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

Animal and Plant Health Inspection Service

7 CFR Part 353

[Docket No. 95–071–1]

RIN 0579–AA75

Export Certification; Accreditation of Non-Government Facilities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the export certification regulations to provide for the establishment of a program under which non-government facilities could become accredited to perform specific laboratory testing or phytosanitary inspection services that could serve as the basis for the issuance of a Federal phytosanitary certificate, export certificate for processed plant products, or phytosanitary certificate for reexport. The accreditation criteria for particular laboratory testing and phytosanitary inspection services would be developed by the Animal and Plant Health Inspection Service in cooperation with other interested government, industry, academic, or research entities. Currently, only tests conducted by public laboratories or inspections carried out by Federal, State, or county inspectors or by agents may be used as the basis for the issuance of Federal certificates. The proposed accreditation program would provide a mechanism for qualified non-government facilities to become accredited to perform testing or inspection services that may be used as supporting documentation for the issuance of certificates for certain plants or plant products.

DATES: Consideration will be given only to comments received on or before January 26, 1998.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 95–071–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 95–071–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Mr. Narcy G. Klag, Operations Officer, Port Operations, PPQ, APHIS, 4700 River Road Unit 139, Riverdale, MD 20737–1236; (301) 734–8537.

SUPPLEMENTARY INFORMATION:

Background

The export certification regulations contained in 7 CFR part 353 (referred to below as the regulations) set forth the procedures for obtaining certification for plants and plant products offered for export or re-export. Export certification is not required by the regulations; rather, it is provided by the Animal and Plant Health Inspection Service (APHIS) as a service to exporters who are shipping plants or plant products to countries that require phytosanitary certification as a condition of entry. After assessing the condition of the plants or plant products intended for export, relative to the receiving country's regulations, an inspector will issue an internationally recognized phytosanitary certificate (PPQ Form 577), a phytosanitary certificate for reexport (PPQ Form 579), or an export certificate for processed plant products (PPQ Form 578), if warranted.

Since 1975, APHIS has participated with State governments in the Cooperative Phytosanitary Export Certification Program, which allows certain State officials, as well as APHIS officials, to issue phytosanitary certificates, phytosanitary certificates for reexport, or export certificates for processed plant products. Because the number of Federal inspectors is limited, the use of State and county inspectors is a considerable service to exporters of plants and plant products in terms of both time and convenience.

In a final rule published in the **Federal Register** on April 8, 1996 (61 FR 15365–15371, Docket No. 90–117–3), we amended the export certification regulations to, among other things: (1) Revise the requirements for a person to qualify as an inspector; (2) allow county-level plant regulatory officials, in addition to State and APHIS officials, to qualify as inspectors; (3) allow persons other than inspectors—those persons being referred to as ''agents''—to perform phytosanitary field inspections; and (4) provide for an industry-based certification, under certain conditions, of certain low-risk plant products such as kiln-dried lumber offered for export. Those amendments were intended, in part, to provide additional qualified personnel and export certification options in order to relieve some of the demands placed upon the existing pool of inspectors by increasingly stringent foreign import requirements and dwindling Federal and State budgets.

In this document, we are proposing to further broaden the options for inspection and export certification by establishing regulations under which non-government facilities such as commercial laboratories and private inspection services could become accredited by APHIS to perform specific laboratory testing or phytosanitary inspection services that could serve as the basis for the issuance of a Federal phytosanitary certificate, phytosanitary certificate for reexport, or export certificate for processed plant products. This proposed approach is consistent with current international trends toward industry self-certification and is based upon the recent efforts of a working group within the North Atlantic Plant Protection Organization (NAPPO) to draft standards for the accreditation of laboratories performing phytosanitary and other export certification activities to ensure compliance with import requirements for products moving into or within the regional territories of the NAPPO member countries (Canada, Mexico, and the United States).

The regulations proposed in this document would establish a means by which non-government facilities could be accredited by APHIS to perform certain functions related to phytosanitary export certification. It is important to note, however, that these proposed regulations would only establish a template upon which accreditation programs for specific functions could be developed—these proposed regulations would not establish specific accreditation

standards for, by way of example, a private laboratory seeking to be accredited to perform virus testing on plant material intended for export. Rather, specific accreditation standards would be developed as demand dictates. If, for example, a private laboratory wishes to perform virus testing on plant material intended for export, APHIS would work with that laboratory, and any other similarly situated laboratory, as well as with any other appropriate and interested government, industry, academic, or research entity, to identify and develop the appropriate specific standards against which the private laboratory's ability and competence to perform that virus testing could be judged. Once completed, those standards would be reviewed by APHIS and its cooperators and published in the **Federal Register** for comment. Once approved and published as a final rule, they would become the standard for the accreditation of non-government facilities to perform virus testing of plant material intended for export. Such standards would be published in 7 CFR part 353.

We believe that this proposed approach is beneficial in two ways: First, it would be difficult, if not impossible, for APHIS to develop a single, one-size-fits-all set of standards for the numerous disciplines that play a role in phytosanitary export certification. Secondly, the proposed approach would allow APHIS to develop specific standards with the participation of those best able to recommend valid scientific criteria, i.e., the government, academic, and private-sector individuals who have the experience and expertise in the particular area for which specific standards are being developed.

Proposed Regulations

To establish this proposed accreditation program, we would first amend § 353.1 to add a definition of *non-government facility*, which we would define as ''laboratory, research facility, inspection service, or other entity that is maintained, at least in part, for the purpose of providing laboratory testing or phytosanitary inspection services and that is not operated by the Federal Government or by the government of a State or a subdivision of a State.'' We believe that laboratories, research facilities, or inspection services are the types of entities most likely to seek accreditation under the proposed regulations. By excluding facilities operated by Federal, State, county, or local governments, the intent is that the accreditation program is to apply only to private entities. The involvement of government-run facilities in phytosanitary export certification is already covered under the current regulations in part 353; it is not our intent to require facilities operated by any level of Federal or State government to become accredited.

The regulations in § 353.7 currently state, with regard to the issuance of certificates, that the Administrator of APHIS may authorize inspectors to issue phytosanitary certificates, phytosanitary certificates for reexport, or export certificates for processed plant products on the basis of inspections made by cooperating Federal, State, and county agencies. Therefore, to accommodate the proposed accreditation program, we are proposing to amend paragraphs (a), (b), and (c) of § 353.7 to further provide that the Administrator may also authorize inspectors to issue those certificates on the basis of a laboratory test or an inspection conducted by a non-government facility that has been accredited in accordance with § 353.8, which is a new section that we would add to the regulations to spell out the specific provisions of the proposed accreditation program.

The proposed new § 353.8 would be divided into three main paragraphs: Paragraph (a) would serve to describe the accreditation program, paragraph (b) would set out the criteria for accreditation, and paragraph (c) would discuss the fees related to the accreditation program. These three paragraphs are discussed in greater detail below.

Paragraph (a) of proposed § 353.8 would begin by stating that the Administrator may accredit a non-government facility to perform specific laboratory testing or phytosanitary inspection services if the Administrator determines that the facility meets the criteria for accreditation found in paragraph (b). (Note: The term ''Administrator'' is used in this document, as it is used throughout APHIS' regulations, to mean the Administrator of APHIS or any person authorized to act for the Administrator.) A list of accredited non-government facilities could be obtained by writing to APHIS.

To determine whether or not a facility meets the criteria for accreditation, APHIS would conduct an assessment of the facility and its fitness to conduct the testing or inspection services for which it is seeking accreditation. A description of the assessment process is found below in the discussion of the criteria for accreditation.

Paragraph (a)(2) of proposed § 353.8 describes the conditions under which the Administrator could deny accreditation to a non-government facility or withdraw the accreditation that had been previously granted to a facility. Clearly, a facility would have to be able to meet and comply with the standards identified as being necessary for the accurate and reliable execution of the testing or inspection services for which it has been, or is seeking to be, accredited. Therefore, the proposed regulations would provide that the Administrator could deny accreditation to a facility that APHIS determines, through its pre-accreditation assessment, does not meet the criteria for accreditation and has failed to take the remedial action recommended to correct identified deficiencies. Similarly, the Administrator could withdraw the accreditation of an accredited facility if APHIS determined that the facility was not adhering to the criteria for the maintenance of accreditation and had failed to take the remedial action recommended to correct the identified deficiencies.

If APHIS denied a facility's application for accreditation, the operator of the facility would be informed of the reasons for the denial and would be afforded the opportunity to appeal the decision to the Administrator. To ensure that there would be an informed and timely review of the appeal, the operator's appeal would have to be in writing and submitted within 10 days after receiving notification of the denial and would have to include all of the facts and reasons upon which the operator was relying to show that the facility had been wrongfully denied accreditation. The Administrator would then grant or deny the operator's appeal in writing as promptly as circumstances permitted, with the response stating the reasons for his or her decision. If there was a conflict as to any material fact regarding the denial or the reasons for the denial, a hearing would be held to resolve the conflict under rules of practice adopted by the Administrator.

The withdrawal of a facility's accreditation would be handled in much the same way. The operator of the facility would be informed of the reasons for the proposed withdrawal before any action was taken and given the opportunity to appeal the proposed withdrawal. The appeal would have to be in writing and submitted to the Administrator within 10 days after the operator was informed of the reasons for the proposed withdrawal. The appeal would have to include all of the facts and reasons upon which the operator of the facility was relying to show that the reasons for the proposed withdrawal

were incorrect or did not support the withdrawal of the facility's accreditation. The Administrator would grant or deny the appeal in writing as promptly as circumstances permitted and would state the reason for his or her decision. If there was a conflict as to any material fact regarding the proposed withdrawal or the reasons for the proposed withdrawal, a hearing would be held to resolve the conflict under rules of practice adopted by the Administrator. However, the proposed regulations would provide that the withdrawal of a facility's accreditation could become effective before a final determination was made regarding an appeal if the Administrator determined that an immediate withdrawal was necessary to protect the public health, interest, or safety. In such a case, the withdrawal would be effective at the time APHIS notifies the operator of the facility either orally or in writing. In the event of an oral notification, a written confirmation would be given to the operator as promptly as circumstances allowed. The withdrawal would continue in effect pending the completion of the withdrawal and appeal proceedings, and any subsequent judicial review of those proceedings, unless the Administrator ordered otherwise.

The proposed regulations also would provide that the Administrator would withdraw a facility's accreditation if the operator of the facility informed APHIS in writing that the facility wished to terminate its accredited status.

We would allow a non-government facility that has had its application for accreditation denied or its accreditation withdrawn to reapply for accreditation using the same application procedures provided for first-time applicants. However, if the facility's accreditation had been denied or withdrawn because it failed to meet or comply with the standards for accreditation, we would require the facility operator to include written documentation with the application that specified what actions had been taken to correct the conditions that led to the denial or withdrawal of the facility's accreditation. It is likely that a pre-accreditation assessment of a reapplying facility would place added emphasis on those areas in which the facility had been deficient, so the documentation describing the actions taken to correct those deficiencies would be useful when determining the scope and design of the assessment.

Because a facility may need to disclose confidential business information to APHIS during the course of its pre-accreditation assessment or during the term of its accreditation, paragraph (a) of proposed § 353.8 would conclude by stating that all information gathered by APHIS during its accreditation-related activities would be treated with the appropriate level of confidentiality. As set forth in the U.S. Department of Agriculture's (USDA's) administrative regulations in 7 CFR 1.11, the USDA is responsible for making the final determination with regard to the disclosure or nondisclosure of information submitted by a business, but the policy of the USDA is to obtain and consider the views of the submitter of any privileged or confidential business information and to provide the submitter the opportunity to object to the disclosure of such information.

Pre-Accreditation Assessment

Paragraph (b) of proposed § 353.8 would set out the criteria for the achievement and retention of accreditation. The paragraph would begin by stating that specific standards for accreditation in a particular area of laboratory testing or phytosanitary inspection could be obtained by writing to APHIS. However, as discussed previously in this document, specific standards have not yet been developed for any area of accreditation. Rather, it is our intention that specific standards would be developed in the future on an ''as needed'' basis when a non-government facility informs APHIS that it would like to become accredited in a particular area of laboratory testing or phytosanitary inspection. Once standards in a particular area have been developed and adopted by APHIS, those standards would be available to non-government facilities that may wish to become similarly accredited.

Because accreditation standards under the proposed regulations would, at least initially, have to be drafted and adopted before the assessment process could begin, the proposed regulations would provide for APHIS' development of standards. Therefore, paragraph (b)(1) would state that if specific standards for accreditation in a particular area of laboratory testing or phytosanitary inspection had not been identified by APHIS, the Administrator would develop the appropriate specific standards applicable to accreditation in that particular area. The regulations would further provide that APHIS would place a notice in the **Federal Register** to inform the public of the opportunity to participate in the development of those standards by submitting suggested criteria or recommending particular considerations that may need to be addressed in the standards. This proposed approach would ensure that APHIS' resources are focused on those areas in which facilities are interested in obtaining accreditation and allow for standards to be prepared through a collaborative, cooperative process that provides for the participation of all interested parties, including the operator of the non-government facility seeking accreditation and any other interested governmental, industry, academic, or research entity.

Once accreditation standards are promulgated, the operator of a non-government facility seeking accreditation would begin the accreditation process by submitting an application to APHIS. The first items on the application would be the legal name and full address of the facility and the name, address, telephone number, and fax number of the operator of the facility or his or her authorized representative. These items would enable APHIS to identify the facility for its records and contact the facility's operator or an authorized representative as the pre-accreditation assessment process begins and during the term of the facility's accreditation.

The application would then have to contain a description of the facility itself. This information would enable APHIS to understand the nature of the facility, i.e., whether the facility is a stand-alone building or is located within a larger office or laboratory building, what the facility's primary function is and the scope of operations within the facility, and, if applicable, the relationship the facility has to a larger corporate entity. This type of information would give APHIS a frame of reference as it considers the suitability of the facility for the type of work it is seeking to perform under the accreditation program and would provide a starting point for the design of a pre-accreditation assessment. The application would conclude with a description of the specific laboratory testing or phytosanitary inspection services for which the facility is seeking accreditation. The completed application would then have to be signed by the operator of the facility or his or her authorized representative.

After it had received the completed application, APHIS would review the application to identify the scope of the assessment that would be necessary to adequately review the facility's fitness to conduct the laboratory testing or phytosanitary inspection services for which it is seeking accreditation. Through that review, APHIS would determine the number of assessors needed for an assessment team, the fields of expertise that should be

represented on the team, and the means by which the facility's competence to conduct the applicable laboratory tests or phytosanitary inspections could be evaluated.

Once the scope of the assessment has been defined, APHIS could identify the individuals who would comprise the assessment team, determine the materials that would be needed for the assessment, and project the length of the assessment process, which would allow APHIS to develop an estimate of the expenses that would be incurred by the government in the course of the pre-accreditation assessment process. Those expenses would have to be reimbursed by the facility seeking accreditation, so APHIS would provide the estimate to the operator of the facility before embarking upon any activities that would result in costs being incurred.

Before the assessment of a facility could begin, the operator of the facility would have to agree, in writing, to allow the assessment team access to its facilities, supply the team with the information it needs to evaluate the facility, and to enter into a trust fund agreement with APHIS to pay the assessment fee regardless of the assessment's outcome (i.e., even if the assessment team recommends that the facility not be accredited), and, if accreditation is granted, to pay the charges related to the subsequent maintenance of the facility's accreditation, such as laboratory fees for the corroboration of check tests. (The specific provisions of the trust fund agreement are explained below under ''Fees and Trust Fund Agreement.'') Once the operator of the facility had agreed, in writing, to these terms, APHIS would assemble the assessment team and commence the assessment as soon as circumstances permitted.

The assessment itself would focus on four major areas: Physical plant, equipment, methods of testing or inspection, and personnel. The assessment team would compare the facility's performance in those areas against the specific accreditation standards that had been identified for the particular laboratory testing or phytosanitary inspection services for which the facility was seeking accreditation. The four areas are explained in greater detail below.

Physical Plant

The facility's physical plant would have to meet the criteria identified in the accreditation standards as necessary to properly conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation. For example, a facility that wished to be accredited to perform laboratory testing would have to have adequate laboratory space in which to perform the testing, storage space for holding samples and supplies, and office space for preparing reports and other documentation.

Equipment

The assessment team would determine whether the facility's personnel had unrestricted access to the equipment identified in the accreditation standards as necessary to properly conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation. To continue with the example in the previous paragraph, a facility seeking accreditation for laboratory testing would have to have the microscopes, computers, scales, analyzers, etc. that would be necessary for the facility to properly conduct that laboratory testing. The assessment team would also verify, where appropriate, that calibration and monitoring of the required equipment is documented and conforms to prescribed standards.

Methods of Testing or Inspection

To ensure that the facility was employing scientifically valid and up-to-date methodology to conduct its laboratory testing or phytosanitary inspection activities, the assessment team would review the facility's quality manual or other equivalent documentation that described the system in place at the facility for the conduct of the laboratory testing or phytosanitary inspection services for which the facility seeks accreditation. The assessors would verify that the manual was available to, and in use by, the facility personnel who perform the services and that the methods and procedures described in the manual were equal to those identified in the accreditation standards.

Personnel

The assessment team would also review the qualifications of the facility's personnel, both management and staff, who were responsible for the testing or inspection services for which the facility was seeking accreditation. Those personnel, who would have to be identified to the assessment team, would have to possess the training, education, or experience identified in the accreditation standards as necessary to properly conduct the testing or inspection services for which the facility was seeking accreditation, and that training, education, or experience would have to be documented. If the particular accreditation standards under which the facility was being reviewed allowed for the use of subcontractors, the assessment team would also review the qualifications of any subcontractors used by the facility in connection with its laboratory testing or phytosanitary inspection activities.

Retaining Accreditation

Once accredited, the non-government facility would have to observe several conditions to maintain its accreditation. First, the facility would have to continue to observe the specific standards applicable to its area of accreditation, i.e., the standards by which it was judged in its initial, pre-accreditation assessment. To give APHIS the ability to monitor the facility's compliance with those standards, the facility would have to agree to be assessed and evaluated on a periodic basis through proficiency tests or check samples and be able to demonstrate on request that it is able to perform the tests or inspection services for which it was accredited. If, in the course of an assessment or evaluation, APHIS identifies any deficiencies in the facility or in its conduct of testing or inspection activities, the operator of the facility would have to ensure that those deficiencies are resolved.

Because the facility's accreditation would have been based largely on APHIS' review and acceptance of specific elements in place at the facility at the time of the assessment, we would require that the facility notify APHIS when those elements changed. Specifically, we would require that the operator of the facility notify APHIS when there are any changes in key management personnel or facility staff accountable for the testing or inspection services for which the facility has been accredited. We would also require the operator of the facility to report any changes involving the location, ownership, physical plant, equipment, or other conditions that existed at the facility at the time accreditation was granted.

Fees and Trust Fund Agreement

To cover the costs of APHIS' involvement in the assessment process, the operator of the facility seeking accreditation would have to enter into a trust fund agreement with APHIS. Under the agreement, the operator of the facility would pay in advance all estimated costs that APHIS expected to incur through its involvement in the pre-accreditation assessment process and the maintenance of the facility's accreditation. Those costs would include administrative expenses incurred in those activities, such as laboratory fees for evaluating check test

results, and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by the APHIS in performing those activities. The agreement would require the operator of the facility to deposit a certified or cashier's check with APHIS for the amount of the costs, as estimated by APHIS. If the deposit was not sufficient to meet all costs incurred by APHIS, the agreement would further require the operator of the facility to deposit another certified or cashier's check with APHIS for the amount of the remaining costs, as determined by APHIS, before APHIS' services would be completed. After a final audit at the conclusion of the pre-accreditation assessment, any overpayment of funds would be returned to the operator of the facility or held on account until needed for future activities related to the maintenance of the facility's accreditation.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

This proposed rule would amend the export certification regulations to provide for the establishment of a program under which non-government facilities could become accredited to perform specific laboratory testing or phytosanitary inspection services that could serve as the basis for the issuance of Federal phytosanitary certificates, phytosanitary certificates for reexport, or an export certificates for processed plant products. The accreditation criteria for particular laboratory testing and phytosanitary inspection services would be developed by APHIS with the participation of other interested governmental, industry, academic, or research entities. Currently, only tests conducted by public laboratories or inspections carried out by Federal, State, or county inspectors or by agents may be used as the basis for the issuance of a Federal certificate. The proposed accreditation program would provide a mechanism for qualified non-government facilities to become accredited to perform the testing or inspection services that may be used as supporting documentation for the issuance of Federal certificates for the export or reexport of certain plants or plant products.

The regulations proposed in this document are intended only to provide a framework upon which accreditation programs for specific functions could be established, so they would not, in and of themselves, entail any costs to APHIS or any non-government facility. However, any specific accreditation program that would be established under these proposed regulations would entail costs to both the entities being accredited and the accrediting body, i.e., APHIS. Because the accreditation program is expected to be self-supporting, the costs to APHIS would be recouped through accreditation fees. The fees charged by APHIS in connection with the initial accreditation of a non-government facility and the maintenance of that accreditation would, therefore, have to be adequate to recover the costs incurred by the government in the course of APHIS' accreditation activities. We expect that the costs that would have to be reimbursed would be largely attributable to the cost of transportation for the assessors to travel to the site of the facility, lodging for the assessors, their salary and per diem, any laboratory fees charged for evaluating check test results, and administrative expenses. Costs for specific accreditation programs would vary depending on the range of activities for which a facility was seeking accreditation, the number of assessors needed to adequately conduct a pre-accreditation assessment, the type and number of any proficiency tests that would have to be conducted, and the frequency with which post-accreditation evaluation activities such as check tests and site visits would have to be conducted.

The proposed regulations would stipulate that APHIS would provide an estimate of its anticipated fees to the operator of the facility prior to undertaking any activities that would result in fees being charged to a facility. Participation in any accreditation program developed under these proposed regulations would be voluntary. At this time, we estimate that 15 individual non-government facilities would be likely to seek and maintain accreditation annually on about 82 accredited procedures, as long as the costs of participating in an accreditation program are lower than the benefits they receive from the program. As a result, this program would have to meet the test of the marketplace.

The domestic seed industry, through the American Seed Trade Association, has indicated its interest in establishing an accreditation program for seed health testing and field inspection of seed, so we have used the domestic seed industry to illustrate the potential benefits that could result from the establishment of specific accreditation programs.

The seed industry would likely benefit from the establishment of an accreditation program because domestic seed exporters routinely require the services of inspectors and agents in order to obtain the phytosanitary certification required by most, if not all, importing countries; the benefits would be realized in terms of more timely certifications, which in turn could lead to reduced costs as well as increased U.S. exports.

The value of seed exported from the United States to other countries continues to grow rapidly, from $665 million in 1994–95 (July to June), to $705 million in 1995–96, to more than $800 million projected for 1996–97. There has been a concomitant rise in demand for laboratory testing and phytosanitary inspection services to meet other countries' import requirements. The ability of Federal, State, and county testing and inspection services to meet this growing demand will be increasingly strained. Already there are instances in which the accreditation of non-government facilities would have prevented the loss of export sales.

For example, some seed export opportunities have been forfeited because the results of pre-harvest field inspections are usually not known until after harvest. It is common for seed from several fields to be blended before shipment. If the sample from one field is subsequently reported to contain an actionable pest, then none of the blended seed—which may have been harvested from as many as eight or nine fields—could be exported. In one case in which this occurred, the affected seed company lost foreign sales worth $250,000. Such losses would be much less likely to occur if there were more timely reporting of pre-harvest inspections; accredited non-government inspection facilities could make timely reporting a reality. In general, non-government testing and inspection services could be expected to be completed with minimal delay, leading to greater marketing flexibility and lower risk of lost sales.

Additional benefits, of even greater potential significance, would be gained through the standardization of testing and inspection protocols that would result from the establishment of accreditation standards, particularly when internationally recognized standards are used. Major seed trading partners of the United States, such as

Canada, France, and The Netherlands, have national seed health organizations that address seed health issues in part by employing laboratory accreditation protocols. The standards that would underlie accreditation of non-government facilities in the United States could help lead to the removal of discrepancies among foreign phytosanitary regulations, thereby expediting U.S. seed exports.

Accreditation of non-government facilities, by promoting more streamlined exports based on internationally recognized standards, could be expected to benefit other export sales besides those of the seed industry. As a self-supporting system, private firms that expect benefits in excess of costs of accreditation would participate. In addition to the net benefits received by these firms directly, society as a whole would benefit from enhanced trade.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 95–071–1. Please send a copy of your comments to: (1) Docket No. 95–071–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OIRM, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would provide for the establishment of a program under which non-government facilities could become accredited to perform specific laboratory testing or phytosanitary inspection services that could serve as the basis for the issuance of a Federal phytosanitary certificate, export certificate for processed plant products, or phytosanitary certificate for reexport. This proposed accreditation program would provide a mechanism for qualified non-government facilities to become accredited to perform testing or inspection services that may be used as supporting documentation for the issuance of certificates for certain plants or plant products.

Launching this accreditation program would necessitate that APHIS use a number of information collection activities to ensure that non-government facilities participating or seeking to participate in the program possess the necessary qualifications. Therefore, we are seeking OMB approval to employ the following information collection activities in connection with the APHIS export certification program:

Application for accreditation: The operator of a non-government facility who wishes to be accredited in a particular area of laboratory testing or phytosanitary inspection must submit an application to APHIS. The application must contain the legal name and full address of the facility; the name, address, telephone, and fax number of the facility's operator; a description of the facility; and a description of the specific laboratory testing or phytosanitary inspection services for which the facility is seeking accreditation.

Agreement to fulfill accreditation procedure: Before APHIS will assess a non-government facility to determine whether it meets the standards for accreditation, the operator of the facility must sign an agreement with APHIS. Specifically, the operator must agree to supply any information needed for the evaluation of the facility, pay the fees charged for the assessment, and accept the charges related to the subsequent maintenance of the facility's accreditation.

Documentation of equipment: The equipment used in the non-government facility (microscopes, computers, etc.) must be calibrated and monitored to ensure that it conforms to the standards for accreditation. This calibration and monitoring must be documented by facility personnel.

Quality manual or equivalent documentation: The operator of a non-government facility is responsible for maintaining a quality manual or similar documentation at the facility that describes the system in place for conducting the laboratory testing or phytosanitary inspection services for which the faculty is accredited. The manual must be available to and used by facility personnel performing the work.

Identity of personnel and subcontractor's qualifications: The personnel employed at the non-government facility must be identified and possess the training, education, or experience necessary to perform the laboratory testing or phytosanitary inspection services for which the facility is accredited. The operator of the facility is responsible for acquiring and maintaining documentation concerning the training, education, and experience of facility personnel. If the non-government facility uses a subcontractor to perform some of its testing or inspection services, the qualifications of the subcontractor must be documented and made available to APHIS. The facility operator is responsible for acquiring and maintaining this documentation.

Notification of changes in personnel: The facility operator must notify APHIS whenever the facility undergoes any change in personnel. This notification may be written, communicated via telephone, or by any other means of communication convenient to the facility's operator.

Report changes in location or ownership: The facility operator must notify APHIS if the facility moves its operations to a new location, undergoes an ownership change, replaces equipment, or experiences any other changes in the conditions that existed at the time the facility received its accreditation. This notification may be written, communicated via telephone, or by any other means of communication convenient to the facility's operator.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. We need this outside input to help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's

functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 3.609 hours per response.

Respondents: Operators of non-government facilities who wish to be accredited to perform laboratory testing or phytosanitary inspection services in connection with APHIS' export certification program and certain employees of such non-government facilities.

Estimated number of respondents: 15.

Estimated number of responses per respondent: 5.466.

Estimated annual number of responses: 82.

Estimated total annual burden on respondents: 296 hours.

Copies of this information collection can be obtained from Clearance Officer, OIRM, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects in 7 CFR Part 353

Exports, Plant diseases and pests, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 353 would be amended as follows:

PART 353—EXPORT CERTIFICATION

1. The authority citation for part 353 would continue to read as follows:

Authority: 7 U.S.C. 147a; 21 U.S.C. 136 and 136a; 44 U.S.C. 35; 7 CFR 2.22, 2.80, and 371.2(c).

2. In § 353.1, a definition of *non-government facility* would be added, in alphabetical order, to read as follows:

§ 353.1 Definitions.

* * * * *

Non-government facility. A laboratory, research facility, inspection service, or other entity that is maintained, at least in part, for the purpose of providing laboratory testing or phytosanitary inspection services and that is not operated by the Federal Government or by the government of a State or a subdivision of a State.

* * * * *

3. In § 353.7, paragraphs (a)(4), (b)(4), and (c)(4) would each be amended by adding a new sentence at the end of each paragraph to read as follows:

§ 353.7 Certificates.

(a) * * *

(4) * * * The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

* * * * *

(b) * * *

(4) * * * The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

* * * * *

(c) * * *

(4) * * * The Administrator may also authorize inspectors to issue a certificate on the basis of laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

* * * * *

4. A new § 353.8 would be added to read as follows:

§ 353.8 Accreditation of non-government facilities.

(a) The Administrator may accredit a non-government facility to perform specific laboratory testing or phytosanitary inspection services if the Administrator determines that the non-government facility meets the criteria of paragraph (b) of this section.[1]

(1) A non-government facility's compliance with the criteria of paragraph (b) of this section shall be determined through an assessment of the facility and its fitness to conduct the laboratory testing or phytosanitary inspection services for which it seeks to be accredited. If, after evaluating the results of the assessment, the Administrator determines that the facility meets the accreditation criteria, the facility's application for accreditation will be approved.

(2) The Administrator may deny accreditation to, or withdraw the accreditation of, any non-government facility to conduct laboratory testing or phytosanitary inspection services upon a determination that the facility does not meet the criteria for accreditation or maintenance of accreditation under paragraph (b) of this section and has failed to take the remedial action recommended to correct identified deficiencies.

(i) In the case of a denial, the operator of the facility will be informed of the reasons for the denial and may appeal the decision in writing to the Administrator within 10 days after receiving notification of the denial. The appeal must include all of the facts and reasons upon which the person relies to show that the facility was wrongfully denied accreditation. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(ii) In the case of withdrawal, before such action is taken, the operator of the facility will be informed of the reasons for the proposed withdrawal. The operator of the facility may appeal the proposed withdrawal in writing to the Administrator within 10 days after being informed of the reasons for the proposed withdrawal. The appeal must include all of the facts and reasons upon which the person relies to show that the reasons for the proposed withdrawal are incorrect or do not support the withdrawal of the accreditation of the facility. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator. However, withdrawal shall become effective pending final determination in the proceeding when the Administrator determines that such action is necessary to protect the public health, interest, or safety. Such withdrawal will be effective upon oral or written notification, whichever is earlier, to the operator of the facility. In the event of oral notification, written

[1] A list of accredited non-government facilities may be obtained by writing to Port Operations, PPQ, APHIS, 4700 River Road Unit 139, Riverdale, MD 20737–1236.

confirmation will be given as promptly as circumstances allow. This withdrawal will continue in effect pending the completion of the proceeding, and any judicial review thereof, unless otherwise ordered by the Administrator.

(3) The Administrator will withdraw the accreditation of a non-government facility if the operator of the facility informs APHIS in writing that the facility wishes to terminate its accredited status.

(4) A non-government facility whose accreditation has been denied or withdrawn may reapply for accreditation using the application procedures in paragraph (b) of this section. If the facility's accreditation was denied or withdrawn under the provisions of paragraph (a)(2) of this section, the facility operator must include with the application written documentation specifying what actions have been taken to correct the conditions that led to the denial or withdrawal of accreditation.

(5) All information gathered during the course of a non-government facility's assessment and during the term of its accreditation will be treated by APHIS with the appropriate level of confidentiality, as set forth in the U.S. Department of Agriculture's administrative regulations in § 1.11 of this title.

(b) *Criteria for accreditation of non-government facilities.* (1) Specific standards for accreditation in a particular area of laboratory testing or phytosanitary inspection are set forth in this part and may be obtained by writing to APHIS. If specific standards for accreditation in a particular area of laboratory testing or phytosanitary inspection have not been promulgated by APHIS, the Administrator will develop appropriate standards applicable to accreditation in the area for which the non-government facility is seeking accreditation and publish a notice of proposed rulemaking in the **Federal Register** to inform the public and other interested persons of the opportunity to comment on and participate in the development of those standards.

(2) The operator of a non-government facility seeking accreditation to conduct laboratory testing or phytosanitary inspection shall submit an application to the Administrator. The application must be completed and signed by the operator of the facility or his or her authorized representative and must contain the following:

(i) Legal name and full address of the facility;

(ii) Name, address, and telephone and fax number of the operator of the facility or his or her authorized representative;

(iii) A description of the facility, including its physical plant, primary function, scope of operation, and, if applicable, its relationship to a larger corporate entity; and

(iv) A description of the specific laboratory testing or phytosanitary inspection services for which the facility is seeking accreditation.

(3) Upon receipt of the application, APHIS will review the application to identify the scope of the assessment that will be required to adequately review the facility's fitness to conduct the laboratory testing or phytosanitary inspection services for which it is seeking accreditation. Before the assessment of the facility begins, the applicant's representative must agree, in writing, to fulfill the accreditation procedure, especially to receive the assessment team, to supply any information needed for the evaluation of the facility, and to enter into a trust fund agreement as provided by paragraph (c) of this section to pay the fees charged to the applicant facility regardless of the result of the assessment and to pay the charges of subsequent maintenance of the accreditation of the facility. Once the agreement has been signed, APHIS will assemble an assessment team and commence the assessment as soon as circumstances permit. The assessment team will measure the facility's fitness to conduct the laboratory testing or phytosanitary inspection services for which it is seeking accreditation against the specific standards identified by the Administrator for those services by reviewing the facility in the following areas:

(i) *Physical plant.* The facility's physical plant (e.g., laboratory space, office space, greenhouses, vehicles, etc.) must meet the criteria identified in the accreditation standards as necessary to properly conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation.

(ii) *Equipment.* The facility's personnel must possess or have unrestricted access to the equipment (e.g., microscopes, computers, scales, triers, etc.) identified in the accreditation standards as necessary to properly conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation. The calibration and monitoring of that equipment must be documented and conform to prescribed standards.

(iii) *Methods of testing or inspection.* The facility must have a quality manual or equivalent documentation that describes the system in place at the facility for the conduct of the laboratory testing or phytosanitary inspection services for which the facility seeks accreditation. The manual must be available to, and in use by, the facility personnel who perform the services. The methods and procedures used by the facility to conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation must be commensurate with those identified in the accreditation standards and must be consistent with or equivalent to recognized international standards for such testing or inspection.

(iv) *Personnel.* The management and facility personnel accountable for the laboratory testing or phytosanitary inspection services for which the facility is seeking accreditation must be identified and must possess the training, education, or experience identified in the accreditation standards as necessary to properly conduct the testing or inspection services for which the facility seeks accreditation, and that training, education, or experience must be documented. Any subcontractor utilized by the facility in connection with the testing or inspection services for which accreditation is sought must be identified to APHIS; the subcontractor's qualifications will be reviewed by APHIS as part of the facility's assessment.

(4) To retain accreditation, the facility must agree to:

(i) Observe the specific standards applicable to its area of accreditation;

(ii) Be assessed and evaluated on a periodic basis by means of proficiency testing or check samples;

(iii) Demonstrate on request that it is able to perform the tests or inspection services representative of those for which it is accredited;

(iv) Resolve all identified deficiencies;

(v) Notify APHIS as soon as circumstances permit of any changes in key management personnel or facility staff accountable for the laboratory testing or phytosanitary inspection services for which the facility is accredited; and

(vi) Report to APHIS as soon as circumstances permit any changes involving the location, ownership, physical plant, equipment, or other conditions that existed at the facility at the time accreditation was granted.

(c) *Fees and trust fund agreement.* The fees charged by APHIS in connection with the initial accreditation of a non-government facility and the maintenance of that accreditation shall be adequate to recover the costs incurred by the government in the course of APHIS' accreditation

activities. To cover those costs, the operator of the facility seeking accreditation must enter into a trust fund agreement with APHIS under which the operator of the facility will pay in advance all estimated costs that APHIS expects to incur through its involvement in the pre-accreditation assessment process and the maintenance of the facility's accreditation. Those costs shall include administrative expenses incurred in those activities, such as laboratory fees for evaluating check test results, and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by the APHIS in performing those activities. The operator of the facility must deposit a certified or cashier's check with APHIS for the amount of the costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the operator of the facility must deposit another certified or cashier's check with APHIS for the amount of the remaining costs, as determined by APHIS, before APHIS' services will be completed. After a final audit at the conclusion of the pre-accreditation assessment, any overpayment of funds will be returned to the operator of the facility or held on account until needed for future activities related to the maintenance of the facility's accreditation.

Done in Washington, DC, this 19th day of November 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–30944 Filed 11–24–97; 8:45 am]

BILLING CODE 3410–34–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 123

Disaster Loan Program

AGENCY: Small Business Administration (SBA).

ACTION: Proposed rule.

SUMMARY: Under this proposed rule, an SBA disaster loan borrower could request an increase in a disaster loan within two years after the loan was approved. The increase must be used to cover eligible damages resulting from events that occurred after the loan was approved and were beyond the borrower's control. Under the proposed rule, the SBA Associate Administrator for Disaster Assistance could waive the two year limit because of extraordinary circumstances.

DATES: Comments must be submitted on or before December 26, 1997.

ADDRESSES: Comments should be mailed to Bernard Kulik, Associate Administrator for Disaster Assistance, Small Business Administration, 409 Third Street, S.W., Washington, D.C. 20416.

FOR FURTHER INFORMATION CONTACT: Bernard Kulik, 202/205–6734.

SUPPLEMENTARY INFORMATION: SBA makes thousands of physical and economic injury disaster loans to repair or replace damaged property or to help a business recover from economic injury. Borrowers must use such loans only to help them recover from the effects of a specific disaster. Borrowers may request increases in their loans after the initial disaster loans were made and, where appropriate, SBA will approve the request. Under this proposed rule, SBA is defining the circumstances under which a borrower can request an increase and limiting the time period for the request to two years. The SBA Associate Administrator for Disaster Assistance (AA/DA) would have the authority to waive the two year limit for extraordinary and unforeseeable circumstances.

Under the proposed rule, a borrower of a disaster loan (whether physical or economic injury) could request an increase in the loan amount if the eligible cost of repair or replacement of damages increases because of events occurring after the loan approval that were beyond the borrower's control. For example, a borrower can request an increase of a physical disaster loan before the repair, renovation or reconstruction is completed if hidden damage is discovered or if official building codes changed since SBA approved the physical disaster loan. With respect to economic injury disaster loans, borrowers could request an increase in working capital if they could not resume business activity as quickly as planned because of events beyond their control. These examples, while not all inclusive, would support a borrower's request for an increase in the amount of a disaster loan. These kinds of events usually will be apparent within two years after SBA approves a disaster loan. However, in extraordinary circumstances, the proposed rule would permit the AA/DA to waive the two year limitation.

Compliance With Executive Orders 12612, 12778, and 12866, the Regulatory Flexibility Act (5 U.S.C. 601, et seq.), and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

SBA certifies that this proposed rule does not constitute a significant rule within the meaning of Executive Order 12866 and will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* It is not likely to have an annual economic effect of $100 million or more on the economy, result in a major increase in costs or prices, or have a significant adverse effect on competition or the United States economy.

For purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA certifies that this proposed rule contains no new reporting or recordkeeping requirements.

For purposes of Executive Order 12612, SBA certifies that this proposed rule has no federalism implications warranting the preparation of a Federalism Assessment.

For purposes of Executive Order 12778, SBA certifies that this rule is drafted, to the extent practicable, in accordance with the standards set forth in section 2 of that Order.

(Catalog of Federal Domestic Assistance Programs, No. 59.012 and 59.008)

List of Subjects in 13 CFR Part 123

Disaster assistance, Loan programs-business, Small Businesses.

Accordingly, pursuant to the authority contained in section 5(b)(6) of the Small Business Act (15 U.S.C. 634(b)(6)), SBA proposes to amend part 123, chapter I, title 13, Code of Federal Regulations, as follows:

PART 123—DISASTER LOAN ASSISTANCE

1. The authority citation for Part 123 would continue to read as follows:

Authority: 15 U.S.C. 634(b)(6), 636(b), 636(c) and 636(f); Pub. L. 102–395, 106 Stat. 1828, 1864; and Pub. L. 103–75, 107 Stat. 739.

2. Sections 123.18, 123.19 and 123.20 would be added to read as follows:

§ 123.18 Can I request an increase in the amount of a physical disaster loan?

SBA will consider your request for an increase in your loan if you can show that the eligible cost of repair or replacement of damages increased because of events occurring after the loan approval that were beyond your control. An eligible cost is one which is