exceed 6 months prior to the phase-in date of the process category, as prescribed in § 381.607, or upon application for the grant of inspection, or when a new process is intended for implementation.

(1) The HACCP plan should be in a format that is similar to the National Advisory Committee on Microbiological Criteria for Foods and FSIS generic models to ensure that both the establishment and program employees can readily identify the requirements in §§ 381.602(c) and 381.603.

(2) Each HACCP principle, as prescribed in § 381.603 must be included in the HACCP plan.

§ 381.603 HACCP principles.

The following principles and associated components shall be included in each HACCP plan:

(a) *Principle No. 1.* A hazard analysis shall be conducted to identify biological (including microbiological), chemical, and/or physical properties of raw materials and processing steps that may cause a product or products to be unsafe for consumption. A list of steps in the process where potentially significant hazards may occur and the preventive measures to be taken shall be prepared. Hazard analysis should take into consideration factors such as: ingredients; physical characteristics and composition; processing procedures; microbial content of the product or products; facility and equipment design; packaging; sanitation; conditions of storage between packaging and the end user; intended use; and intended consumer. All identified hazards associated with each step in the process must be listed and its significant risk and severity evaluated. The preventive measures to control identified hazards must be listed. The steps in application of this principle shall, at a minimum, include:

(1) A flow chart describing the steps of each process and product flow in the establishment; and

(2) Identification of the intended use and consumers of the product based upon normal use by the general public or a particular segment of the population.

(b) *Principle No. 2.* Identify the CCP's in the process using a decision tree and the information derived from § 381.603(a). CCP's shall be identified for purposes of product safety only. They must include physical, chemical, and biological (including microbiological and residue) hazards; must encompass the health and safety process control points required by FSIS regulations, or their equivalents; and must be specified for each identified hazard.

(c) *Principle No. 3.* Establish specific critical limits for preventive measures associated with each identified CCP. Critical limits which are a part of other portions of relevant regulations must be included.

(1) All critical limits shall meet or exceed any requirement set forth in this part pertaining to a specific process and which are currently a part of FSIS regulations or other FSIS requirements.

(2) The responsible establishment official shall ensure that the critical limits are sufficient to control the identified hazards through a validation process consisting of verification and monitoring activities.

(d) *Principle No. 4.* Establish CCP monitoring requirements. Establish specific procedures for using the results of CCP monitoring to adjust and maintain process control.

(1) The responsible establishment official shall ensure that establishment employees are assigned to monitor each CCP effectively, as determined by Hazard Analysis.

(2) When monitoring is not possible on a continuous basis, the monitoring interval established shall reliably indicate that the hazard can be controlled as demonstrated by process validation performed during the Hazard Analysis and plan development.

(3) All records and documents associated with CCP monitoring shall be dated and signed or initialed by the person(s) conducting the monitoring.

(e) *Principle No. 5.* Establish corrective action(s) to be taken when monitoring indicates that there is a deviation from an established critical limit.

(1) The corrective actions shall describe the step(s) taken to identify and correct the cause of noncompliance to assure that the CCP is under control, ensure that no safety hazards exist after these actions, and define measures to prevent recurrence.

(2) Corrective actions shall include a determination of the effect of the deviation(s) on product safety; how noncompliant product will be handled, including segregation and holding procedures; a definition of lot size; whether the deviation indicates a modification or revision of the HACCP plan is required; and time frames for modification or revision of the HACCP plan.

(f) *Principle No. 6.* Establish effective recordkeeping and systematic review procedures that document the HACCP system. The required records are specified in § 381.606.

(g) *Principle No. 7.* Establish procedures for verification by a HACCP-trained individual that the HACCP system is functioning effectively to ensure product safety and process control. This is the plan validation process and therefore includes methods, procedures, or tests in addition to those used for monitoring. Such validation shall ensure:

(1) The adequacy of the critical limits at each CCP;

(2) The continuing effectiveness of the establishment's HACCP plan and system, including taking into account changes in production volumes, procedures, personnel, and product use;

(3) The accuracy of the HACCP plan through the completion of all seven principles and their associated actions including revalidation whenever significant product, process, deviations, or packaging changes require modification of the plan; and

(4) The evaluation of product safety in situations where the establishment identifies deviations from critical limits, all steps taken in response to a deviation, and the adequacy of the corrective response.

§ 381.604 Implementation of the HACCP plan.

(a) Upon completion of the Hazard Analysis and development of the HACCP plan, a responsible establishment official shall review and approve the written plan by signing it.

(b) Upon completion of the Hazard Analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended, ensuring the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions. During this initial HACCP plan validation period, the establishment shall conduct repeated verifications and meet frequently with Program employees to assure the HACCP system is functioning as intended, which shall include a review of the records generated by the HACCP system.

(c) When an ingredient change, product reformulation, manufacturing process or procedure modification, equipment change, or any other such change requires modifications to the establishment's HACCP plan, the responsible establishment official, in consultation with a HACCP-trained individual employed by the establishment, shall ensure that the HACCP plan is modified to reflect such changes. The development of the modified HACCP plan shall be