

prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with § 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with § 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) [Reserved]

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

[68 FR 34224, June 6, 2003, as amended at 80 FR 35188, June 19, 2015]

## PART 439—ACCREDITATION OF NON-FEDERAL CHEMISTRY LABORATORIES

Sec.

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### § 439.1 Definitions.

(a) *Accreditation*—Determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation specified in this part, for the presence and amount of all four food chemistry analytes (protein, moisture, fat, and salt); or a determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation in this part, for the presence and amount of a specified chemical residue of any one of several classes of chemical residues. A laboratory may hold more than one accreditation.

(b) *Accredited laboratory*—A non-Federal analytical laboratory that has met the requirements for accreditation specified in this Part and, therefore, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

(c) *Accredited Laboratory Program (ALP)*—The FSIS program in which non-Federal laboratories are accredited as eligible to perform analyses on official regulatory samples of raw or processed meat and poultry products, and through which a check sample program for quality assurance is conducted.

(d) *Chemical residue misidentification*—see “Correct chemical residue identification” definition.

(e) *Coefficient of variation (CV)*—The standard deviation of a distribution of analytical values multiplied by 100 and divided by the mean of those values.

(f) *Comparison mean*—The average result, for a sample, obtained from all

submitted results that have a large deviation measure of zero. When only two laboratories perform the analysis and the large deviation measure is not zero, alternative procedures for establishing a comparison mean may be employed by FSIS. For purposes of computing the comparison mean, a laboratory's "result" for a food chemistry analyte is the obtained analytical value; a laboratory's "result" for a chemical residue is the logarithmic transformation of the obtained analytical value.

(g) *Correct chemical residue identification*—Reporting by a laboratory of the presence and analytical value of a chemical residue that was included in the ALP check sample above the minimum reporting level. Failure of a laboratory to report the presence of such a chemical residue is considered a misidentification. In addition, reporting the presence of and analytical value for a residue that was not included in the ALP check sample above the minimum reporting level is considered a misidentification.

(h) *CUSUM*—A class of statistical procedures for assessing whether or not a process is "in control." Each CUSUM value is constructed by accumulating incremental values obtained from observed results of the process, and then determined to either exceed or fall within acceptable limits for that process. The initial CUSUM values for each laboratory whose application for accreditation is accepted are set at zero. The CUSUM values are reset to zero at the beginning of each year; that is, the CUSUM values associated with the first maintenance check sample each year are set equal to the CUSUM increment for that sample. The four CUSUM procedures are:

(1) Positive systematic laboratory difference CUSUM (CUSUM-P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

(2) Negative systematic laboratory difference CUSUM (CUSUM-N)—monitors how consistently an accredited laboratory gets numerically smaller results than the comparison mean;

(3) Variability CUSUM (CUSUM-V)—monitors the average "total deviation" (i.e., the combination of the random fluctuations and systematic dif-

ferences) between an accredited laboratory's results and the comparison mean; and

(4) Individual large deviation CUSUM (CUSUM-D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

(i) *Food chemistry*—For the purposes of part 439, "food chemistry" will refer to analysis of raw or processed meat or poultry products for the analytes moisture, protein, fat, and salt. All four analytes must be determined when a food chemistry analysis is conducted, unless otherwise advised by the ALP.

(j) *Individual large deviation*—An analytical result that differs from the sample comparison mean by more than would be expected assuming normal laboratory variability.

(k) *Initial accreditation check sample*—A sample provided by the ALP to a non-Federal laboratory to determine whether the laboratory's analytical capability meets the standards for granting accreditation.

(l) *Inter-laboratory accreditation maintenance check sample*—A sample provided by FSIS to an accredited laboratory to assist in determining whether the laboratory is maintaining acceptable levels of analytical capability.

(m) *Large deviation measure*—A measure that quantifies an unacceptably large difference between a laboratory's analytical result and the sample comparison mean.

(n) *Minimum proficiency level (MPL)*—The minimum concentration of a residue at which an analytical result will be used to assess a laboratory's quantification capability. This concentration is an estimate of the smallest concentration for which the average coefficient of variation (CV) for reproducibility (i.e., combined within and between laboratory variability) does not exceed 20 percent.

(o) *Minimum reporting level (MRL)*—The number such that if any obtained analytical value for a residue in a check sample or official sample equals or exceeds this number, then the residue is reported together with the obtained analytical value.

(p) *Official sample*—A sample selected by an inspector or inspection service

employee in accordance with FSIS procedures for regulatory use.

(q) *Probation*—The period commencing with official notification to an accredited laboratory that its check sample results no longer satisfy the performance requirements specified in this rule, and ending with official notification that accreditation either is fully restored, is suspended, or is revoked.

(r) *QA* (See Quality assurance recovery).

(s) *QC* (See Quality control recovery).

(t) *Quality assurance (QA) recovery*—The ratio of a laboratory's analytical value for a check sample residue to the established level of the analyte in the check sample, multiplied by 100. As dictated by the procedures for the analyte, the analytical value may be adjusted prior to the recovery computation.

(u) *Quality control (QC) recovery*—The ratio of a laboratory's analytical value of a quality control standard to the established level of the analyte in the standard, multiplied by 100. As dictated by the procedures for the analyte, the analytical value may be adjusted prior to the recovery computation.

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

(w) *Responsibly connected*—Any individual, or entity, that is a partner, offi-

cer, 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 chemical analysis of FSIS official samples.

(x) *Revocation of accreditation*—An action taken by FSIS against a laboratory, removing the laboratory's right to analyze official samples.

(y) *Standardizing constant*—A number that results from a mathematical adjustment to the "standardizing value" and is used to compute the standardized difference for a check sample result. The number takes into consideration the expected variance of the difference between the accredited or applying laboratory's result(s) and the comparison mean for a sample, the standardizing value, the correlation and number of repeated results by a laboratory on a sample, and the number of laboratories that analyzed a sample.

(z) *Standardized difference*—The quotient of the difference between a laboratory's result on a sample and the comparison mean of the sample divided by the standardizing constant.

(aa) *Standardizing value*—A number representing the performance standard deviation of an individual result. The number is given, or computed by, the information provided in Tables 1 and 2 to this paragraph (aa).

TABLE 1 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR FOOD CHEMISTRY  
[By product class and analyte]

Product/class	Moisture	Protein <sup>1</sup>	Fat <sup>1</sup>		Salt <sup>1</sup>		
			<12.5%	≥12.5%	<1%	1–4%	≥4% <sup>2</sup>
Cured Pork/ Canned Ham .....	0.50	0.060 (X <sup>0.65</sup> )	0.26 (X <sup>0.25</sup> )	0.30 (X <sup>0.25</sup> )	0.127	0.127 (X <sup>0.25</sup> )	0.22
Ground Beef .....	0.71	0.060 (X <sup>0.65</sup> )	N/A	0.35 (X <sup>0.25</sup> )	0.127	0.127 (X <sup>0.25</sup> )	0.22
Other Meat Prod- ucts .....	0.57	0.060 (X <sup>0.65</sup> )	0.26 (X <sup>0.25</sup> )	0.30 (X <sup>0.25</sup> )	0.127	0.127 (X <sup>0.25</sup> )	0.22
Poultry Products ....	0.57	0.060 (X <sup>0.65</sup> )	0.26 (X <sup>0.25</sup> )	0.30 (X <sup>0.25</sup> )	0.127	0.127 (X <sup>0.25</sup> )	0.22

<sup>1</sup> The standardizing value is either the value given in the table or is computed by the formula set forth in the table, where X is the comparison mean of the sample. Standardizing values are provided for different percentages of fat and salt as indicated in the table.

<sup>2</sup> For dry salami and pepperoni products.

TABLE 2 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Standardizing value <sup>3</sup>
Chlorinated Hydrocarbons: <sup>1</sup>	
Aldrin .....	0.20
Benzene Hexachloride .....	0.20

TABLE 2 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR CHEMICAL RESIDUES—Continued

Class of residues	Standardizing value <sup>3</sup>
Chlordane .....	0.20
Dieldrin .....	0.20
DDT .....	0.20

TABLE 2 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR CHEMICAL RESIDUES—Continued

Class of residues	Standardizing value <sup>3</sup>
DDE .....	0.20
TDE .....	0.20
Endrin .....	0.20
Heptachlor .....	0.20
Heptachlor Epoxide .....	0.20
Lindane .....	0.20
Methoxychlor .....	0.20
Toxaphene .....	0.20
Hexachlorobenzene .....	0.20
Mirex .....	0.20
Nonachlor .....	0.20
Polychlorinated Biphenyls:	0.20
Arsenic <sup>2</sup> .....	0.25
Sulfonamides <sup>2</sup> .....	0.25
Volatile Nitrosamine <sup>2</sup> .....	0.25

<sup>1</sup> Laboratory statistics are computed over all results (excluding PCB results), and for specific chemical residues.

<sup>2</sup> Laboratory statistics are only computed for specific chemical residues.

<sup>3</sup> The standardizing value of all initial accreditation and probationary check samples computations is 0.15.

(bb) *Suspension of accreditation*—Action taken by FSIS against a laboratory that temporarily removes the laboratory's right to analyze official samples. Suspension of accreditation ends when accreditation either is fully restored or is revoked.

(cc) *Systematic laboratory difference*—A comparison of one laboratory's results with the comparison mean for samples that show, on average, a consistent relationship. A laboratory that is reporting, on average, numerically greater results than the comparison mean has a positive systematic laboratory difference. Conversely, numerically smaller results indicate a negative systematic laboratory difference.

(dd) *Variability*—Random fluctuations in a laboratory's processes that cause its analytical results to deviate from a true value.

(ee) *Variance*—The expected average of the squared differences of sample results from an expected sample mean.

**§ 439.5 Applications for accreditation.**

(a) Application for accreditation shall 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. The forms shall be sent to the ALP or may be submitted electronically when so provided for by FSIS. The application shall specify the kinds of accreditation that are wanted by the owner or manager of the labora-

tory. A laboratory whose accreditation has been refused or revoked may re-apply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

(b) At the time that an Application for Accreditation is filed with the ALP, the management of a laboratory shall, for each accreditation sought, submit a check, bank draft, or money order in the amount specified in 9 CFR 391.5, made payable to the U.S. Department of Agriculture, along with the completed application for the accreditation(s). When so provided for by FSIS, electronic transfer of funds may be accepted.

(c) Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid will be non-refundable and will be credited to the account from which the expenses of the laboratory accreditation program are paid.

(d) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5 for each accreditation held. Bills are payable upon receipt by check, bank draft, or money order made payable to the U.S. Department of Agriculture and become delinquent 30 days from the date of the bill.

(e) Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid will be nonrefundable and will be credited to the account from which the expenses of the ALP are paid.

**§ 439.10 Criteria for obtaining accreditation.**

(a) Analytical laboratories may be accredited for the analyses of food chemistry analytes, as defined in § 439.1 of this part, or a specific chemical residue or a class of chemical residues in raw or processed meat and poultry products.

(b) Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below. For food chemistry accreditation, the requirements must be satisfied for all four analytes.