EFFECTIVE DATE NOTE: At 64 FR 72175, Dec. 23, 1999, § 381.147 was removed, effective Jan. 24, 2000.

§ 381.148 Processing and handling requirements for frozen poultry products.

Procedures with respect to processing of frozen ready-to-heat-and-eat poultry products or stuffed ready-to-roast poultry shall be in accordance with sound operating practices and carried out in a manner which will assure freedom from adulteration of the products. Products to be frozen shall be moved into the freezer promptly under such supervision by an inspector as is necessary to assure preservation of the products by prompt and efficient freezing. Adequate freezing facilities shall be provided within the official establishment where products to be frozen are prepared, except that, upon written request, and under such conditions as may be prescribed by the Administrator in specific cases, such products may be moved from the official establishment prior to freezing: *Provided*, That the official establishment and freezer are so located and the necessary arrangements are made so that the Inspection Service will have access to the freezing room and adequate opportunity to determine that the products are being properly handled and frozen.

§ 381.149 Irradiation of poultry product to control foodborne pathogens.

(a) Definitions of food irradiation terms:

(1) *Absorbed dose* is the amount of energy imparted by ionizing radiation to a quantity of product.

(2) *Bulk density* is the mass (weight) of a product unit divided by its total volume.

(3) *Dose mapping* is the identification of the regions of minimum and maximum absorbed dose in a product unit.

(4) A *dosimeter* is the device for measuring absorbed dose.

(5) *Dosimetry* is the process of measuring absorbed dose.

(6) *Ionizing radiation* is radiation with sufficient energy to cause the removal of electrons from atoms or molecules, thereby creating ions.

(7) *Irradiate* means to expose a material to ionizing radiation.

(8) A *product unit* is the volume of product, made up of one or more packages of product, which is collectively transported past the radiation source (e.g., in boxes or totes or on pallets or carriers).

(9) A *production lot* is the quantity of like product units designated as such by the operator of the irradiation facility or their agent to be processed in no more than one continuous shift of up to 8 hours.

(10) *Radiation source* is the radioactive material (e.g., cobalt-60) or machine that emits ionizing radiation.

(11) *Source activity decay* is the decrease in the radioactivity of radionuclide source material (e.g., cobalt-60) with the passing of time.

(12) *Traceability* is the capacity, through documentation, to relate an end-point measurement to recognized standards.

(b) Poultry product may be treated to reduce foodborne pathogens by the use of ionizing radiation as identified in § 381.147(f)(4) of this subpart. Only irradiation facilities operating under a FSIS-approved quality control system, in accordance with paragraph (c) of this section, may irradiate poultry product for food uses.

(c) A description of the quality control system must be sent to the Administrator identifying the responsible official for quality control and stating that all data and information generated by the system will be maintained to enable the Department to monitor compliance. The quality control system will be evaluated and approved in accordance with § 381.145(e) of this subpart. A copy of the description will be placed on file in the irradiation facility and be available to any duly authorized representative of the Secretary. At a minimum, the operator of the irradiation facility must establish and comply with a quality control system which provides for the following:

(1) Licensing, Sanitation, and Facility. (i) Documentation showing that the irradiation facility is licensed and/or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate

State government acting under authority granted by the NRC, and that a worker safety program addressing regulations of the Occupational Safety and Health Administration (OSHA) is in place.

(ii) Documentation showing that the machine radiation source irradiation facility is registered with the Occupational Safety and Health Administration (OSHA) or the appropriate State government acting under authority granted by OSHA, and that a worker safety program addressing OSHA regulations is in place.

(iii) Procedures to ensure that the irradiation facility complies with the applicable provisions of subpart H of this part, as determined by the Administrator.

(iv) Procedures to ensure that, if the facility has no refrigerated storage capacity, adequate numbers of refrigerated units (such as trucks or carriers) will be made available during the radiation processing of poultry.

(2) Training. (i) A statement by the operator certifying that the irradiation facility personnel would operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(ii) A statement by the operator certifying that the key facility quality control personnel have been trained in quality control, food technology, irradiation processing, and radiation health and safety.

(3) Poultry Product; Packaging, handling. (i) Procedures to ensure that each production lot of packaged poultry is accompanied by a certificate or traceable certification that states that the food-contact packaging material is guaranteed by the supplier as complying with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and regulations in 21 CFR 179.45 for food irradiation processing and that the food-contact packaging material is air-permeable, but does exclude moisture and microorganisms from penetrating the package barrier.

(ii) Procedures to ensure that product units throughout each production lot are uniform in size, weight, thickness, and orientation to the radiation source.

(iii) Procedures to ensure that packages are distributed throughout each production lot uniformly with respect to package stacking arrangements, bulk density, and orientation of the packages to the radiation source.

(iv) Procedures to ensure that the product(s) is uniform throughout the production lot (e.g., all wings, all breasts, all combination packages of breasts and wings).

(v) Procedures to ensure that product temperature is kept uniform within a production lot, such that fresh refrigerated product is processed separately from frozen product.

(vi) Procedures to ensure that product unit bulk density is uniform throughout a production lot.

(vii) Procedures to ensure that product is kept intact and in sealed packages.

(viii) Procedures to ensure that product is not reirradiated.

(ix) Procedures to ensure that non-irradiated product is not commingled with irradiated product.

(x) Procedures to ensure that irradiated product within each production lot is identified to permit product recall.

(xi) Procedures to dispose of poultry with damaged packaging or poultry which has been improperly irradiated.

(4) Dosimetry.

(i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(ii) Calibration criteria for verifying the accuracy and consistency of any means of measurement (e.g., time clocks and weight scales).

(iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months.

(iv) Procedures for assuring the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(v) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).

(vi) Procedures for verifying routine dosimetry (i.e., assuring each production lot receives the total absorbed dose). Each production lot must have at least one dosimeter positioned at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit.

(vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.

(5) Labeling. Procedures for verifying that the product is accurately and appropriately labeled in accordance with § 381.135.

(6) Transportation, Storage, and Handling. Procedures for assuring that temperature and time requirements of subpart I, § 381.66 are maintained during shipping of the poultry product to the irradiation facility, radiation processing, storage, and shipping of poultry product to the point of purchase.

(7) Corrective Action. (i) Procedures for corrective action for failure to adhere to any of the above procedures.

(ii) Procedures to dispose of product affected during the failure to adhere to any of the above procedures.

(iii) Procedures to prevent reocurrence of any failures to adhere to any of the above procedures.

(d) The quality control system shall be subject to periodic review, and the approval of such system may be terminated in accordance with § 381.145(g) of this subpart.

[57 FR 43598, Sept. 21, 1992]

EFFECTIVE DATE NOTE: At 65 FR 2285, Jan. 14, 2000, § 381.149 was removed effective Feb. 22, 2000.

§ 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.

(a) Fully cooked poultry products must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality.* A 7-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) *Stabilization.* There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum,* and no more than a 1 $\log_{10}$ multiplication of *Clostridium perfringens* within the product.

(b) Partially cooked poultry breakfast strips must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section. Labeling for these products must comply with § 381.125. In addition, the statement ''Partially Cooked: For Safety, Cook Until Well Done'' must appear on the principal display panel in letters no smaller than ½ the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 381.1(b). Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and