

unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(3) Any misdemeanor based upon a false statement to any governmental agency.

(4) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

#### § 439.60 Notifications and hearings.

Accreditation of any laboratory will be refused, suspended, or revoked under the conditions previously described in this part. The owner or operator of the laboratory will be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension, or revocation decision. An oral hearing will be granted if there is any dispute of material fact joined in such responsive statement. The proceeding will be conducted thereafter in accordance with the applicable rules of practice, which will be adopted for the proceeding. Any such refusal, suspension, or revocation will be effective upon the receipt by the laboratory of the notification and will continue in effect until final determination of the matter by the Administrator.

### PART 441—CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 66 FR 1771, Jan. 9, 2001, unless otherwise noted.

#### § 441.10 Retained water.

(a) Raw livestock, poultry, and fish carcasses and parts will not be permitted to retain water resulting from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected in accordance with a written protocol, that any water retained in the carcasses or parts is an

unavoidable consequence of the process used to meet applicable food safety requirements.

(b) Raw livestock, poultry, and fish carcasses and parts that retain water from post-evisceration processing and that are sold, transported, offered for sale or transportation, or received for transportation, in commerce, must bear a statement on the label in prominent letters and contiguous to the product name or elsewhere on the principal display panel of the label stating the maximum percentage of water that may be retained (*e.g.*, “up to X% retained water,” “less than X% retained water,” “up to X% water added from processing”). The percent water statement need not accompany the product name on other parts of the label. Raw livestock and poultry carcasses and parts that retain no water may bear a statement that no water is retained.

(c)(1) An establishment subject to paragraph (a) of this section must maintain on file and available to FSIS its written data-collection protocol. The protocol must explain how data will be collected and used to demonstrate the amount of retained water in the product covered by the protocol that is an unavoidable consequence of the process used to meet specified food safety requirements.

(2) The establishment must notify FSIS as soon as it has a new or revised protocol available for review by the Agency. Within 30 days after receipt of this notification, FSIS may object to or require the establishment to make changes in the protocol.

(d) Expected elements of a protocol for gathering water retention data:

(1) *Purpose statement.* The primary purpose of the protocol should be to determine the amount or percentage of water absorption and retention that is unavoidable using a particular chilling system while achieving the regulatory pathogen reduction performance standard for *Salmonella* as set forth in the PR/HACCP regulations (9 CFR 310.25(b), 381.94(b)) and the time/temperature requirements set forth in 9 CFR 381.66. Additional purposes that could be included are determining chilling system efficiency and evaluating product quality.

(2) *Type of washing and chilling system used by the establishment.* Any post-evisceration washing or chilling processes that affect water retention levels in and microbial loads on raw products should be described. For poultry establishments, the main chiller types, identified by the mechanism used to transport the birds through the chiller or to agitate the water in the chiller, are the drag-through, the screw type, and the rocker-arm type.

(3) *Configuration and any modifications of the chiller system components.* A description of chiller-system configurations and modifications should be provided. The description should include the number and type of chillers in a series and arrangements of chilling system components, and the number of evisceration lines feeding into a chiller system. If there is a pre-chilling step in the process, its purpose and the type of equipment used should be accurately described. Any mechanical or design changes made to the chilling equipment should be described.

(4) *Special features in the chilling process.* Any special features in the chilling process, such as antimicrobial treatments, should be described. Also, the length and velocity of the dripping line should be described, as well as the total time allowed for dripping. Any special apparatus, such as a mechanism for squeezing excessive water from chilled birds, should be explained.

(5) *Description of variable factors in the chilling system.* The protocol should describe variable factors that affect water absorption and retention. In poultry processing, such factors are typically considered to be the time in chiller water, the water temperature, and agitation. The protocol should consider air agitation, where applicable. Additional factors that may affect water absorption and retention are scalding temperature and the pressure or amount of buffeting applied to birds by feather removal machinery, and the resultant loosening of the skin. Another factor that should be considered is the method used to open the bird for evisceration.

(6) *Standards to be met by the chilling system.* For example, the chilling system may be designed simply to achieve

a reduction in temperature of ready-to-cook poultry to less than 40 °F within the time limit specified by the regulations, or in less time. As to the standard for pathogen minimization, the *Salmonella* pathogen reduction standards, as set forth in the PR/HACCP final rule, have been suggested. Although there is not yet an applicable *Salmonella* standard for turkeys, establishments are free to adopt practicable criteria for use in gathering data on turkeys under the protocols here suggested. Additional microbiological targets, such as *E. coli* or *Campylobacter* levels, or reductions in numbers of other microorganisms, may also be used.

(7) *Testing methods to be employed.* The protocol should detail the testing methods to be used both for measuring water absorption and retention and for sampling and testing product for pathogen reductions. The protocol should call for water retention and pathogen reduction tests at various chilling equipment settings and chilling time-and-temperature combinations. The method to be used in calculating water absorption and retention should be reproducible and statistically verifiable. With respect to the pathogen-reduction aspect of the testing, FSIS recommends the methods used for *E. coli* and *Salmonella* testing under the PR/HACCP regulations. The number of samples, the type of samples, the sampling time period, and the type of testing or measurement should be included in the protocol.

(8) *Reporting of data and evaluation of results.* The protocol should explain how data obtained are to be reported and summarized. The criteria for evaluating the results and the basis for conclusions to be drawn should be explained.

(9) *Conclusions.* The protocol should provide for a statement of what the data obtained demonstrate and what conclusions were reached.

[66 FR 1771, Jan. 9, 2001, as amended at 80 FR 75616, Dec. 2, 2015]