

(5) Reviewing the critical limits,
(6) Reviewing other records pertaining to the HACCP plan or system,

(7) Random sample collection and analysis to determine the safety of the product, and/or

(8) On-site observations and records review for revalidation of HACCP plans.

(c) *Suspension, correction of invalid plans.* (1) If the Program finds a HACCP plan to be invalid, inspection service for the process covered by the HACCP plan will be suspended using the procedures in § 335.33. The processing facilities identified shall not be used for production of meat or meat food product pending completion of the specified corrective action(s), as prescribed (c)(3) of this section and written acknowledgement thereof by the designated Program official. Products produced by the process prior to the suspension suspected of being adulterated shall be retained at the establishment pending disposition by the Program, and if such product has been shipped, it shall be subject to voluntary recall as necessary to protect public health.

(2) A HACCP plan may be found invalid if:

(i) The HACCP plan does not meet the requirements of this part,

(ii) HACCP records are not being maintained as required to validate the plan or verify process control under the plan, or

(iii) A processing failure results in production of adulterated product.

(3) Invalid HACCP plans must be corrected by:

(i) Submission to the designated Program official of a written, detailed verification by a HACCP-trained individual that a modified HACCP plan has been developed in consultation with that individual and that, as modified, the plan corrects the deficiencies found, and

(ii) In the case of a processing deficiency resulting in production of adulterated product, submission to the designated Program official of and adherence to a written plan for finished product produced under the modified HACCP plan to be tested by an external laboratory for chemical or microbial characteristics, at the establishment's expense, as appropriate to demonstrate that the process under the modified HACCP plan corrects the identified problem.

(4) If the establishment fails to adhere to the modified HACCP plan and, if applicable, the testing plan, resulting in a subsequent suspension of the same process for the same or a related deficiency, the designated Program official will, upon receipt and before

acknowledgement of any subsequent modified plan(s) under paragraph (c)(3) of this section, also review the establishment's performance under the inspection regulations generally and make a written recommendation to the Administrator whether any additional inspection or enforcement measures may be required.

PART 327—IMPORTED PRODUCTS

14. The authority citation for Part 327 would continue to read as follows:

Authority: 21 U.S.C. 601–695, 7 CFR 2.17, 2.55.

15. Section 327.2 would be amended by redesignating paragraph (a)(2)(ii)(h) as (a)(2)(ii)(i) and by adding a new paragraph (a)(2)(ii)(h) to read as follows:

§ 327.2 Eligibility of foreign countries for importation of products into the United States.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(h) Development and maintenance of a Hazard Analysis and Critical Control Point (HACCP) system pursuant to part 326 of this subchapter in each certified establishment;

* * * * *

16. Subpart E of part 335 would be redesignated as subpart F, and a new subpart E would be added to read as follows:

Subpart E—Rules Applicable to the Suspension of Inspection for Failure To Have a Validated HACCP Plan

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 335.33 Refusal or suspension of inspection service for failure to comply with HACCP requirements.

(a) In any situation in which the Administrator determines that an establishment which is applying for inspection or receiving inspection under Title I of the Federal Meat Inspection Act does not have a valid HACCP plan as required by § 326.7, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as “inspected and passed.” The Administrator shall notify the applicant or operator of the establishment, orally or in writing, as promptly as circumstances permit, of such refusal to inspect and pass the meat or meat food products and the reasons therefor, and the action which the Administrator deems necessary to have a 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.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

17. The authority citation for Part 381 would continue to read as follows:

Authority: 7 U.S.C. 138F; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

Subpart H—Sanitation

18. Section 381.45 would be revised to read as follows:

§ 381.45 Minimum standards for sanitation, facilities and operating procedures in official establishments.

The provisions of §§ 381.45 through 381.61, inclusive, shall apply with respect to all official establishments.

(a) The establishment shall develop and maintain written Sanitation Standard Operating Procedures (Sanitation SOP's) which must be available to program employees for verification and monitoring. Sanitation SOP's shall, at a minimum, detail daily sanitation procedures to be conducted, before and during operations, to prevent direct contamination or adulteration of product(s). Sanitation SOP's must also identify plant officials responsible for monitoring daily sanitation activities, evaluating the effectiveness of SOP's, and initiating corrective actions when needed.

(1) A “US Rejected” tag will be attached to the applicable equipment, utensil, room or compartment if a Program employee determines that the establishment has failed to adhere to the Sanitation SOP's specifically required by paragraph (a) of this section. No equipment, utensil, room, or compartment so tagged shall be used until reinspected and found acceptable by a Program employee. The establishment shall maintain daily records for a minimum of 6 months.

(2) The establishment owner or operator shall be responsible for the establishment's adherence to the SOP's, as well as for all sanitary requirements specified elsewhere in these regulations.