

The Administrator shall notify the applicant or operator of the establishment, orally or in writing, as promptly as circumstances permit, of such refusal and the reasons therefor, and the action which the Administrator deems necessary to have valid HACCP plan. In the event of oral notification, written confirmation shall be given, as promptly as circumstances permit, to the applicant or operator of the establishment in the manner prescribed in § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) If any applicant or operator of an establishment so notified fails to take the necessary action to have a valid HACCP plan within the period specified in the notice, the Administrator may issue a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service shall be refused or withdrawn from such establishment pending final determination in the proceeding.

30. A new subpart Z would be added to read as follows:

Subpart Z—Hazard Analysis and Critical Control Points (HACCP) System

Sec.

- 381.601 Definitions.
- 381.602 Development of HACCP plan.
- 381.603 HACCP principles.
- 381.604 Implementation of the HACCP plan.
- 381.605 Operation of HACCP system.
- 381.606 Record review and maintenance.
- 381.607 Enforcement.

§ 381.601 Definitions.

For purposes of this subpart, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Criterion. A requirement on which a judgment or decision can be based.

Critical control point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical control point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.

Deviation. Failure to meet a critical limit.

HACCP. A hazard analysis and critical control point (HACCP) system that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the

control of a specific process or procedure.

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to poultry processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

HACCP system. The result of the implementation of the HACCP plan.

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.

Hazard Analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCP's are identical, except that optional operations or CCP's, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, poultry, poultry byproduct, or poultry food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees which satisfies the following: consists of at least 3 days, 1 day devoted to understanding the seven principles of HACCP, 1 day devoted to applying these concepts to this and other regulatory requirements of FSIS, and 1 day devoted to development of a HACCP plan for a specified process.

Responsible establishment official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its

efficacy for the production of safe and wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.

§ 381.602 Development of HACCP plan.

(a) Every official establishment shall develop, implement, and operate a HACCP plan, as set forth in paragraph (c) of this section, for each process listed below conducted by the establishment.

Categories of Processes for HACCP:

- 01 Raw-Ground
- 02 Raw Other—Inclusive
- 03 Thermally Processed/Commercially Sterile
- 04 All Other Shelf Stable, Not Heat Treated
- 05 Fully Cooked—Not Shelf Stable
- 06 All Other Shelf Stable, Heat Treated
- 07 All Non-Shelf Stable, Heat Treated, Not Fully Cooked
- 08 Non-Shelf Stable, w/Secondary Inhibitors
- 09 Slaughter—All Poultry Kind

(b) At a minimum, the HACCP plan(s) shall be developed with the assistance of a HACCP-trained individual employed by the establishment, whose name and resume is on file at the establishment, and who is knowledgeable of each process conducted by the establishment. The person(s) developing the plan shall be knowledgeable of HACCP and the associated recordkeeping procedures, and shall be capable of: identifying the hazards of the establishment's process and of understanding the source of such hazards; establishing relevant CCP's throughout the process; and developing appropriate critical limits, monitoring procedures, corrective action procedures, verification procedures and their frequency, and operating procedures to implement the HACCP plan.

(c) Prior to the initiation of the Hazard Analysis phase of HACCP plan development, each establishment shall have on file a copy of its procedures for maintaining adherence to recommended Standard Operating Procedures for sanitation as set forth in § 381.45.

(d) The development of the HACCP plan shall consist of two stages: a Hazard Analysis, as provided under Principle 1 in § 381.603(a); and the development of the remainder of the HACCP plan for each specific process as defined in § 381.602(a), including activities to ensure that the HACCP plan, as developed, is valid. These steps shall be completed over a period not to