

## § 381.145

## 9 CFR Ch. III (1–1–07 Edition)

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2236, Jan. 19, 1984]

### **Subpart O—Entry of Articles Into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements**

#### **§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.**

(a) No poultry product (including poultry broth for use in any poultry product in any official establishment) may be brought into any official establishment unless it has been processed in the United States only in an official establishment or imported from a foreign country listed in § 381.196(b), and inspected and passed, in accordance with the regulations; and unless the container of such product is marked so as to identify the product as so inspected and passed, in accordance with § 381.115 or § 381.205, except that poultry products inspected and passed and identified as such under the laws of an “at least equal” State or territory listed in § 381.187 may be brought into any official establishment solely for storage and distribution therefrom without repackaging, relabeling, or processing in such establishment. No carcass, part thereof, meat or meat food product of cattle, sheep, swine, goats, or equines may be brought into an official establishment unless it has been prepared in the United States only in an official meat packing establishment, or imported, and inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (Subchapter A of this chapter) and is properly marked as so inspected and passed; or has been inspected and passed and is identified as such in accordance with the requirements of the law and regulations of a State not designated in § 331.2 of this chapter; or is present in the official establishment by reason of an exemption

allowed in the Federal Meat Inspection Act and the regulations under such Act (Subchapter A of this chapter) or the law and regulations of a State not so designated. However, such exempted articles may enter only under conditions approved by the Administrator in specific cases, including but not limited to, complete separation of inspected poultry products and processing and other operations with respect thereto from the exempted articles and operations with respect thereto, complete cleanup of facilities and equipment between processing of inspected poultry products and the exempted articles and no commingling of inspected and exempted articles in receiving, holding or storage areas.

(b) All poultry products and all carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines which enter any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment. All poultry products, and all carcasses, parts thereof, meat and meat food products of such animals, which are processed or otherwise handled at any official establishment shall be subject to examination by an inspector at the official establishment in such manner and at such times as may be deemed necessary by the inspector in charge to assure compliance with the regulations. Upon such examination, if any such article or portion thereof is found to be adulterated, such article or portion shall, in the case of poultry products, be condemned and disposed of as prescribed in § 381.95, unless by reprocessing they may be made not adulterated, and shall, in the case of such other articles be disposed of according to applicable law.

Such examination may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The inspector in charge shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.<sup>1</sup>

<sup>1</sup>Further information concerning sampling plans which have been adopted for specific

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing poultry product who has a total plant quality control system or plan for controlling such products, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of a small establish-

ments which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will also be responsible for the quality control system.

products may be obtained from the Circuit Supervisor. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved.

(3) A list identifying those subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action—ranging from the least to most severe: *Provided*, That subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d)-(e) [Reserved]

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and

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any wording of explanation with respect to this logo shall be approved as required by subparts M and N of this part.



(g) *Termination of Quality Control Systems.* (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or a quality control system for irradiation facilities may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded poultry product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system to which it has agreed after being notified by letter from the Administrator or his

designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(4) If approval of a quality control system for irradiation facilities, as specified in section 381.149 of this subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

(h)(1) *Operating Schedule Under Total Plant Quality Control.* An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permissions will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in § 381.145(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspection services at the discretion of the circuit supervisor and charged for such services.

(i) To ensure the safe use of preparations used in poultry scald water, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B or 9 CFR Chapter III, Subchapter A or Subchapter E.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

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**§ 381.146 Sampling at official establishments.**

Inspectors may take, without cost to the Department, such samples as are necessary of any poultry product, or other article for use as an ingredient of any poultry product, at any official establishment to determine whether it complies with the requirements of the regulations.

**§ 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.

**§ 381.150 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<sub>10</sub> 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<sub>10</sub> 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