

be utilized. Whenever the Administrator finds that reprocessing operations cannot be conducted in such area in accordance with all of the requirements of this part or that the reprocessing methods utilized are not capable of removing all visible specks of contamination on the inner surface of a carcass, he may withdraw approval of such area, effective upon oral or written notification, whichever is earlier, to the operator of the establishment. In the event of oral notification, a written confirmation thereof shall be given to the operator as promptly as circumstances permit. The notification shall specify the reasons for such withdrawal and shall afford the operator of the establishment an opportunity to present his views. In any instance where there is a conflict as to the facts, a hearing shall be held to resolve such conflict.

[37 FR 9706, May 16, 1972, as amended at 43 FR 12847, Mar. 28, 1978]

§ 381.92 Overscald.

Carcasses of poultry which have been overscalded, resulting in a cooked appearance of the flesh, shall be condemned.

§ 381.93 Decomposition.

Carcasses of poultry deleteriously affected by post mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) Any part of a carcass which is green struck shall be condemned and, if the carcass is so extensively affected that removal of affected parts is impracticable, the whole carcass shall be condemned.

(c) Carcasses affected by types of post mortem change which are superficial in nature may be passed for human food after removal and condemnation of the affected parts.

§ 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; *E. coli* testing.

(1) Each official establishment that slaughters poultry shall test for *Esch-*

erichia coli Biotype I (*E. coli*). Establishments that slaughter more than one type of poultry and/or poultry and livestock, shall test the type of poultry or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) *Written procedures.* Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection.* A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys also may be collected by sponging the carcass on the back and thigh.¹

(iii) *Sampling frequency.* Slaughter establishments, *except* very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but at a minimum one sample per each week of operation.

Turkeys: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation.

¹A copy of FSIS's "Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments," and "FSIS Turkey Microbiological Procedures for Sponge Sample Collection and Methods of Analysis" are available for inspection in the FSIS Docket Room.

(iv) *Sampling frequency alternatives.* An establishment operating under a validated HACCP plan in accordance with §417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment’s verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment’s processing controls.

(v) *Sampling in very low volume establishments.*

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys or a combination of chickens and turkeys not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments slaughtering turkeys in the largest number shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continuing sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment’s meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless

changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)² or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5)(i) *Criteria for Evaluation of test results.* An establishment is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS

| Types of poultry | Lower limit of marginal range (m) | Upper limit of marginal range (M) | Number of sample tested (n) | Maximum number permitted in marginal range (c) |
|------------------|-----------------------------------|-----------------------------------|-----------------------------|--|
| Chickens | 100 CFU/ml | 1,000 CFU/ml | 13 | 3 |

²A copy of the current edition/revision of the “Official Methods of AOAC International,” 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Fed-

eral Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417.

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS—Continued

| Types of poultry | Lower limit of marginal range (m) | Upper limit of marginal range (M) | Number of sample tested (n) | Maximum number permitted in marginal range (c) |
|------------------|-----------------------------------|-----------------------------------|-----------------------------|--|
| Turkeys | ^a N.A. | N.A. | N.A. | N.A. |

^a Not available; values for turkeys will be added upon completion of data collection program for turkeys.

(ii) For types of poultry appearing in paragraph (a)(5)(1) Table 1 of this section that do not have m/N criteria, establishments shall evaluate *E. coli* test results using statistical process control techniques.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection will be suspended in accordance

with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a) (1)–(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standards; *Salmonella*.

(1) *Raw poultry product performance standards for Salmonella.* (i) An establishment's raw poultry products, when sampled and tested by FSIS for *Salmonella* as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2.—SALMONELLA PERFORMANCE STANDARDS

| Class of product | Performance Standard (percent positive for <i>Salmonella</i>) ^a | Number of samples tested (n) | Maximum number of positives to achieve Standard (c) |
|----------------------|---|------------------------------|---|
| Broilers | 20.0% | 51 | 12 |
| Ground chicken | 44.6 | 53 | 26 |
| Ground turkey | 49.9 | 53 | 29 |
| Turkeys | ^b N.A. | N.A. | N.A. |

^a Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are available in the FSIS Docket Room.)

^b Not available; baseline targets for turkeys will be added upon completion of the data collection programs for that product.

(2) *Enforcement.* FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction

standard, FSIS may sample any or all such classes of products.³

(3) *Noncompliance and establishment response.* When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

³A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

[61 FR 38866, July 25, 1996, as amended at 62 FR 26218, May 13, 1997; 62 FR 61009, Nov. 14, 1997]

Subpart L—Handling and Disposal of Condemned or Other Inedible Products at Official Establishments

§ 381.95 Disposal of condemned poultry products.

All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishment.)

(a) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, for a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. (Tanks and equipment used for this purpose or for rendering or pre-

paring inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection by means of pipes, or otherwise, between tanks containing inedible products and those containing edible products.)

(b) Incineration or complete destruction by burning.

(c) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(1) Crude carbolic acid,

(2) Kerosene, fuel oil, or used crankcase oil, or

(3) Any phenolic disinfectant conforming to commercial standards CS 70-41 or CS 71-41 which shall be used in at least 2 percent emulsion or solution.

(d) Any other substance or method that the Administrator approves in specific cases, which will denature the poultry product to the extent necessary to accomplish the purposes of this section.

(e) Carcasses and parts of carcasses condemned for biological residue shall be disposed of in accordance with paragraph (b) of this section or by burying under the supervision of an inspector.

Subpart M—Official Marks, Devices, and Certificates; Export Certificates; Certification Procedures

§ 381.96 Wording and form of the official inspection legend.

Except as otherwise provided in this subpart, the official inspection legend required to be used with respect to inspected and passed poultry products shall include wording as follows: "Inspected for wholesomeness by U.S. Department of Agriculture." This wording shall be contained within a circle. The form and arrangement of such wording shall be exactly as indicated in the example in Figure 1, except that the appropriate official establishment number shall be shown, and if the establishment number appears elsewhere on the labeling material in the manner prescribed in § 381.123(b), it may be omitted from the inspection mark. The administrator may approve the use of abbreviations of such inspection mark;