interfere with or adversely affect the law enforcement and counterintelligence purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case by case basis.

A notice of system of records DHS/ALL–046 Counterintelligence Program System of Records is also publishing elsewhere in this issue of the **Federal Register**.

List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

For the reasons stated in the preamble, DHS proposes to amend chapter I of title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for part 5 continues to read in part as follows:

Authority: 6 U.S.C. 101 *et seq.;* Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301.

* * * * *

■ 2. In appendix C to part 5, add paragraph 83 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

83. The DHS/ALL–046 Counterintelligence Program System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/ALL–046 Counterintelligence Program System of Records covers information held by DHS in connection with various missions and functions, including, but not limited to the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under; and national security and intelligence activities. The system of records covers information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other federal, state, local, tribal, foreign, or international government agencies.

The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (c)(4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8), (e)(12); (f); and (g)(1). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f).

Where a record received from another system has been exempted in that source system under 5 U.S.C. 552a(j)(2), 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions set forth here.

Exemptions from these particular subsections are justified on a case-by-case basis and determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) and (4) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS and the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and efforts to preserve national security. Disclosure of the accounting would also permit the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process. When an investigation has been completed, information on disclosures made may continue to be exempted if the fact that an investigation occurred remains sensitive after completion.

(b) From subsection (d) (Access and Amendment to Records) because providing access or permitting amendment to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities and would impose an unreasonable administrative burden by requiring investigations to be continually reinvestigated. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsection (e)(2) (Collection of Information from Individuals) because requiring that information be collected from the subject of an investigation would alert the subject to the nature or existence of the investigation, thereby interfering with that investigation and related law enforcement activities.

(e) From subsection (e)(3) (Notice to Subjects) because providing such detailed information could impede law enforcement by compromising the existence of a confidential investigation or reveal the identity of witnesses or confidential informants.

(f) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

(g) From subsection (e)(5) (Collection of Information) because with the collection of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely, and complete. Compliance with subsection (e)(5) would preclude DHS agents from using their investigative training and exercise of good judgment to both conduct and report on investigations.

(h) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(i) From subsection (e)(12) (Matching Agreements) because requiring DHS to provide notice of a new or revised matching agreement with a non-Federal agency, if one existed, would impair DHS operations by indicating which data elements and information are valuable to DHS's analytical functions, thereby providing harmful disclosure of information to individuals who would seek to circumvent or interfere with DHS's missions.

(j) From subsection (g)(1) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

Constantina Kozanas,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2020–27314 Filed 12–11–20; 8:45 am]

BILLING CODE 9110–9N–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 439

[Docket No. FSIS–2016–0026]

RIN 0583–AD70

Changes to Accreditation of Non-Federal Analytical Testing Laboratories.

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: FSIS is proposing to revise the regulations prescribing the statistical

methods used in measuring the performance of chemistry laboratories in its voluntary Accredited Laboratory Program (ALP) and to expand the scope of accreditations offered by the program. Currently, participants in the ALP are accredited for the analysis of food chemistry (moisture, protein, fat, and salt), specific chemical residues, and classes of chemical residues. FSIS is proposing to change the statistical method it uses to evaluate laboratory proficiency testing (PT) sample results to the z score approach for those accreditations that are currently evaluated by Cumulative Summation (CUSUM). FSIS also is proposing to accredit non-Federal laboratories for microbiological indicator organisms and pathogen testing, in response to industry interest. Additionally, the Agency is proposing to make various minor edits and changes to the regulation for the sake of clarity and to incorporate all sample types under the jurisdiction of FSIS (*e.g.,* to include egg products), as appropriate for the associated analyte, and to improve program flexibility. Improving program flexibility includes updating definitions to remove specific references that are currently limiting the program.

DATES: Comments on this proposed rule must be received on or before February 12, 2021.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one 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. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2016–0026. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202)720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 720–0399.

SUPPLEMENTARY INFORMATION:

Background

FSIS accredits non-Federal analytical laboratories under its Accredited Laboratory Program (ALP). Under this voluntary program, FSIS accredits laboratories to conduct analyses of official meat and poultry samples for food chemistry (moisture, protein, fat, and salt), specific chemical residues, and classes of chemical residues. In response to the meat and poultry industries' need for more rapid analytical results as food testing expanded, and because of limitations in FSIS laboratory capacity at the time of this need, these programs were established to accredit 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 ALP that contained standards and procedures for non-Federal laboratories eligible to analyze official samples when necessary. 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. A non-Federal laboratory seeking FSIS accreditation must pay a nonrefundable accreditation fee to cover the costs of the ALP.

In 2008, a final rule was issued (73 FR 52193) to accommodate the adoption of newer methods for analyzing chemical residues and to make editorial changes to the accredited laboratory regulations to reflect Agency reorganizations and program changes. This rule also consolidated the accredited laboratory regulations from 9 CFR 318.21 of the meat inspection regulations and 9 CFR 381.153 of the poultry products inspection regulations into a single new part, 9 CFR part 439.

The ALP monitors each non-Federal laboratory currently accredited under the program to ensure that these laboratories are operating at a level of quality that produces reliable results that can be used to support decisions in establishments' food safety systems. The PT program administered by the ALP supports this effort. Monitoring is achieved by evaluating PT results for acceptable analytical performance and assessing quality assurance through on-site reviews of each laboratory's management system and facility assets.

Statistical Methods

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. These tests are conducted to determine the content of food chemistry components and the presence of violative concentrations of veterinary drugs or other chemical residues. FSIS's own laboratories, as well as accredited non-Federal laboratories carry out these analyses. To assess the proficiency of the non-Federal laboratories participating in the ALP, testing events are administered by FSIS, whereby PT samples of meat and poultry products are prepared and sent to participating laboratories for chemical analysis of targeted food chemistry components as well as targeted compounds, such as residues of veterinary drugs, polychlorinated biphenyls (PCBs), and pesticides. The concentration of the targeted analytes is unknown to the non-Federal laboratories. The laboratories' performance on the analysis of the PT sample is then evaluated and scored by the ALP using a statistical tool (CUSUM) developed by FSIS. The FSIS CUSUM, currently defined at 9 CFR 439.1(h), is based on a class of cumulative summation statistical procedures for assessing whether a process is in control.

The use of CUSUM statistics for scoring laboratory performance in the ALP was implemented in 1987 (''Meat and Poultry Inspection; Accredited Laboratory Program,'' (52 FR 2176; January 20, 1987)). At the time that this rule was published, the analytical chemistry community did not have consensus-based guidance and standards for statistical evaluation of PT results. Consequently, FSIS developed the CUSUM PT sample scoring system specifically to evaluate the analytical performance of the laboratories in the ALP. However, Cumulative Summation statistics do not completely address all aspects of analytical process quality control. Instead, *z score* based statistics are now considered the appropriate tool for evaluating PT performance, and are better suited for the accreditations currently offered by the ALP. The z

score is widely used for evaluating laboratory performance on PT sample analysis and is easily understood. *Z score* based statistics are accepted by the analytical chemistry community and consensus-based standard-setting bodies, such as International Organization for Standardization (ISO) and The NELAC Institute. Expanding the ALP to include additional accreditations could result in accreditations in which the z score may not be applicable. In such cases, the ALP intends to begin using ISO 13528:2015(E) Corrected version 2016 (''ISO 13528'') ''Statistical methods for use in proficiency testing by interlaboratory comparison,'' October 15, 2016) as the source for statistical tools and PT performance evaluation. As the ISO standard is updated, FSIS will adopt the changes, as appropriate. Regarding any significant, substantive changes, FSIS may issue a **Federal Register** notice about changes to its statistical methods.

The intended use of CUSUM statistics, on which FSIS based its creation of the customized CUSUM PT scoring system, is to detect trends, typically in quality control, for a process in a single facility. A level of acceptability (maximum or minimum CUSUM) is established in each case. If this level is exceeded, corrective actions are implemented to bring the process back in control and then the cumulative sum is reset. The FSIS CUSUM PT scoring system has thresholds for acceptability. Participants receive CUSUM scores in three different categories for each PT event. For each sequential event over the period of one calendar year, the scores in each category are added to the scores from the previous event. If a participant's score in any category exceeds the thresholds for acceptability in the one-year time period, the participant is notified and must take corrective actions. Unlike cumulative summation statistics that are only reset after corrective actions, the FSIS CUSUM scores for each participant are reset to zero at the beginning of each year without cause.

FSIS is proposing to amend the ALP regulations at 9 CFR part 439 to replace the prescriptive statistics with requirements presented in the ISO 13528 Standard as the measures it would use to evaluate chemistry laboratory performance based on PT-sample analysis. *Z* score statistics consistent with ISO 13528 would be used where CUSUM scoring is currently used by the ALP. The *z* score statistics are described in detail in ISO 13528 and are briefly described here along with reasons why *z* scores adequately replace CUSUM scoring for PT evaluation.

The *z* score and the common variation *z*′ score (which includes uncertainty in the calculation of the performance score) are widely used and easy to calculate. The *z* score is currently calculated as:

$$z_i = (x_i - x_{pt})/\sigma_{pt}$$

where x_i is the participant's result, x_{pt} is the assigned value of the PT sample analyte, and σ_{pt} is the standard deviation for the proficiency assessment.

The *z*′ score is calculated as:

$$z'_i = (x_i - x_{pt})/(\sigma^2_{pt} + \mu^2(x_{pt}))^{0.5}$$

where μ is the uncertainty of the assigned value.

For the purposes of the ALP, the *z*′ score is considered part of *z* score statistics.

CUSUM scoring, as currently set forth in 9 CFR 439.1(h) and 439.20(h)(3)–(5), addressed three main categories in evaluating PTs:

(1) *Systematic Laboratory Difference:* Which is consistent positive or negative bias for a single laboratory's results over time. Both positive and negative biases are determined in the same manner (only changing for the direction of the bias). Scoring for Systematic Laboratory Difference is represented by CUSUM P for positive bias and CUSUM N for negative bias.

(2) *Variability:* Which is the combination of random fluctuations and systematic differences. Scoring for Variability is represented by CUSUM V.

(3) *Individual Large Discrepancy:* Which is the magnitude and frequency of large differences between the results of an accredited laboratory and the accepted value of the PT. Scoring for Individual Large Discrepancy is represented by CUSUM D.

All of the ALP CUSUM scoring (P, N, V, and D) is performed on the individual laboratory-reported PT results relative to the accepted or assigned value of the PT material. Each ALP CUSUM category has a limit that, if exceeded, incurs a penalty. Scores are monitored over the calendar year to detect exceedances.

The proposed change from the use of CUSUM scoring to *z* score procedures for statistical evaluation of laboratory performance would not affect the ability of FSIS to address these three main categories (Systemic Laboratory Difference, Variability, and Individual Large Discrepancy) in evaluating PTs and would provide evaluation of equivalent purpose and depth.

First, with regard to Systematic Laboratory Difference, CUSUM analyzes for both the direction and magnitude of bias via positive and negative scores. The *z* score equivalently provides this information by the value of the score. The sign of the *z* score value (positive or negative) indicates the direction of the bias relative to the accepted value of the PT sample. Because *z* score statistics are based on standard deviation, the score is normalized around the accepted value of the sample (represented by zero). A participant's PT result that exactly matches the accepted value incurs a zero *z* score. A PT result that is slightly greater than the accepted value will have a *z* score that is slightly greater than zero. This presents an advantage over CUSUM scoring because one can easily visualize the *z* scores compared to zero in graphic form.

CUSUM scoring often returns a zero score, even for deviations from the accepted value. CUSUM scoring will accept PT results up to a threshold and return a zero score. The threshold is dynamic and depends on the magnitude of difference between the PT result and the accepted value and also on the concentration of the analyte in the PT sample. Therefore, CUSUM P and N do not allow the same level of preciseness that *z* scores do in evaluating closeness of the reported result to the accepted value of the PT sample.

Second, with regard to Variability, *z* score statistics provide the magnitude of the deviation from the accepted value. This would successfully replace CUSUM V for Variability. The *z* score has the added benefit of being directional (it indicates both positive and negative variation), while CUSUM V is not. The variations are also easier to detect visually because the *z* scores are normalized relative to the PT accepted value and graphs generated from these data are easily understood.

Third, with regard to Individual Large Discrepancy, CUSUM D is readily replaceable by *z* score statistics. For *z* scores, typically a value greater than 3.0 or less than −3.0 indicates an unacceptable value and may indicate performance problems. The *z* score has the added benefit of being directional (it indicates both positive and negative deviation). The CUSUM D is not directional. Currently, the CUSUM D is monitored over time in order to detect repeated failures. It is expected that any laboratory will occasionally report a PT sample result that falls outside the acceptable range for the sample accepted value, which results in an individual failing score that is random in nature. Repeated failures are not random and constitute a trend. Under this proposed rule, FSIS would continue to monitor the *z* scores for each accredited laboratory to detect trends

that indicate performance issues. As stated above, FSIS monitors CUSUM scores for one calendar year for exceedances. After this period of time, FSIS resets CUSUMs. Because z scores are not reset, changing from CUSUMs to z score statistics offers the advantage of detecting repeated exceedances over an extended period of time.

Updating the ALP statistical tools would also eliminate the need for employing a standardizing value, which is a number used to transform the result of a computation to a unitless measure, representing the performance standard deviation of an individual result. The *z* score is already unitless and is directly based on standard deviation statistics. Eliminating the need for a standardizing value would have the added benefit of making it easier to add relevant chemical residues of current concern to the PT sample program. The added flexibility for the ALP to create and offer PT samples that contain veterinary drug and chemical residues of current concern would increase the opportunities for laboratories to prove that they can successfully analyze samples for these compounds. Standardizing values are specific to each matrix/residue combination and require the evaluation of extensive background information in order to calculate each standardizing value. The *z score* approach does not involve such a requirement and is readily adaptable to the addition of new residues.

Another limitation of the current ALP PT structure has been that analytes in samples must be easy to detect, with minimal measurement uncertainty, for the CUSUM statistics to remain viable. It is common to have some chemical elements and compounds that are difficult to measure in a sample, even under the best of circumstances. Laboratory PT sample results for these difficult analytes are expected to be relatively poor, exhibiting large measurement uncertainty. The *z* score would allow the ALP to take the uncertainty into account when scoring laboratory performance for these difficult analytes. There is no such consideration with CUSUM scoring. As a result, the PT samples in the past largely excluded difficult analytes, regardless of the food safety concerns that those residues might have. Because the *z′* score takes the uncertainty into account, the ALP would be able to include analytes that are difficult to analyze in PT samples and generate resulting scores that do not penalize laboratories for an issue that lies with the analyte instead of the laboratory.

Furthermore, when there is more than one residue analyte in a single PT sample, the ALP has been combining the results for a single score. Combining results is not an accepted practice in the PT community. Changing to the *z* score approach would easily allow scoring for individual analytes.

A comparison of *z* scores and CUSUM scores from seventeen separate ALP food chemistry PT sample events with a focus on outliers shows that it is a good replacement for CUSUM scoring.[1] When using both CUSUM scoring and *z* scores, individual results are evaluated for outliers. The outliers are removed to determine the study comparison mean and then placed back into the study evaluation for scoring the individual laboratories. The ALP evaluation, which used 61 individual ALP CUSUM scores and 61 individual *z* scores for the same sets of laboratory results, showed that when CUSUM scoring indicated the presence of an outlier, the *z* scores either also indicated the outlier or returned a score warning that the result was close to becoming an outlier. Conversely, when the *z* scores indicated an outlier that CUSUM scoring did not, the result still sustained a relatively large ALP CUSUM score increase. One of the 61 results that was an outlier among the ALP CUSUMs was not an outlier among the *z* scores and there was no warning that the result was close to becoming an outlier. However, the *z* score was very close to the warning limit. Warning limits are *z* scores between –3 and –2, and also between 2 and 3. Results that incur a *z* score in the warning limit are not considered outliers, but are a signal to the laboratory that it may have an emerging problem and should be prepared to troubleshoot the analytical system.

The ALP evaluation also considered use of the product code, which is currently part of CUSUM calculations, to determine if it needed to be retained in any capacity within the ALP. This was done by examining the percent relative standard deviation (Percent RSD) of the PT comparison means within and among product classes (classes are defined by meat type and fat content, *e.g.,* low-fat ham). Product classes are represented numerically by product codes, which are assigned by product type, salt content, and moisture content. Product codes are then used in selecting the standardizing values for calculating CUSUMs. Not all product codes were available for this assessment. In the evaluation, the Percent RSD appears to be largely affected by the relative amount of a constituent, just as the product code is determined, in part, by the relative amount of a target analyte. As expected, the lower the constituent content, the larger the Percent RSD. All Percent RSD values were less than 8, which is well within accepted norms for inter-laboratory studies of this type. If the Percent RSD results for the evaluation had approached 20, it may have indicated the need to retain product codes. No other trends were detected related to the product codes. The product codes are only needed for CUSUM scoring and are not required for any other purpose in the ALP. Therefore, removing the use of product codes from the program is supported.

Expansion of the ALP To Include Foodborne Pathogen Testing

Under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*) (AMA), FSIS provides certain laboratory services, for a fee, to establishments and others upon request. FSIS provides four general types of analytic testing to industry: Microbiological testing (*i.e.,* indicator organisms and foodborne pathogens), chemical residue and contaminant testing, food composition testing including speciation, and pathology testing. As discussed throughout this proposal, FSIS also accredits non-Federal laboratories, for a fee, to conduct analytic testing of meat and poultry. Under the AMA at 7 U.S.C. 1622(o),[2] FSIS accredits non-Federal laboratories to conduct food chemistry testing, *i.e.,* testing of a food's nutritional components. Additionally, under the Food, Agriculture, Conservation, and Trade Act (1990 Farm Bill), FSIS accredits non-Federal laboratories, for a fee, to conduct testing for chemical residues on food (7 U.S.C. 138–138i).

FSIS's current regulations provide for accreditation of non-Federal laboratories to conduct only the chemical analysis of the nutritional components of and specific chemical residues in food. This limits the opportunities for industry to use analytical results from accredited non-Federal laboratories as part of their food safety systems in support of the Agency's food safety mission. FSIS is thus proposing to accredit non-Federal laboratories for microbiological testing,[3]

[1] The FSIS ALP Evaluation Report comparing samples using *z* scores and CUSUM statistics is available on the FSIS website at: *http://www.fsis.usda.gov/wps/wcm/connect.*

[2] Citation of 7 U.S.C. 1622(o) was inadvertently omitted from the regulations at 9 CFR part 439. FSIS proposes to add it to the regulations with this proposed rule.

[3] Like accreditation for food chemistry testing, this new accreditation for microbiological testing would be authorized by the AMA at 7 U.S.C.

Continued

in response to industry interest. In the future, these changes would potentially allow ALP-accredited laboratories that conduct process control laboratory testing, already done by regulated establishments to support their food safety systems, to include those results in future FSIS databases for Agency consideration in process performance categorizations. Participating laboratories that join the ALP as a result of this expansion would be required to participate in the program PT events and undergo on-site audits just as ALP-accredited laboratories currently do.

Request for Stakeholder Comments

The Agency is interested in comments concerning this proposal. The Agency specifically requests comments from regulated industry and non-Federal laboratories on (1) how to best manage data associated with an expanded ALP program, (2) any food matrix and analyte pairs they are interested in seeing offered in a possible expanded ALP accreditation program, (3) whether ISO 17025 accreditation should be a prerequisite to membership in the ALP since it is recognized as providing the general requirements for the competence of testing and calibration laboratories, and (4) ways to incentivize membership in the ALP, to include a possible annual fee reduction for laboratories already ISO 17025 accredited if not a requirement.

Additional Regulatory Changes

Most of the proposed changes to 9 CFR part 439 are associated with the removal of the ALP CUSUM statistics and expanding the program to include microbiological testing (*e.g.,* indicator organisms and foodborne pathogens). Expanding the program would potentially allow FSIS to include data from industry, in addition to data from official samples, for Agency consideration in assessing an establishment's process performance. The Agency is proposing to remove the ''official sample'' definition from the regulation because this will allow the Agency the flexibility to consider data from industry to assess process performance. The proposed changes also provide the flexibility to add matrices of interest to industry that are under FSIS jurisdiction, such as egg products, and would better align the program description and requirements with the way the program currently operates and with future program updates. A robust ALP can provide industry with additional accredited non-federal analytical laboratories to perform their testing in order to provide quality and reliable results to support their food safety systems. Other existing ALP requirements in 9 CFR part 439 for obtaining and maintaining accreditation, including education, experience, and legal requirements, would remain the same.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order (E.O.)13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Need for the Rule

According to Agency experts, there were approximately 55 food chemistry laboratories participating in the ALP in 2012. Since then, participation has declined to 38 laboratories in 2019. Of those laboratories, 29 were accredited for food chemistry, 13 for chemical residue chlorinated pesticides analysis, and 4 for chemical residue PCBs analysis. Participation in the ALP might be bolstered by expanding the ALP to include additional analytes, such as indicator organisms and foodborne pathogens. In addition, switching from the CUSUM PT sample scoring system currently used by the ALP to *z score*-based statistics should simplify the accreditation process for both the laboratories and the Agency.

Expected Industry Cost Savings

Although the proposed rule does not change the accreditation fee structure,[4] it would reduce the number of samples non-Federal food chemistry laboratories would have to analyze to attain and maintain food chemistry accreditation. Based on industry data, laboratories charge approximately $67 [5] per sample. Current criteria for obtaining accreditation (9 CFR 439.10(d)(2)(i)) require that laboratories analyze a set of 36 samples (9 CFR part 439.1 (k) ''Initial accreditation check sample'') for food chemistry to obtain initial accreditation or to remove probationary status in food chemistry. The estimated cost for analyzing the sample set (also known as qualification set) is approximately $2,412 (36 × $67 = $2,412). This number of samples is not necessary to statistically evaluate laboratory performance for admittance to the program. FSIS is proposing to permit the ALP to offer laboratories smaller sets for food chemistry accreditation. The smaller qualification sets would reduce costs for laboratories and still be large enough to evaluate laboratory performance. Agency experts provided an estimated cost of analysis of approximately $938 when using 14 samples per set (14 × $67 = $938), a reduction of $1,474 ($2,412 − $938 = $1,474) per qualification set for food chemistry. This analysis assumes that between 1 and 6 establishments would have to complete qualification sets in any given year.[6] The Agency seeks comment on this assumption. Based on this assumption the annual savings ranges from $1,474 (1 × $1,474) to $8,844 (6 × $1,474), with a mid-point of $5,159 (3.5 × $1,474).

Additionally, the proposed changes to the accreditation process (9 CFR 439.10(d)(4)(ii)) are expected to reduce industry costs. Current criteria state that if a laboratory's second set of qualification samples do not meet the criteria for obtaining accreditation, laboratories must submit a new application, all fees, and all documentation of corrective action required for accreditation. FSIS is proposing to no longer require food chemistry laboratories to reapply and pay the fees again before receiving the third qualification sample set. Instead, fees would be paid after the third set or if the initial accreditation process is not completed within eleven months. This is expected to reduce an applicable laboratory's accreditation cost between $2,100 and $5,000.

Regulatory Flexibility Analysis

The FSIS Administrator (Administrator) has made a preliminary determination that this proposed rule

1622(o). Notably, that provision directs and authorizes the Secretary to conduct any activities and provide any services (such as accreditation services) necessary to facilitate the marketing, distribution, processing, and utilization of agricultural products, including meat and poultry products.

[4] Fees and charges for laboratory accreditation are provided in 9 CFR 391.

[5] This cost is based on publicly listed industry prices provided by N.P Analytical Laboratories, *https://www.npal.com/#/Services/OurServices,* accessed on 1/9/2018.

[6] In 2016, there were 2 new applicants and 4 probation applicants, in 2017, there were no new applicants and 1 probation applicant.

would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). First, this rule's impact is limited to a small number of entities and participation in the program is voluntary. Second, while the proposed changes are expected to reduce accreditation costs, these cost savings are not anticipated to be significant and would apply to accredited laboratories regardless of size.

Executive Order 13771

Consistent with E.O. 13771 (82 *FR* 9339, February 3, 2017), we have estimated that this proposed rule would yield cost savings. Therefore, if finalized as proposed, this rule is expected to be an E.O. 13771 deregulatory action.

Paperwork Reduction Act

FSIS has reviewed this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and has determined that there is no new information collection related to this proposed rule. FSIS collects information for the ALP under OMB approval numbers 0583–0082 and 0583–0163.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this proposed regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410, *Fax:* (202) 690–7442, *Email: program.intake@usda.gov.*

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

List of Subjects in 9 CFR Part 439

Laboratories.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III by revising part 439 to read as follows:

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.

§ 439.1 Definitions.

(a) *Accredited Laboratory Program (ALP)*—The voluntary 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 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 FSIS 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) *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 proficiency testing samples. The ALP calculates and interprets *z* scores consistent with ISO 13528.

§ 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 a check, bank draft, or money order in the amount specified by FSIS as directed in 9 CFR 391.5, made payable to the U.S. Department of Agriculture, along with the completed application for the accreditation(s).

(c) 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 by check, bank draft, or money order made payable to 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 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 AOAC analytical test procedures are acceptable for use in this program. FSIS procedures may be found on the 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) 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) 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) *Accreditation.* 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) *Samples.* 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 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 ISO 13528, 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 and 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 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 ISO 13528, 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 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.

Paul Kiecker,

Administrator.

[FR Doc. 2020–27016 Filed 12–11–20; 8:45 am]

BILLING CODE 3410–DM–P

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 120 and 123

RIN 3245–AG98

Regulatory Reform Initiative: Streamlining and Modernizing the 7(a), Microloan, and 504 Loan Programs To Reduce Unnecessary Regulatory Burden

AGENCY: U.S. Small Business Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Small Business Administration (SBA) is proposing to remove or revise various regulations affecting its business loan programs because these regulations are obsolete, unnecessary, ineffective, or burdensome. In addition, one of the regulations that SBA is proposing to remove is cross-referenced in a regulation in SBA's Disaster Loan Program; SBA is proposing to make a conforming change to that regulation. SBA also is making several technical amendments to the regulations to incorporate recent statutory changes and other non-substantive changes. These changes are being proposed to carry out the mandate in various Executive Orders to reduce the number and costs of the regulations that Federal agencies impose on the public.

DATES: Comments are requested on or before February 12, 2021.

ADDRESSES: You may submit comments, identified by RIN 3245–AG98, using any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Search for the rule by RIN number 3245–AG98 and follow the instructions for submitting comments.

Mail: Linda Reilly, Chief, 504 Loan Program Division, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

SBA will post all comments on *http://www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *http://www.regulations.gov,* please submit the information to Linda Reilly, Chief, 504 Loan Program Division, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416. Highlight the information that you consider to be CBI and explain why you believe this information should be held confidential. SBA will review the information and make the final determination as to whether to publish the information.

FOR FURTHER INFORMATION CONTACT: Linda Reilly, Chief, 504 Loan Program Division, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416; phone: (202) 205–9949; email address: *linda.reilly@sba.gov.*

SUPPLEMENTARY INFORMATION:

A. General Information

The mission of SBA is to maintain and strengthen the Nation's economy by enabling the establishment and viability of small businesses, and by assisting in economic recovery of communities after disasters. In carrying out this mission, SBA has developed a regulatory policy that is implemented primarily through several core program offices: Office of Capital Access, Office of Disaster Assistance, Office of Entrepreneurial Development, Office of Government Contracting and Business Development, Office of International Trade, and Office of Investment and Innovation. SBA's regulations are codified at title 13 of the Code of Federal Regulations (CFR),