Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318, 381, and 439

[Docket No. 03–020P; FDMS Docket Number FSIS–2005–0023]

RIN: 0583–AD09

Accredited Laboratory Program

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to revise, edit, and consolidate provisions of the standards and procedures for the accreditation of non-Federal analytical chemistry laboratories. Laboratories in the Accredited Laboratory Program (ALP) are accredited to analyze official meat and poultry samples for specific chemical residues or classes of chemical residues, and moisture, protein, fat, and salt. In particular, FSIS is proposing to amend its current regulations regarding the accreditation of non-Federal analytical chemistry laboratories to accommodate the adoption of newer methods for analyzing chemical residues and to correct some data. In addition, FSIS is proposing to make editorial changes to its accredited laboratory regulations to reflect Agency reorganizations and program changes and to improve the clarity and consistency of application for all laboratories participating in the ALP. Finally, FSIS is proposing to consolidate the accredited laboratory regulations from 9 CFR Part 318.21 of the meat inspection regulations and 9 CFR Part 381.153 of the poultry products inspection regulations into a single new part, 9 CFR Part 439, that is applicable to both meat and poultry establishments. Along with the consolidation, redundancies within the regulations have been reduced, with the net result being a more succinct set of regulations.

DATES: Comments must be submitted by March 20, 2006.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

- Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. FSIS prefers to receive comments through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and, in the ''Search for Open Regulations'' box, select ''Food Safety and Inspection Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select FDMS Docket Number FSIS–2005–0023 to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the ''Advanced Search'' function in Regulations.gov.
- Mail, including floppy disks or CD–ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.
- Electronic mail: *fsis.regulationscomments@fsis.usda.gov*.

All submissions received must include the Agency name and docket number 03–020P.

All comments submitted in response to this proposal, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations_&_policies/2005_Proposed_Rules_Index/index.asp*.

FOR FURTHER INFORMATION CONTACT: Lynn Larsen, Ph.D., Senior Director for Program Services, Office of Public Health Science, FSIS, at (202) 690–6492 or fax (202) 690–6632.

SUPPLEMENTARY INFORMATION:

Background

In order to ensure compliance with the regulatory provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), samples of meat and poultry products are periodically tested to determine moisture, protein, fat, and salt content. Analyses also are conducted to determine the presence of violative concentrations of drugs or other chemical residues.

When there is an indication of noncompliance with the FMIA and the PPIA, FSIS takes appropriate action against the processor of the noncompliant product. Depending on the type of product and the severity of the noncompliance, such actions may range from requiring that a product be reprocessed to the taking of an enforcement action. Because correct and accurate test results help prevent the distribution of adulterated and misbranded meat and poultry products, it is necessary that laboratories that conduct the tests in FSIS' accredited laboratory program maintain a high degree of integrity.

Before 1962, most official samples were analyzed by FSIS laboratories. However, in response to the meat and poultry industries' need for more rapid analytical results, and because of limitations in FSIS laboratory capacity, programs were established to certify non-Federal laboratories for certain tests of both meat and poultry products. In 1980 (45 FR 73947) and again in 1985 (50 FR 15435), the Agency proposed to consolidate these programs and establish an Accredited Laboratory Program (ALP) that contained standards and procedures for non-Federal laboratories eligible to analyze official samples. A final rule was issued in 1987 (52 FR 2176). A subsequent 1993 final rule (58 FR 65254) established user fees for the ALP and adjusted the standards and procedures established in the earlier rule for this program. User fees, which cover the costs of the ALP, are mandated by the Food, Agriculture, Conservation, and Trade Act of 1990 (the 1990 Farm Bill), as amended.

A processor whose sample is to be analyzed generally has the option of using an FSIS laboratory or a non-Federal FSIS-accredited laboratory. The cost of FSIS analysis is borne by the government; the cost of non-Federal analysis is borne by the processor. Because of the limited number (three) of FSIS laboratories and their heavy workload, processors may prefer to use

non-Federal accredited laboratories given the convenience of their location or the fact they can provide test results more quickly. Some non-Federal accredited laboratories are separate entities, while others are located in and owned by official establishments.

The Proposed Rule

This proposal updates the regulations governing the accredited laboratory program and clarifies and corrects some data. Issuance of these proposed regulations will give FSIS more flexibility in keeping up with current and future scientific changes without having to periodically reissue new regulations. For example, this proposal deletes from the regulations all references and footnotes to the Association of Official Analytical Chemists (AOAC) contained in the current food chemistry accreditation regulations and the definitions. The name and address of the organization have changed, and the cited edition of the methods manual is not the current edition. AOAC will no longer be specifically cited. Instead, the ALP will advise accredited laboratories, as provided in the proposed accreditation regulations, about suitable methods that are available from various compendia, such as FSIS guidebooks or current AOAC manuals, for determining the presence of the analytes covered by the ALP.

This proposed rule deletes all references to split samples because they are no longer part of the ALP program. In addition, this rule modifies Table 1 of the current regulations in §§ 318.21 and 381.153 by moving its footnote information into the main body of the table. The proposed rule modifies Table 2 and provisions for Quality Assurance (QA) and Quality Control (QC) recovery throughout the regulations by removing explicit figures for minimum proficiency levels (MPLs) and recoveries. Information on current recoveries established by FSIS for laboratory quality assurance and quality control will be available from the ALP Web site at *http://www.fsis.gov/Science/Accredited_Laboratories/index.asp.* A link to information on current MPLs is available on the ALP Web site, or you can access the information directly at *http://www.fsis.usda.gov/PDF/2003_Red_Book_Appendix3–4.PDF.*

Finally, the proposed rule eliminates duplicative provisions within the current regulations and consolidates §§ 318.21 and 381.153 into a single set of regulations in new Part 439. For example, new § 439.20 contains the criteria for maintaining either a food chemistry accreditation or a chemical residue accreditation for both meat and poultry products. A summary of the changes made is contained in the following table:

Meat	Poultry	New	Changes
318.21	381.153	Part 439	Editorial and conforming changes throughout the regulations are made, along with certain other revisions.
318.21(a)	381.153(a)	439.1	Updated to reflect change of address and to delete specific references to the Association of Official Analytical Chemists, amended to delete definition of split samples, to modify Tables 1 and 2 to revise performance standards, to add new definitions and to reuse certain current definitions.
318.21(b)(1), 318.21(c)(1)	381.153(b)(1), 381.153(c)(1)	439.5	Updated and consolidated application requirements.
318.21(b)(2), 318.21(c)(2)	381.153(b)(2), 381.153(c)(2)	439.10	Revised, consolidated, and clarified accreditation criteria.
318.21(b)(3), 318.21(c)(3)	381.153(b)(3), 381.153(c)(3)	439.20	Revised and consolidated criteria for maintaining accreditation.
318.21(d)	381.153(d)	439.50	Deletes current (d)(4) and replaces it with a cross reference to ''violations of law'' in new § 439.60 and makes certain other revisions.
318.21(e)	381.153(e)	439.51	Updated to cross reference sections of new § 439.20 and to make certain other revisions.
318.21(f)	381.153(f)	439.52	Deletes current (f) and instead cross references new § 439.60.
318.21(g)	381.153(g)	439.53	Updates and consolidates bases for revocation of accreditation. Deletes current (g)(4) and instead cross references new § 439.60, ''violations of law.''
318.21(e), 318.21(f)	381.153(e), 381.153(f)	439.60	New section that consolidates references to ''violations of law.''
318.21(h)	381.153(h)	439.70	Editorial changes.

Expansion of the Laboratory Program; Request for Comments

Although recent rulemakings and Agency policy decisions address a range of chemical contaminants, including most that present biosecurity concerns, FSIS does not intend to expand the ALP at this time. Expansion of the program to other analytes would require a statistical evaluation of historical data in order to develop the appropriate algorithms and correction factors needed to implement the same type of quality assurance procedures that are applied to the analytes currently included in the program. It would also require FSIS to make policy decisions regarding the acceptance of test results from non-Federal laboratories for these new analytes. The Agency does not intend to include the additional analytes (e.g., pesticide or drug residues) by laboratories in the ALP until such policy decisions have been made, and the necessary scientific foundation is established for them.

FSIS, however, would like to receive comments from the public on whether non-Federal laboratories should be accredited to analyze official samples for additional analytes and whether the laboratories should be used to supplement further the analytical capabilities of the three FSIS laboratories.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. The rule updates the quality standards and procedures that govern the accredited laboratory program.

States and local jurisdictions are preempted under the FMIA and the PPIA from imposing any requirements with respect to federally inspected

premises, facilities, and operations that are in addition to, or different than, those imposed under the FMIA or PPIA. However, State or local jurisdictions may exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA or, in the case of imported products, after their entry into the United States. State and local jurisdictions also may take other actions that are consistent with the FMIA and PPIA, with respect to any other matters regulated under the Acts.

Under FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the Acts. However, these States may impose more stringent requirements on such State-inspected products and establishments.

Executive Order 12866

This proposed rule has been determined to be non-significant and has not been reviewed by the Office of Management and Budget under Executive Order 12866. The rule will not result in an annual effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, governments or geographic regions.

Effect on Small Entities

There are about 90 laboratories that have a total of about 110 accreditations in the FSIS Accredited Laboratory Program (ALP). About three-quarters of these are large entities, based on their volume of business, or are part of entities such as large business corporations, State universities, or State governments. The smaller laboratories participating in the ALP range from medium-sized laboratory facilities to one- or two-person operations. These laboratories provide analytical services of official samples to large and small establishments.

Participation in the Agency's ALP is voluntary. It is expected that a decision to participate would be based on a calculation of the benefits and costs to the firm, including a determination whether the resulting loss of business as a result of non-participation in ALP would be significant.

The Administrator has made an initial determination that this proposed rule would not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The effects of this proposed rule on the laboratories and on the establishments they serve will not be significant and will apply equally to large and small entities. The proposed rule does not involve a change in the accreditation fee, but rather adjustments and clarifications in the operational procedures and standards. The cost savings brought about by improved efficiencies in the requirements for participants in the ALP are likely to be small.

Paperwork Requirements

FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The Agency has determined that the paperwork requirements for the regulations that govern the accreditation of non-Federal analytical chemistry laboratories have already been accounted for in the Application for Inspection, Sanitation, and Accredited Laboratories information collection approved by the Office of Management and Budget (OMB). The OMB approval number for the Application for Inspection, Sanitation, and Accredited Laboratories information collection is 0583–0082.

Government Paperwork Elimination Act (GPEA)

FSIS is committed to compliance with the GPEA, which requires Government agencies, in general, to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. The Agency will ensure that to the extent possible, all forms used by the laboratories are made available electronically.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular that minorities, women, and persons with disabilities are aware of this proposal, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2005_Proposed_Rules_Index/index.asp.*

The Regulations.gov Web site is the central online rulemaking portal of the United States Government. It is being offered as a public service to increase participation in the Federal Government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

List of Subjects

9 CFR Part 318

Accredited laboratory program, Meat inspection, Recordkeeping and reporting requirements.

9 CFR Part 381

Accredited laboratory program, Poultry and poultry products inspection, Recordkeeping and reporting requirements.

9 CFR Part 439

Meat inspection, Poultry and poultry products inspection, Laboratory accreditation.

Accordingly, Title 9, Chapter III, Subchapter E of the Code of Federal Regulations is proposed to be amended as follows:

Subchapter E—Regulatory Requirements Under the Federal Meat Inspection Act and the Poultry Products Inspection Act

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 318.21 [Removed and reserved]

2. Section 318.21 would be removed and reserved.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

§ 381.153 [Removed and reserved]

4. Section 381.153 would be removed and reserved.

5. A new part 439 would be added to Subchapter E of Chapter III to read as follows:

PART 439—ACCREDITATION OF CHEMISTRY LABORATORIES

Sec.

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 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. Program information and guidance can be obtained from the ALP Web site at *www.fsis.usda.gov/Science/Accredited_Laboratories/index.asp* or by writing to: Accredited Laboratory Program, Box 17 Aerospace Center, Room 377, 901 D Street SW, Washington, DC 20024; facsimile telephone number (202) 690–6632; voicemail telephone number (202) 690–6582.

(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 differences) 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. Information on the current MPLs may be obtained from the ALP staff at the address provided above in the definition of ''Accredited Laboratory Program,'' in § 439.1 or from the ALP Web site at *http://www.fsis@usda.gov/Science/Accredited_Laboratories/index.as.*

(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. Information on the current MRLs may be obtained from the ALP staff at the address provided above, in the definition of ''Accredited Laboratory Program,'' in § 439.1. Official sample—A sample selected by an inspector or inspection service employee in accordance with FSIS procedures for regulatory use.

(p) *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.

(q) *QA:* (See *Quality assurance recovery*)

(r) *QC:* (See *Quality control recovery*)

(s) *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.

(t) *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.

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

(v) *Responsibly connected:* Any individual who or entity which 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 chemical analysis of FSIS official samples.

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

(x) *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. Information on the computation of the standardizing constant may be obtained from the ALP staff at the address provided above in the definition of ''Accredited Laboratory Program,'' in § 439.1.

(y) *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.

(z) *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 and their footnotes.

(aa) *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.

(bb) *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.

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

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

TABLE 1.—STANDARDIZING VALUES FOR FOOD CHEMISTRY

[By product class and analyte]

Product/class	Moisture	Protein [1]	Fat [1]		Salt [1]		
			<12.5%	>12.5%	<1%	1–4%	>4% [2]
Cured Pork/Canned Ham	0.50	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Ground Beef	0.71	0.060 ($X^{0.65}$)	N/A	0.35 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Other Meat Products	0.57	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Poultry Products	0.57	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22

[1] 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.

[2] For dry salami and pepperoni products.

TABLE 2.—STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Standardizing value [3]
Chlorinated Hydrocarbons: [1]	
Aldrin	0.20
Benzene Hexachloride	0.20
Chlordane	0.20
Dieldrin	0.20
DDT	0.20
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 [2]	0.25
Sulfonamides [2]	0.25

[1] Laboratory statistics are computed over all results (excluding PCB results), and for specific chemical residues.

[2] Laboratory statistics are only computed for specific chemical residues.

[3] The standardizing value of all initial accreditation and probationary check samples computations is 0.15.

§ 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 at the address provided above in the definition of ''Accredited laboratory'' § 439.1 of this part, 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 laboratory. A laboratory whose accreditation has been refused or revoked may reapply 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 nonrefundable 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, 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.

(c) This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples.

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

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

(i) For food chemistry accreditation, the supervisor must also have 1 year's experience in food chemistry analysis, or equivalent qualifications, as determined by the Administrator.

(ii) For chemical residue accreditation, either the supervisor or the analyst assigned to analyze the sample must also have 3 years' experience determining analytes at or below part per million levels, or equivalent qualifications, as determined by the Administrator.

(2) Demonstrate an ability to achieve quality assurance levels that are within acceptable limits for systemic laboratory difference, variability, and individual large deviations, in the analyte category for which accreditation is sought, using analytical procedures designated by the FSIS ALP as being acceptable. An applying laboratory will successfully demonstrate these capabilities for:

(i) Food chemistry if its results from a 36 check sample accreditation study each satisfy the criteria presented in paragraph (e) of this section.

(ii) Chemical residues if its analytical results for each specific chemical residue provided in a check sample accreditation study containing a minimum of 14 check samples satisfy the criteria presented in paragraph (e) of this section, including criteria for QA and QC recovery and for residue identification. In addition, if the laboratory is requesting accreditation for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria. [Conformance to criteria in paragraph (e) of this section will only be determined when six or more analytical results with associated comparison means at or above the logarithm of the minimum proficiency level are available.]

(3) Round all check sample statistical computations to the nearest tenth, except where otherwise noted.

(4) Complete a second set of the requisite number of check samples if the results of the first set of check samples do not meet the criteria for obtaining accreditation.

(i) The second set of check 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 food chemistry check samples will be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory.

(ii) If the results of the second set of check samples do not meet the accreditation criteria, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

(5) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

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

(e) *Quality assurance levels.* (1) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed the following:

(i) For food chemistry, 0.73 minus the product of 0.17 and the standard deviation of the standardized differences; and

(ii) For chemical residues, 1.67 (2.00 if there are less than 12 analytical results) minus the product of 0.29 and

the standard deviation of the standardized differences.

(2) *Variability:* The estimated standard deviation of the standardized difference must not exceed the following:

(i) For food chemistry, 1.15; and

(ii) For chemical residues, a computed limit that is a function of the number of analytical results used in the computation of the standard deviation, and of the amount of variability.

(3) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual samples must be less than 5.0. A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5 and otherwise a measure equal to $1-(2.5/d)$.

(4) For residue analyses, the following additional quality assurance requirements must be met.

(i) *QA recovery:* The average of the QA recoveries of the individual check sample analytical results must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this chapter.

(ii) *QC recovery:* All QC recoveries must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this chapter. Supporting documentation must be made available to FSIS upon request.

(iii) *Correct identification:* There must be correct identification of all chemical residues in all samples.

§ 439.20 Criteria for maintaining accreditation.

(a) To maintain accreditation, an analytical laboratory must fulfill the requirements of paragraphs (b) through (i) of this section.

(b) *Official samples.* (1) An accredited laboratory must expeditiously report analytical results, in the analyte category for which accreditation was granted, of official samples on designated forms to the Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, P.O. Box 6085, Athens, GA 30604 (for U.S. Postal Service delivery), or Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, 950 College Station Road, Athens, GA 30605 (for commercial carrier delivery). When so provided for by FSIS, analytical results may be reported to the Data Center Staff by facsimile at 706–546–3589, or electronically. The Federal inspector at any establishment may assign the analysis of official samples to an FSIS laboratory if, in the inspector's judgment, there are delays in receiving test results on official samples from an accredited laboratory.

(2) Every QC recovery associated with reporting of official samples must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this chapter. Supporting documentation must be made available to FSIS upon request.

(c) *Records.* An accredited laboratory must:

(1) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(2) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under this Program.

(3) Maintain in a secure electronic format or in a standards book, which is preferably a permanently bound book with sequentially numbered pages, all records, readings, and calculations for standard solutions. All entries are to be dated and signed by the analyst immediately upon completion of the entry, and by the supervisor, or in the absence of the supervisor by the supervisor's designee, before use of the standard solution but no later than within 1 week. The standards book is to be retained for 3 years after the last recorded entry.

(4) Maintain records and supervisor approvals of recoveries, and of instrument maintenance and calibration. The records are to be retained for 3 years after the last recorded entry.

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

(d) *Check samples.* (1) An accredited laboratory must analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3 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 maintenance check samples shall not be contracted out by the accredited laboratory.

(3) As provided by the requirements in paragraph (h) of this section, a check sample report will be considered complete only if laboratories report all analytes present in the check sample for the analyte category in which accreditation was granted.

(e) *Corporate changes.* The ALP must be informed at the address provided in § 439.1 in the definition of ''Accredited laboratory'' of this part, by certified or registered mail, 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.

(f) *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.

(g) *Analytical procedures.* An accredited laboratory must use analytical procedures designated by the FSIS ALP as being acceptable.

(h) *Quality assurance levels.* (1) An accredited laboratory must demonstrate an ability to maintain quality assurance levels that are within acceptable limits for systematic laboratory difference, variability, and individual large deviations in the analysis of interlaboratory check samples for the analyte category for which accreditation was granted. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results from interlaboratory accreditation maintenance check samples satisfy the criteria presented in this paragraph, § 439.20(h). All statistical computations are to be rounded to the nearest tenth, except where otherwise noted.

(2) In addition, a laboratory accredited for a specific chemical residue or a chemical residue class:

(i) Must satisfy criteria presented in this paragraph, § 439.20(h), for chemical residue recoveries and proper identification;

(ii) Will demonstrate the maintenance of its capabilities by reporting its analytical results for each specific chemical residue found above the minimum proficiency level; and

(iii) Must, if accredited for the analysis of chlorinated hydrocarbons, obtain analytical results that collectively satisfy the criteria.

(3) *Systematic laboratory difference:* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine two CUSUM values, designated as CUSUM–P and CUSUM–N.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The average of the standardized differences of the analytical results within the sample, divided by a constant, is used in place of a single standardized difference to determine the CUSUM–P (or CUSUM–N) value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) Positive systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM–P increment for the sample.

(*1*) The CUSUM–P increment for food chemistry, as defined in § 439.1 of this Chapter, is set equal to:

2.0, if the standardized difference is greater than 2.4,

−2.0, if the standardized difference is less than −1.6, or

the standardized difference minus 0.4, if the standardized difference lies between −1.6 and 2.4, inclusive.

(*2*) The CUSUM–P increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 2.5,

−2.0, if the standardized difference is less than −1.5, or

the standardized difference minus 0.5, if the standardized difference lies between −1.5 and 2.5, inclusive.

(B) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM–P increment to the last previously computed CUSUM–P value. If this computation yields a value smaller than 0, the new CUSUM–P value is set equal to 0.

(C) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed:

(*1*) 5.2 for food chemistry.

(*2*) 4.8 for chemical residues.

(iii) Negative systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM–N increment for the sample.

(*1*) The CUSUM–N increment for food chemistry is set equal to:

2.0, if the standardized difference is greater than 1.6,

−2.0, if the standardized difference is less than −2.4, or

the standardized difference plus 0.4, if the standardized difference lies between − 2.4 and 1.6, inclusive.

(*2*) The CUSUM–N increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 1.5,

−2.0, if the standardized difference is less than −2.5, or

the standardized difference plus 0.5, if the standardized difference lies between −2.5 and 1.5, inclusive.

(B) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM–N increment from the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0.

(C) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed:

(*1*) 5.2 for food chemistry.

(*2*) 4.8 for chemical residues.

(4) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The square root of the sum of the within sample variance and the average standardized difference of the sample, divided by a constant, is used in place of the absolute value of the standardized difference to determine the CUSUM–V value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) The variability value is computed and designated as follows:

(A) Determine the CUSUM–V increment for the sample. The CUSUM increment is set equal to the larger of −0.4 or the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

(B) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM–V increment to the last previously computed CUSUM–V value. If this computation yields a value less than 0, the new CUSUM–V value is set equal to 0.

(C) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(5) *Large deviations:* The large deviation measure of the accredited laboratory's result for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.

(i) A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to 1 − (2.5/d).

(ii) The large deviation value is computed and evaluated as follows:

(A) Determine the CUSUM–D increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(B) Compute the new CUSUM–D value. The new CUSUM–D value is obtained by adding, algebraically, the CUSUM–D increment to the last previously computed CUSUM–D value. If this computation yields a value less than 0, the new CUSUM–D value is set equal to 0.

(C) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(6) For chemical residues:

(i) Each QC recovery must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this Chapter. Supporting documentation must be made available to FSIS upon request.

(ii) Not more than 1 residue misidentification may be made in any 2 consecutive check samples.

(iii) Not more than 2 residue misidentifications may be made in any 8 consecutive check samples.

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

(j) *Probation.* An accredited laboratory must meet the following requirements if placed on probation pursuant to § 439.51 of this chapter:

(1) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS laboratory by certified mail or private carrier or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analyte(s). Mailing expenses will be paid by FSIS.

(2) Analyze a set of check samples similar to those used for initial accreditation, and submit the analytical results to FSIS within 3 weeks of receipt of the samples.

(3) Satisfy criteria for accreditation check samples specified in § 439.10 of this chapter.

§ 439.50 Refusal of accreditation.

Upon a determination by the 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 § 439.5 or § 439.10 of this chapter.

(b) A laboratory will be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analytes, all official samples that have not been analyzed as of the notification of a loss of accreditation.

(c) A laboratory will be refused accreditation for the reasons described in § 439.60 of this chapter.

§ 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 interlaboratory accreditation maintenance check sample analysis as required by § 439.20(d) of this part within 12 consecutive months, unless written permission is granted by the Administrator.

(b) If the laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this chapter.

§ 439.52 Suspension of accreditation.

The accreditation of a laboratory will be suspended for the reasons described in § 439.60 of this chapter.

§ 439.53 Revocation of accreditation.

The accreditation of a laboratory will be revoked for the following reasons:

(a) An accredited laboratory that is accredited to perform analysis under §§ 439.5, 439.10 and 439.20 of this chapter will have its accreditation revoked for failure to meet any of the requirements of § 439.20 of this chapter, except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this chapter and it has not failed during the 12 months preceding its failure to meet the criteria, it shall be placed on probation, but if it has failed at any time during those 12 months, its accreditation will be revoked.

(b) 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.

(c) An accredited laboratory will have its accreditation revoked for violations of law as described in § 439.60 of this chapter.

§ 439.60 Violations of law.

An applicant or an accredited laboratory will have its accreditation refused, suspended, or revoked, as appropriate, if the laboratory or any individual or entity responsibly connected with the laboratory is convicted of, or is under indictment for, or has had charges on an information brought against them in a Federal or State court concerning any of the following violations of law:

(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.

§ 439.70 Notification and hearings.

Accreditation of any laboratory will be refused, suspended, or revoked under the conditions previously described in this Part 439. 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.

Done in Washington, DC, on January 9, 2006.

Barbara J. Masters,

Administrator.

[FR Doc. 06–284 Filed 1–13–06; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NE–21–AD]

RIN 2120–AA64

Airworthiness Directives; International Aero Engines AG (IAE) V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: This notice revises an earlier proposed airworthiness directive (AD) that applies to certain IAE V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 turbofan engines. That proposal would have required initial and repetitive inspections of the master magnetic chip detector (MCD) or the No. 1, 2, 3 bearing chamber MCD. That proposal would also have required replacing certain No. 3 bearings and replacing or recoating certain high pressure compressor (HPC) stubshaft assemblies as mandatory terminating actions to the repetitive MCD inspections. That proposal resulted from IAE developing a terminating action to the repetitive inspections of the chip detectors. This action revises the proposed rule by expanding its applicability to include additional serial-numbered engines with certain No. 3 bearings installed. We are proposing this AD to prevent failure of the No. 3 bearing, which could result in an in-flight shutdown (IFSD) and smoke in the cockpit and cabin.

DATES: We must receive comments by March 20, 2006.

ADDRESSES: Use one of the following addresses to comment on this proposed AD:

- By mail: Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–NE–21–AD, 12 New England Executive Park, Burlington, MA 01803–5299.
- By fax: (781) 238–7055.
- By e-mail: *9-ane-adcomment@faa.gov.*

You can get the service information identified in this proposed AD from International Aero Engines AG, 400 Main Street, East Hartford, CT 06108; telephone: (860) 565–5515; fax: (860) 565–5510.

You may examine the AD docket, by appointment, at the FAA, New England