(2) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment must inform the inspector, and the affected code lot(s) must not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

§ 431.11 Personnel and training.

All operators of thermal processing systems specified in § 431.6 and container closure technicians must be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

§ 431.12 Recall procedure.

Establishments must prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure must be made available to Program employees for review.

PART 439—ACCREDITATION OF NON-FEDERAL LABORATORIES FOR ANALYTICAL TESTING OF MEAT, POULTRY, AND EGG PRODUCTS

Sec.

AUTHORITY: 7 U.S.C. 138f, 450, 1901–1906, 1622(o); 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 87 FR 51864, Aug. 24, 2022, unless otherwise noted.

§ 439.1 Definitions.

(a) *Accredited Laboratory Program (ALP).* The voluntary Food Safety and Inspection Service (FSIS) program in which non-Federal laboratories are accredited as capable of performing analyses with the level of quality that is necessary to maintain accreditation in the program, on samples of raw or processed meat, poultry, and egg products, and through which a proficiency testing sample program for quality assurance is conducted.

(b) *Food chemistry.* Analysis of raw or processed meat or poultry products for the components moisture, protein, fat, and salt.

(c) *Initial accreditation proficiency testing sample.* A sample provided by the FSIS ALP to a non-Federal laboratory to determine whether the laboratory's analytical capability meets the standards for acceptance into the program. The concentration or presence of the targeted analyte(s) and the composition of the components in the sample is unknown to the laboratory.

(d) *Inter-laboratory accreditation maintenance proficiency testing sample.* A sample provided by the FSIS ALP to an accredited laboratory to assist in determining whether the laboratory is maintaining acceptable analytical performance for a given analyte or component. The concentration or presence of the targeted analyte(s) and the composition of the components in the sample is unknown to the laboratory.

(e) *International Organization for Standardization (ISO) 13528.* ISO 13528:2015(E) Corrected version 2016, ''Statistical methods for use in proficiency testing by interlaboratory comparison,'' October 15, 2016, or updated versions.

(f) *Probation.* The period commencing with official notification to an accredited laboratory that it no longer satisfies the ALP performance requirements specified in this part and ending with official notification that accreditation is fully restored, is suspended, or is revoked.

(g) *Refusal of accreditation.* An action taken by FSIS when a laboratory that is applying for accreditation is denied the accreditation.

(h) *Responsibly connected.* Any individual, or entity, that is a partner, officer, director, manager, or owner of 10 percent or more of the voting stock of

the applicant or recipient of accreditation or an employee in a managerial or executive capacity or any employee who conducts or supervises the analysis of FSIS samples.

(i) *Revocation of accreditation.* An action taken by FSIS against a laboratory thereby removing the laboratory's certification of accreditation and participation in inter-laboratory accreditation maintenance proficiency testing sample events.

(j) *Suspension of accreditation.* An action taken by FSIS against a laboratory thereby temporarily removing the laboratory's certification of accreditation and participation in the inter-laboratory accreditation maintenance proficiency testing sample events. Suspension of accreditation ends when accreditation either is fully restored or is revoked.

(k) *z score.* A statistically derived number representing a laboratory's performance for analyzing quantitative proficiency testing samples. The ALP calculates and interprets *z* scores consistent with the ISO 13528 standard.

§ 439.5 Applications for accreditation.

(a) Participation in the ALP is voluntary. Application for accreditation must be made on designated paper or electronic forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory. Application forms may be obtained by contacting the ALP at *ALP@usda.gov*. The forms must be sent to the ALP or may be submitted electronically. The application must specify the kinds of accreditation sought by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked for performance reasons may reapply for accreditation after 60 days from the effective date of that action and must provide written documentation specifying what corrections were made and illustrate to FSIS that the corrections are effective or would reasonably be expected to be effective.

(b) At the time that an application for accreditation is filed with the ALP, the laboratory must submit fees payable to the U.S. Department of Agriculture by check, bank draft, money order, or other form of payment accepted by the U.S. Department of Agriculture, in the amount specified by FSIS as directed in 9 CFR 391.5, along with the completed application for the accreditation(s).

(c) An application for accreditation will not be processed or allowed to advance, without further procedure, if the accreditation fee(s) is delinquent.

(d) FSIS will issue a bill annually in the amount specified by FSIS in 9 CFR 391.5 for each accreditation held and are due by the date required. Bills are payable to the U.S. Department of Agriculture by check, bank draft, money order, or other form of payment accepted by the U.S. Department of Agriculture.

§ 439.10 Criteria for obtaining accreditation.

(a) Analytical laboratories may be accredited for the analyses of foodborne indicator and pathogen analytes, or a specified chemical residue or a class of chemical residues, in raw or processed meat, poultry, and egg products. Analytical laboratories also may be accredited for the analyses of food chemistry components in raw or processed meat and poultry products.

(b) Accreditation will be granted only if the applying laboratory successfully satisfies FSIS requirements that are stated in this part.

(c) To obtain FSIS accreditation, an analytical laboratory must:

(1) Be supervised by a person holding, at a minimum, a bachelor's degree in biology, chemistry, microbiology, food science, food technology, or a related field.

(i) For food chemistry accreditation, the supervisor must also have one year of experience in food chemistry analysis, or equivalent qualifications.

(ii) For chemical residue accreditation, either the supervisor or the analyst assigned to analyze the sample must also have three years of experience determining analytes at or below part per million levels, or equivalent qualifications.

(iii) For indicator organisms or pathogen accreditation, either the supervisor or the analyst assigned to analyze the sample must also have three

years of experience in foodborne pathogen analyses or equivalent qualifications.

(2) Demonstrate the capability to achieve quality assurance levels that are within acceptable limits as determined by evaluation that is consistent with ISO 13528 for the analysis of initial accreditation proficiency testing samples, in the analyte category for which accreditation is sought. FSIS and some Association of Official Analytical Collaboration (AOAC) International analytical test procedures are acceptable for use in this program. FSIS procedures may be found on the U.S. Department of Agriculture (USDA) FSIS website at *www.fsis.usda.gov*. AOAC procedures may be found on the AOAC website at *www.aoac.org*.

(3) Complete a second set of proficiency testing samples if the results of the first set of proficiency testing samples are unsuccessful.

(i) The second set of proficiency testing samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. The second set of proficiency testing samples will be analyzed only for the analyte(s) or analyte classes for which unacceptable initial results had been obtained by the laboratory.

(ii) If the results of the second set of proficiency testing samples are unsuccessful, the laboratory may request a third set of proficiency testing samples after a 60-day waiting period, commencing from the date of notification by FSIS of unsuccessful results. The third set of proficiency testing samples will be analyzed only for the analyte(s) or analyte classes for which unacceptable initial results had been obtained by the laboratory.

(iii) If the laboratory is unsuccessful for the third set and still wishes to pursue accreditation, the ALP will require a new application and an application fee if the initial accreditation process is not completed within eleven months. Documentation of corrective action(s) related to the previous unsuccessful accreditation attempt must be submitted to and accepted by the ALP.

(4) Allow inspection of the laboratory facility and pertinent documents by FSIS officials prior to the determination of granting accredited status.

(5) Pay the accreditation fee by the date required.

§ 439.20 Criteria for maintaining accreditation.

(a) *Criteria*. To maintain accreditation, an analytical laboratory must fulfill the requirements of this section.

(b) *Records*. To demonstrate traceable and appropriate application of equipment, standards, procedures, analysts, and approvals related to accreditation, an accredited laboratory must:

(1) Maintain laboratory quality control records for the most recent three years that samples have been analyzed.

(2) Maintain complete records of the receipt, analysis, and disposition of samples for the most recent three years that samples have been analyzed.

(3) Maintain in a secure electronic format or in a standards book, all records, readings, and calculations for prepared standards. Entries are to be dated and the analyst identified at the time of the entry, and manual calculations verified and documented by the supervisor, or by the supervisor's designee, before use of the standard. The standards records are to be retained for three years after the last recorded entry. The certificates of analysis are to be kept on file for purchased standards for at least the period of time that the materials are in use.

(4) Maintain records of instrument maintenance and calibration. The records are to be retained for three years after the last recorded entry.

(5) As provided in paragraph (e) of this section, records are to be made available for review by any duly authorized representative of the Secretary of Agriculture, including ALP personnel or their designees.

(c) *Inter-laboratory accreditation maintenance proficiency testing sample*. (1) An accredited laboratory must analyze inter-laboratory accreditation maintenance proficiency testing samples and return the results to the ALP by the due date, which is usually within approximately three weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(2) Results must be those of the accredited laboratory. Analyses of proficiency testing samples must not be contracted out by the accredited laboratory.

(d) *Corporate changes.* The ALP must be informed within 30 days of any change of address or in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(e) *On-site review.* An accredited laboratory must permit any duly authorized representative of the Secretary to perform both announced and unannounced on-site laboratory reviews of facilities and records, both hard copy and electronic, during normal business hours, and to copy any records pertaining to the laboratory's participation in the ALP.

(f) *Analytical test procedures.* An accredited laboratory must use analytical test procedures designated by the FSIS ALP as being acceptable. FSIS and some AOAC analytical test procedures are acceptable.

(g) *Quality assurance levels.* An accredited laboratory must demonstrate the capability to maintain quality assurance levels that are within acceptable limits as evaluated by the ALP in the analysis of inter-laboratory accreditation maintenance proficiency testing samples for the analyte category for which accreditation was granted. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its results from inter-laboratory accreditation maintenance proficiency testing samples satisfy ALP evaluation criteria based on the ISO 13528 standard, to include performance evaluation by z score statistics.

(h) *Fees.* An accredited laboratory must pay the annual required accreditation fee when it is due.

(i) *Probation.* If placed on probation, an accredited laboratory must meet the ALP requirements as prescribed in this section in order to remove the probation status.

(1) The laboratory must successfully analyze a set of initial accreditation proficiency testing samples for the analyte(s) that triggered the probation and submit the analytical results to FSIS by the due date, which is typically within approximately three weeks of receipt of the samples.

(2) Similarly satisfy criteria for accreditation maintenance proficiency testing samples specified by the ALP in this part.

(3) Provide written corrective action documentation, related to the issue that triggered the probation, to the ALP by the date required.

(j) *Suspension.* If placed on suspension, an accredited laboratory must meet the ALP requirements as prescribed in this section in order to remove the suspension status. If the laboratory is unsuccessful in meeting the requirements to remove the suspension status, accreditation will be revoked.

(1) Laboratories that are suspended due to performance or response issues enter a waiting period of 60 days from the effective date of that action. After the 60-day period has passed, if the laboratory wishes to pursue reinstatement to the ALP, the laboratory must submit a written corrective action plan specifying what corrections were made and illustrate to FSIS that the corrections are effective or would reasonably be expected to be effective.

(i) After the corrective action plan has been accepted by the ALP, the laboratory must successfully analyze a set of initial accreditation proficiency testing samples for the analyte(s) that triggered the suspension and meet all other program requirements including payment of any annual fees that are due. The ALP may perform an on-site inspection at the laboratory's facility and/or require the laboratory to provide documentation to confirm that it meets the requirements of the program.

(ii) The suspended laboratory is allowed two attempts to successfully analyze the initial accreditation proficiency testing set(s) of samples.

(2) Laboratories that are suspended due to indictment or charges as described in § 439.52 may not seek removal of suspension status until being cleared of said indictment or charges.

§ 439.50 Refusal of accreditation.

Upon a determination by the FSIS Administrator (Administrator), a laboratory will be refused accreditation for the following reasons:

(a) A laboratory will be refused accreditation for failure to meet the requirements of the ALP as stated in this part.

(b) A laboratory will be refused accreditation if the laboratory or any individual or entity responsibly connected with the laboratory has been convicted of, or is under indictment for, or has charges on any information brought against them in a Federal or State court concerning any of the following violations of law:

(1) Any felony.

(2) Any misdemeanor based upon acquiring, handling, or distributing of 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.

(5) Altering any official sample or analytical finding; or substituting any analytical result from any other laboratory and representing the result as its own.

§ 439.51 Probation of accreditation.

Upon a determination by the Administrator, a laboratory will be placed on probation for the following reasons:

(a) If the laboratory fails to complete more than one inter-laboratory accreditation maintenance proficiency testing sample analysis within 12 consecutive months, unless written permission is granted by the Administrator.

(b) If the laboratory does not respond to ALP inquiries related to its participation in the program or fails to meet any of the requirements or criteria set in this part.

(c) If the laboratory does not successfully demonstrate the maintenance of quality assurance capabilities including its results from inter-laboratory accreditation maintenance proficiency testing samples. ALP evaluation criteria are based on the ISO 13528 standard, to include performance evaluation by *z* score statistics.

§ 439.52 Suspension of accreditation.

A laboratory will be suspended from the program if probation status is not rectified according to program requirements stated in this part. The accreditation of a laboratory will be immediately suspended if the laboratory or any individual or entity responsibly connected with the laboratory is indicted or has charges on information brought against them in a Federal or State court for any of the following violations of law. A laboratory must notify the ALP within 30 calendar days if any of these situations occur.

(a) Any felony.

(b) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

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

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

(e) Altering any official sample or analytical finding; or substituting any analytical result from any other laboratory and representing the result as its own.

§ 439.53 Revocation of accreditation.

A laboratory will have its accreditation revoked from the program if suspension status is not rectified. The accreditation of a laboratory will also be revoked for the following reasons:

(a) An accredited laboratory will have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(1) Altered any official sample or analytical finding; or

(2) Substituted any analytical result from any other laboratory and represented the result as its own.

(b) An accredited laboratory will have its accreditation revoked if the laboratory or any individual or entity responsibly connected with the laboratory is convicted in a Federal or State court of any of the following violations of law. A laboratory must notify the ALP within 30 calendar days if any of these situations occur.

(1) Any felony.

(2) Any misdemeanor based upon acquiring, handling, or distributing of

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.