(a) Low-Acid Canned Foods

The low-acid canned food industry has had a remarkably good record over the past 50 years, during which more than 1 trillion cans of commercially canned foods were consumed. Beginning in 1970, however, botulinum toxin and C. botulinum were found in commercially canned product produced under the jurisdiction of both FDA and USDA. From 1970 until 1990, nine incidents of botulinum outbreaks occurred, resulting in death on six occasions. The products implicated included mushrooms, peppers, salmon, boned turkey, chicken vegetable soup, tuna, and bean salad.

In response to the botulism outbreaks, the canning industry identified CCPs that must be controlled and monitored to ensure that canning operations produce safe canned foods. For products under its jurisdiction, FDA in 1973 codified the CCPs into a good manufacturing practice regulation for thermally processed low-acid canned foods packed in hermetically sealed containers(21 CFR 110).

Since FDA's promulgation of that regulation (revised in 1978), the threat of botulism in canned product has been greatly reduced. While sporadic incidents continue, investigations of such incidents have attributed the causes to establishments' failure to comply with the regulation rather than inadequacies in the regulation.

To address problems in the canned meat and poultry industry, in 1986 FSIS promulgated HACCP-based low acid canned food regulations similar to those of the FDA. CCPs identified in those regulations were incorporated into the Agency's Performance Based Inspection System, so that inspectors' tasks include verification of establishments compliance with the regulations. Incidents of foodborne illness involving canned meat and poultry products that occurred following the publication of the rules have been attributed to establishments' noncompliance with the regulations.

(b) Commercially Processed Cooked Roast Beef

Five outbreaks of salmonellosis associated with the consumption of commercially processed cooked beef products occurred in the northeastern United States from 1975 until 1981. These outbreaks resulting from five different serotypes of *Salmonella*, caused up to 200 reported cases of illness per incidence.

FSIS responded to the outbreaks by supervising the voluntary recall and destruction of thousands of pounds of affected product on a case-by-case basis. Additionally, whole, intact, cooked roast beef products from several establishments were sampled and found positive for salmonellae. As a result of the outbreaks, it became apparent that salmonellae contamination of cooked beef products needed to be addressed on an industry-wide basis.

In 1977, FSIS promulgated a regulation requiring that all cooked beef products be prepared by "a cooking procedure that produces a minimum temperature of 145 degrees F in all parts of each roast" to destroy any salmonellae that might be present. This regulation was amended in 1978 to provide alternate cooking times and temperatures to preserve the rare appearance of the product but still destroy all salmonellae. (See 9 CFR 381.17.)

During the summer of 1981, eight additional outbreaks of the disease were linked to the consumption of roast beef produced by four separate establishments in the northeastern United States.

Epidemiologic investigations revealed that inadequate cooking times and temperatures were not the major problems. A new regulation was implemented in 1983 that addressed the necessary handling, processing, cooling times and temperatures, and storage requirements to ensure the wholesomeness of cooked roast beef.

In total, the changes that evolved in the roast beef regulations represented a HACCP approach in identifying the CCP's in roast beef processing that must be monitored and controlled by an establishment to ensure production of unadulterated product. These HACCPbased CCP's have subsequently been incorporated into the FSIS-PBIS system for scheduling inspectors' tasks in establishments that produce cooked roast beef. Since 1983, no confirmed salmonellae outbreaks have been traced to commercially prepared roast beef.

(c) Uncured Cooked Meat Patties

In response to recent outbreaks of foodborne illness caused by E. coli 0157:H7, FSIS promulgated a rule dealing with the heat-processing, cooking, cooling, handling, and storage requirements for uncured meat patties. HACCP principles were used to identify CCP's, critical limits, and corrective actions; as a result, cooking times and temperatures, cooling requirements, sanitary handling and storage practices, and requirements for the handling of heating or cooling deviations were established. The CCP's identified in that rule have been incorporated into the Agency's PBIS for scheduling inspector

tasks to ensure establishments' compliance with the regulations.

The "Heat Processing Procedures, Cooking Instructions, Cooling, Handling and Storage Requirements for Uncured Meat Patties" (8/2/93 at 58 FR 41151) incorporated HACCP concepts (CCPs, critical limits, corrective actions, etc.) associated with the manufacture of uncooked, partially cooked, charmarked, comminuted products.

(d) Current Process Control Systems

The development and implementation of standardized process control procedures, such as Total Quality Control (TQC) systems and Partial Quality Control (PQC) programs have been part of an effort to focus the responsibility for compliance on the processing establishment. FSIS first began approving industry operated quality control programs in the mid 1970's. The QC policy evolved throughout the late 1970's until in 1980 when it was codified in 9 CFR 318.4 and 381.145 providing a regulatory basis for FSIS policies for PQC and TQC. At present, there are over 9,000 approved PQC programs in operation in inspected establishments and 361 approved and operating TQC systems.

TQC systems are defined by regulation as plans or systems for controlling product after antemortem and postmortem inspection throughout all stages of preparation adequate to result in product being in compliance with the regulations (9 CFR 318.4(c) and 381.145(c)). This definition had traditionally been interpreted to mean that an establishment's TQC system must include control for all aspects of a process. By regulation, PQC programs may be approved for controlling the production of individual products, individual operations within the establishment, or parts of operations (9 CFR 318.4(d) and 381.145(d)).

In processing establishments, most approved PQC programs are designed to control economic and quality aspects of meat and poultry products, such as net weight and label claims. Such PQC programs are generally voluntary or are a condition of label approval. A smaller number of procedures operate to control product wholesomeness factors and are mandated in current regulations. These include the production of cooked roast beef (§ 318.17), mechanically deboned product (§ 319.5), and irradiated poultry product (§ 381.145). In addition, some PQC programs are approved as alternative procedures to regulatory requirements such as handling thermal processing deviations (§§ 318/381.308) and finished product inspections (§§ 318/381.309) of shelf stable canned