

§318.2

the denuding of tripe, 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.

(e) Dyes, chemicals, or other substances the use of which is restricted to certain products may be brought into or kept in an official establishment only if such products are prepared thereat. No prohibited dye, chemical, preservative, or other substance shall be brought into or kept in an official establishment.

(f) [Reserved]

(g) Glands and organs, such as cotyledons, ovaries, prostate glands, tonsils, spinal cords, and detached lymphatic, pineal, pituitary, parathyroid, suprarenal, pancreatic and thyroid glands, used in preparing pharmaceutical, organotherapeutic, or technical products and which are not used as human food (whether or not prepared at official establishments) may be brought into and stored in edible product departments of inspected establishments if packaged in suitable containers so that the presence of such glands and organ will in no way interfere with the maintenance of sanitary conditions or constitute an interference with inspection. Glands or organs which are regarded as human food products, such as livers, testicles, and thymus glands, may be brought into official establishments for pharmaceutical, organotherapeutic or technical purposes, only if U.S. inspected and passed and so identified. Lungs and lung lobes derived from livestock slaughtered in any establishment may not be brought into any official establishment except as provided in §318.12(a).

(h)(1) Carcasses of game animals, and carcasses derived from the slaughter by any person of livestock of his own raising in accordance with the exemption provisions of paragraph 23(a) of the Act, and parts of such carcasses, may be brought into an official establishment for preparation, packaging, and storing in accordance with the provisions of §303.1(a)(2) of this subchapter.

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(2) Meat, meat byproducts, and meat food products bearing official marks showing that they were inspected and passed under State inspection in any State not designated in §331.2 of this subchapter may be received by official establishments for storage and distribution solely in intrastate commerce. The presence of such State inspected products must not create any unsanitary condition or otherwise result in adulteration of any products at the official establishment or interfere with the conduct of inspection under this subchapter. In addition, such State inspected products must be stored separately and apart from the federally inspected products in the official establishment.

(i) The operator of the official establishment shall furnish such information as is necessary to determine the origin of any product or other article entering the official establishment. Such information shall include, but is not limited to, the name and address of the seller or supplier, transportation company, agent, or broker involved in the sale or delivery of the product or article in question.

(j) Any product or any poultry or poultry product or other article that is brought into an official establishment contrary to any provision of this section may be required by the Administrator to be removed immediately from such establishment by the operator thereof, and failure to comply with such requirement shall be deemed a violation of this regulation. If any slaughtered poultry or poultry products or other articles are received at an official establishment and are suspected of being adulterated or misbranded under the Poultry Products Inspection Act or the Federal Food, Drug, and Cosmetic Act, or applicable State laws, the appropriate governmental authorities will be notified.

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 38 FR 5152, Feb. 26, 1973; 48 FR 6091, Feb. 10, 1983; 49 FR 32055, Aug. 10, 1984; 64 FR 72174, Dec. 23, 1999]

§318.2 Reinspection, retention, and disposal of meat and poultry products at official establishments.

(a) All products and all slaughtered poultry and poultry products brought

into any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment and shall be subject to reinspection by a Program employee at the official establishment in such manner and at such times as may be deemed necessary to assure compliance with the regulations in this subchapter.

(b) All products, whether fresh, cured, or otherwise prepared, even though previously inspected and passed, shall be reinspected by Program employees as often as they may deem necessary in order to ascertain that they are not adulterated or misbranded at the time they enter or leave official establishments and that the requirements of the regulations in this subchapter are complied with.

(c) Reinspection may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The circuit supervisor 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.¹

(d) A U.S. retained tag shall be placed by a Program employee at the time of reinspection at any official establishment on all products which are suspected on such reinspection of being adulterated or misbranded, and such products shall be held for further inspection. Such tags shall be removed only by authorized Program employees. When further inspection is made, if the product is found to be adulterated, all official inspection legends or other official marks for which the product is found to be ineligible under the regulations in this subchapter, shall be removed or defaced and the product will

¹Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisors of Program circuits. 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, such as liver, oxtails, etc.

be subject to condemnation and disposal in accordance with part 314 of this subchapter, except that a determination regarding adulteration may be deferred if a product has become soiled or unclean by falling on the floor or in any other accidental way or if the product is affected with any other condition which the inspector deems capable of correction, in which case the product shall be cleaned (including trimming if necessary) or otherwise handled in a manner approved by the inspector to assure that it will not be adulterated or misbranded and shall then be presented for reinspection and disposal in accordance with this section. If upon final inspection, the product is found to be neither adulterated nor misbranded, the inspector shall remove the U.S. retained tag. If a product is found upon reinspection to be misbranded, it shall be held under a U.S. retained tag, or a U.S. detention tag as provided in part 329 of this subchapter, pending correction of the misbranding or issuance of an order under section 7 of the Act to withhold from use the labeling or container of the product, or the institution of a judicial seizure action under section 403 of Act or other appropriate action. The inspector shall make a complete record of each transaction under this paragraph and shall report his action to the area supervisor.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 318.3 Designation of places of receipt of products and other articles for reinspection.

Every official establishment shall designate, with the approval of the circuit supervisor, a dock or place at which products and other articles subject to reinspection under § 318.2 shall be received, and such products and articles shall be received only at such dock or place.

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

(a) All processes used in curing, pickling, rendering, canning, or otherwise