

documented by data which has been developed by following an experimental protocol previously reviewed and accepted by the Department.

(d) General instructions: When necessary to comply with the requirements of this section, the smokehouses, drying rooms, and other compartments used in the treatment of pork to destroy possible live trichinae shall be suitably equipped, by the operator of the official establishment, with accurate automatic recording thermometers. Circuit supervisors are authorized to approve for use in sausage smokehouses, drying rooms, and other compartments, such automatic recording thermometers as are found to give satisfactory service and to disapprove and require discontinuance of use, for purposes of the regulations in this subchapter, any thermometers (including any automatic recording thermometers) of the establishment that are found to be inaccurate or unreliable.

(e) The requirements for using the pooled sample digestion technique to analyze pork for the presence of trichina cysts are:

(1) The establishment shall submit for the approval of the Regional Director its proposed procedure for identifying and pooling carcasses, collecting and pooling samples, testing samples (including the name and address of the laboratory), communicating test results, retesting individual carcasses, and maintaining positive identification and clear separation of pork found to be trichina-free from untested pork or trichina-positive pork.

(2) The establishment shall use the services of a laboratory approved by the Administrator for all required testing. Such approval shall be based on adequacy of facilities, reagents, and equipment, and on demonstration of continuing competency and reliability in performing the pooled sample digestion technique for trichinae.

(3) The establishment shall sample no less than 5 grams of diaphragm muscle or tongue tissue from each carcass or no less than 10 grams of other muscle tissue. Samples may be pooled but a pool shall not consist of more than 100 grams of sample. Sampling and sample preparation are subject to inspection supervision.

(4) Pork or products made from tested pork shall not be released as trichina free from the official establishment without treatment until the inspector in charge receives a laboratory report that the tested pork is free of trichina cysts.

(f) *Approval of other tests for trichinosis in pork.* The Administrator shall consider any additional analytical method for trichinosis upon petition by a manufacturer, and may approve that method upon the determination that it will detect at least 98 percent of swine bearing cysts present at a tissue density equal to or less than one cyst per gram of muscle from the diaphragm pillars at a 95 percent confidence level. Any such petitions shall be supported by any data and other information that the Administrator finds necessary. Notice of any approval shall be given in the FEDERAL REGISTER, and the approved method will be incorporated into this section.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 31517; Nov. 15, 1973; 39 FR 40580, Nov. 19, 1974; 50 FR 5229, Feb. 7, 1985; 50 FR 48075, Nov. 21, 1985; 52 FR 12517, Apr. 17, 1987; 57 FR 27874, June 22, 1992; 57 FR 33633, July 30, 1992; 57 FR 56440, Nov. 30, 1992]

§ 318.11 [Reserved]

§ 318.12 **Manufacture of dog food or similar uninspected article at official establishments.**

(a) When dog food, or similar uninspected article is manufactured in an edible product department, there shall be sufficient space allotted and adequate equipment provided so that the manufacture of the uninspected article in no way interferes with the handling or preparation of edible products. Where necessary to avoid adulteration of edible products, separate equipment shall be provided for the uninspected article. To assure the maintenance of sanitary conditions in the edible product departments, the operations incident to the manufacture of the uninspected article will be subject to the same sanitary requirements that apply to all operations in edible product departments. The manufacture of the uninspected article shall be limited to those hours during which the establishment operates under inspectional

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supervision; and there shall be no handling, other than receiving at the official establishment, of any of the product ingredient of the uninspected article, other than during the regular hours of inspection. The materials used in the manufacture of the uninspected article shall not be used so as to interfere with the inspection of edible product or the maintenance of sanitary conditions in the department or render any edible product adulterated. The meat, meat byproducts, and meat food product ingredients of the uninspected article may be admitted into any edible products department of an official establishment only if they are U.S. Inspected and Passed. Products within §314.11 of this subchapter or parts of carcasses of kinds not permitted under the regulations in this subchapter to be prepared for human food (e.g., lungs or intestines), which are produced at any official establishment, may be brought into the inedible products department of any official establishment for use in uninspected articles under this section. The uninspected article may be stored in, and distributed from, edible product departments: *Provided*, That adequate facilities are furnished, there is no interference with the maintenance of sanitary conditions, and such article is properly identified.

(b) When dog food or similar uninspected article is manufactured in a part of an official establishment other than an edible product department, the area in which the article is manufactured shall be separated from edible product departments in the manner required for separation between edible product departments and inedible product departments. Sufficient space must be allotted and adequate equipment provided so that the manufacture of the uninspected article does not interfere with the proper functioning of the other operations at the establishment. Except as provided in §314.11 of this subchapter, nothing in this paragraph shall be construed as permitting any deviation from the requirement that dead animals, condemned products, and similar materials of whatever origin, must be placed in the inedible product rendering equipment, and without undue delay. The manufacture of the uninspected article must be such

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as not to interfere with the maintenance of general sanitary conditions on the premises, and it shall be subject to inspectional supervision similar to that exercised over other inedible product departments. There shall be no movement of any product from an inedible product department to any edible product department. Trucks, barrels, and other equipment shall be cleaned before being returned to edible product departments from inedible product departments. Unoffensive material prepared outside edible product departments may be stored in, and distributed from, edible product departments only if packaged in clean, properly identified, sealed containers.

(c) Animal food shall be distinguished from articles of human food, so as to avoid distribution of such animal food as human food. To accomplish this, such animal food shall be labeled or otherwise identified in accordance with §325.11(d) of this subchapter.

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 53 FR 24679, June 30, 1988]

§318.13 Mixtures containing product but not amendable to the Act.

Mixtures containing product but not classed as a meat food product under the Act shall not bear the inspection legend or any abbreviation or representation thereof unless manufactured under the food inspection service provided for in part 350 of subchapter B of this chapter. When such mixtures are manufactured in any part of an official establishment, the sanitation of that part of the establishment shall be supervised by Program employees, and the manufacture of such mixtures shall not cause any deviation from the requirement of §318.1.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973]

§318.14 Adulteration of product by polluted water; procedure for handling.

(a) In the event there is polluted water (including but not limited to flood water) in an official establishment, all products and ingredients for use in the preparation of such products that have been rendered adulterated by the water shall be condemned.