. NELs and NTIS were designed not only to address safety hazards associated with raw poultry carcasses, but quality factors as well. The proposed HACCP system focuses on hazards associated with safety of product.

International Efforts on HACCP

Between 1990 and 1992, a working group of the Codex Committee on Food Hygiene developed a guideline document that covered the principles and application of HACCP to all sectors of the food chain from producer to consumer. The Codex Alimentarius Commission in 1993 adopted the HACCP document that now serves as a

benchmark for countries to incorporate HACCP principles into their food industries. The seven HACCP principles adopted by the Codex Alimentarius Commission are identical to those proposed in this rule with the exception that HACCP principles six (i.e., recordkeeping) and seven (i.e., verification) are reversed.

In 1993, Agriculture Canada implemented a Food Safety Enhancement Program, which is designed to encourage the adoption of HACCP principles across all agri-food processed commodity groups and shell eggs. The food industry will be required to control and monitor its manufacturing process and maintain records at CCP's. FSEP will also provide a means to help government inspectors prioritize their responsibilities and focus their attention on CCP's in the process to ensure the production of safe food. Full implementation of the FSEP program is scheduled to be completed by September 1996.

Recently, the European Union (EU) adopted two Directives that made reference to the HACCP system. One Directive (93/43/EEC) focuses on the hygiene of foodstuffs and specifies that food business operations must identify and control any step in their process critical for ensuring food safety using the HACCP system. The other Directive (92/5/EEC) is one specific to meat products, which also embraces HACCP principles. These Directives were adopted on June 14, 1993 and February 10, 1992, respectively. EU members have up to 30 months from the date of adoption to implement the provisions of the Directives into national law. Detailed guidelines are now under development for meat products.

New Zealand has also been proactive in adopting HACCP principles in the food industry. Through the publication of *Guide to the Implementation of Hazard Analysis and Critical Control Point Systems in the Meat Industry*, the Ministry of Agriculture and Fisheries provided: (1) a generic model from which an understanding of the HACCP approach to food safety can be obtained; (2) a guide to the application of HACCP systems, especially in the case of raw foods; and (3) specific examples of application.

Adopting a HACCP system could potentially enhance international trade opportunities for the United States. Although enhancing trade has no direct effect on public health, participation in international trade in food products is critical to the U.S. economy. The United States is by far the world's major food exporter, with exports of raw agricultural and processed food

products of over \$40 billion per year. The United States also imports a substantial quantity of food products each year from many countries around the world. HACCP will improve FSIS's ability to monitor imports and thus ensure greater confidence in their safety. Also, HACCP is becoming the world-wide standard to ensure the safety of food and will thus serve as the basis for harmonizing U.S. food safety regulations with those of other nations.

The Uruguay Round Negotiations under the General Agreement on Tariffs and Trade (GATT) has resulted in further focus on this area. The Agreement on the Application of Sanitary and Phytosanitary Measures states the desire of member countries including the United States, to further " * * * the use of harmonized sanitary and phytosanitary measures between members, on the basis of international standards, guidelines, and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission * * *". This trend toward harmonization coupled with the current recommendations of the Codex Alimentarius Commission encouraging the international use of HACCP, provide further support for FSIS's proposal for a mandatory HACCP program for the production of all meat and poultry products.

FSIS Guidance on Development of HACCP Plans

FSIS believes that it can facilitate development of HACCP plans in various ways without compromising the principle that these are industry process control plans and, as such, plan development is the responsibility of the regulated establishment. Therefore, FSIS has underway a series of planned assistance efforts, which will continue and be completed over the next 6-12 months.

(a) Generic Models: FSIS has published the generic models developed at Agency workshops and will publish generic models developed by NACMCF as they become available. An example, the "Generic HACCP for Raw Beef," is provided in the Appendix.

FSIS has categorized in this proposed regulation all processes carried out in the establishments it regulates. Because FSIS pilot-testing has shown generic plans to be useful to establishments as they develop plans specific to their own processes and products, FSIS will publish and make widely available a generic model for each of the nine process categories at least six months in advance of the due date for each process category. FSIS believes that use of