

§ 326.4 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 conducted in accordance with §§ 326.2 and 326.3.

§ 326.5 Operation of HACCP system.

(a) The establishment's HACCP system, as set forth in the establishment's HACCP plan, shall be operated with the advice and guidance of a HACCP-trained individual, as defined in § 326.1.

(b) The responsible establishment official shall be held responsible for the operation of the HACCP system to ensure compliance with the Act and regulations thereunder. In all respects, however, the Administrator shall continue to provide the Federal inspection necessary to carry out the provisions of the Act.

§ 326.6 Record review and maintenance.

(a) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the time recorded, and the record shall be signed or initialed by the establishment employee making the entry. Prior to shipping product produced under each process, the establishment shall review, on a defined, systematic basis, all processing and production records associated with

the HACCP plan to ensure completeness, to determine whether all critical limits were met and, if appropriate, corrective action(s) were taken, including proper disposition of product. This review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by the HACCP-trained individual, or the responsible establishment official.

(b) The following records supporting the establishment's HACCP plan shall be maintained:

(1) The written HACCP plan including all portions of the Hazard Analysis as prescribed in this part;

(2) Records associated with the monitoring of CCP's, which include the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), identity, or slaughter production lot; and date the record was made; and

(3) Records associated with supporting documentation for the Hazard Analysis, development of the selected CCP's, critical limits, frequency of monitoring and verification procedures, and corrective actions taken.

(c) All such records shall be made available to any Program employee upon request. A deviation from a critical limit shall be brought to the attention of the appropriate Program employee promptly.

(d) All records shall be retained at the establishment at all times, except that records for monitoring CCP's, corrective actions, and verification procedures shall be retained at the establishment for no less than 1 year, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees.

§ 326.7 Enforcement.

(a) *Implementation.* (1) The following establishments shall meet the requirements of this part by the date prescribed:

(i) Establishments that conduct the following categories of processes shall comply by [insert date 12 months after publication of final rule]: Raw, Ground (including mechanically separated (species)); Thermally Processed/Commercially Sterile; and All Other, Shelf Stable, Heat Treated.

(ii) Establishments that conduct the following categories of processes shall comply by (insert date 18 months after publication of final rule): Non-Shelf

Stable, Heat Treated, Not Fully Cooked; and Shelf Stable, Not Heat Treated.

(iii) Establishments that conduct the following categories of processes shall comply by [insert date 24 months after publication of final rule]: Fully Cooked, Non-Shelf Stable; and Non-Shelf Stable, with Secondary Inhibitors.

(iv) Establishments that conduct the following categories of processes shall meet the requirements of this part by [insert date 30 months after publication of final rule]: Raw, other; and Slaughter, all livestock.

(v) Small entities that generate less than \$2.5 million dollars of product per year shall comply by [insert date 36 months after publication of final rule].

(2) Any establishment that obtains Federal inspection on or after the effective date(s) for the process category(ies) to be conducted shall conduct a Hazard Analysis, and shall develop and validate its HACCP plan(s), as set forth in § 326.2(d) of this part, concurrent with the grant of inspection. Process analysis, as set forth in § 326.4(c), shall commence after obtaining Federal inspection to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(3) Any establishment that institutes a new process requiring development of a HACCP plan on or after the applicable effective date(s) of this regulation shall conduct all activities required for hazard analysis, development, and validation of its HACCP plan(s) for the process category(ies) as set forth in § 326.2(d) of this part, before commencing production and shall conduct process analyses, as set forth in § 326.4(b), to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(4) Commencing with the applicable effective date(s), the Program shall refuse new inspection services requested for, or, using the procedures in § 335.33, suspend inspection services from establishments or specific processes within establishments not having HACCP plans.

(b) *Verification.* The Program shall verify that HACCP plan(s) are effective and validated, and otherwise in compliance with this regulation. Such verification and process validation may include:

(1) Reviewing the HACCP plan,

(2) Reviewing the CCP records,

(3) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs,

(4) Conducting verification activities to determine whether CCP's are under control,