PART 90—INTRODUCTION

Subpart A—Scope of Subchapter

Sec.
90.1 General.

Subpart B—Subchapter Definitions

90.2 General terms defined.

Subpart C—Good Laboratory Practices for Commodity Laboratory Analyses

90.3 General.
90.4–90.100 [Reserved]

Subpart D—Quality Assurance

90.101 General.
90.102 Quality assurance review.
90.103 Maintenance of quality control records.
90.104–90.200 [Reserved]


SOURCE: 58 FR 42414, Aug. 9, 1993, unless otherwise noted.

Subpart A—Scope of Subchapter

§ 90.1 General.

This subchapter sets forth the functions and responsibilities of the Science and Technology (S&T) of the Agricultural Marketing Service (AMS) relating to:

(a) The performance of comprehensive analytical tests and laboratory determinations of agricultural commodities and processed products.

(b) The conduct of experiments and collaborative studies to validate new analytical procedures and improved methodologies in order to promote faster, more precise, or safer laboratory testing for agricultural commodities and processed products.

(c) The supervised issuance of external quality control or proficiency check samples to laboratories under the Science and Technology’s direction or performance review in order to regularly spot check and assess that analytical or test data produced by each laboratory is reproducible, precise, and reliable for a specific test program.

(d) The granting of laboratory program accreditation or certification or approval for specialty testing of agricultural commodities and products.

(e) The licensing of chemists to analyze cottonseed in order to certify its quality and grade.

(f) The granting of certification to non-federal laboratories for testing for trichinae in horsemeat for export to the European Community (EC).

(g) The granting of acceptance of standardized methodology or new procedures for commodity testing.

(h) The auditing of the facilities, equipment, quality control procedures, standard methodologies, and good laboratory practices for a commodity testing program of a laboratory.

(i) The examination of plants for novelty and distinctiveness in order to grant certificates of protection for new varieties of sexually reproduced plants, and the provision of other fee based services authorized by the Plant Variety Protection Act.

(j) The extension or coordination of research for the determination of a new chemical analyte or microorganism in a commodity product or food.

(k) The analysis of imported flue-cured and burley tobacco for pesticide residues.

(l) The supervision and implementation of the State enforcement of the recordkeeping requirements for private applicators of restricted-use pesticides for agricultural production.


Subpart B—Subchapter Definitions

§ 90.2 General terms defined.

Words used in the regulations in this subchapter in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this subchapter and unless the context requires otherwise, the following terms will be construed to mean:
Agicultural Marketing Service, USDA § 90.102


Administrator. The Administrator of the Agricultural Marketing Service, or any officer or employee of the Service, to whom authority has been delegated, or to whom authority may be delegated, to act in his or her stead.

Cooperative agreement. An agreement between the Agricultural Marketing Service and another Federal agency or a State agency, or other agency, organization or person that defines in the general terms the basis on which the parties concerned will cooperate to serve a mutual interest on an agricultural service project. The responsibilities for AMS and each cooperator are stated in the document along with the conditions as applicable.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator of the Science and Technology program of the Agricultural Marketing Service agency, or any officer or employee of this agency to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act.

Laboratories. Science and Technology laboratories performing the official analyses described in this subchapter.

Program. The Science and Technology (S&T) program of the Agricultural Marketing Service (AMS) which performs official analytical testing services, issues licenses for cottonseed chemists, and conducts quality assurance reviews and grants accreditation or certification for commodity testing programs of laboratories.

Quality assurance. The assurance that there is accuracy of analytical data using proficiency check sample or analyte recovery techniques. In addition, the certainty that there is strict adherence by the analysts in following the quality control details in the recommended or official methods for reagents, laboratory apparatus and procedures. The overall objective of quality assurance, as a comprehensive program, is to ensure that all analytical data produced by the laboratory meets certain quality criteria and that all data produced is reproducible, precise, and accurate.

Quality control. The system of close examination of the critical details of an analytical procedure in order to have the proper equipment parameters, techniques, supplies and reagents to achieve a predetermined level of quality data, with the performance of a particular laboratory analysis.

Secretary. The Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his or her stead.

Service. The Agricultural Marketing Service of the United States Department of Agriculture.

Subpart C—Good Laboratory Practices for Commodity Laboratory Analyses

§ 90.4–90.100 [Reserved]

Subpart D—Quality Assurance

§ 90.101 General.

Laboratory service programs of laboratories certified and approved by the Science and Technology shall have good laboratory practice (GLP) requirements that are generalized in this subpart.

§§ 90.4–90.100 [Reserved]

§ 90.102 Quality assurance review.

(a) Each laboratory performing tests and analysis under this subchapter will be subject to a quality assurance program evaluation at least annually, and
§ 90.103 Maintenance of quality control records.

Quality control records pertaining, but not limited to the following areas, shall be retained by the laboratory for at least the 3 most recent years:

(a) Prepared solution standardizations;
(b) Recovery studies by known analyte additions;
(c) The purity checks of reagents and test materials;
(d) Apparatus and equipment calibrations;
(e) The quality examination and testing of materials;
(f) The mandatory participation in proficiency check sample testing or collaborative studies;
(g) Daily critical parameter checks of equipment, such as temperature readings;
(h) The equivalency tests of new procedures with standard methodologies.

§ 90.104–90.200 [Reserved]

PART 91—SERVICES AND GENERAL INFORMATION

Subpart A—Administration

Sec.
91.1 General.
91.2 Definitions.
91.3 Authority.

Subpart B—General Services

91.4 Kinds of services.
91.5 Where services are offered.
91.6 Availability of services.

Subpart C—Application for Services

91.7 Nondiscrimination.
91.8 Who may apply.
91.9 Who may apply.
91.10 Information required in connection with an application.
91.11 Filing of an application.
91.12 Record of filing time and laboratory tests.
91.13 When an application may be rejected.
91.14 When an application may be withdrawn.

Subpart D—Laboratory Service

91.15 Basis of a laboratory service.
91.16 Order of a laboratory service.
91.17 Postponing a laboratory service.
91.18 Financial interest of a scientist.

Subpart E—Samples

91.19 General requirements of suitable samples.
91.20 Shipping.
91.21 Protecting samples.
91.22 Disposition of analyzed sample.

Subpart F—Method Manuals

91.23 Analytical methods.

Subpart G—Reporting

91.24 Reports of test results.
91.25 Certificate requirements.
91.26 Issuance of certificates.
91.27 Corrections to certificates prior to issuance.
91.28 Issuance of corrected certificates or amendments for analysis reports.
91.29 Issuance of duplicate certificates or reissuance of an analysis report.
91.30 Maintenance and retention of copies of certificates or analysis reports.
Agricultural Marketing Service, USDA

Subpart H—Appeal of Laboratory Services

91.31 When an appeal of a laboratory service may be requested.
91.32 Where to file for an appeal of a laboratory service and information required.
91.33 When an application for an appeal of a laboratory service may be withdrawn.
91.34 When an appeal of a laboratory service may be refused.
91.35 Who shall perform an appealed laboratory service.
91.36 Appeal laboratory certificate.

Subpart I—Fees and Charges

91.37 Standard hourly fee rate for laboratory testing, analysis, and other services.
91.38 Additional fees for appeal of analysis.
91.39 Premium hourly fee rates for overtime and legal holiday service.
91.40 Fees for courier service and facsimile of the analysis report.
91.41 Charges for demonstrations and courses of instruction.
91.42 Billing.
91.43 Payment of fees and charges.
91.44 Charges on overdue accounts and issuance of delinquency notices.
91.45 Charges for laboratory services on a contract basis.

Subpart J—Designation of Approved Symbols for Identification of Commodities Officially Tested By AMS

91.100 Scope.
91.101 Definitions.
91.102 Form of official identification symbols.


Source: 58 FR 42415, Aug. 9, 1993, unless otherwise noted.


Subpart A—Administration

§ 91.1 General.

This part consolidates the procedural and administrative rules of the Science and Technology of the Agricultural Marketing Service for conducting the analytical testing and laboratory audits with quality assurance reviews. It also contains the fees, charges and laboratories applicable to such services.


§ 91.2 Definitions.

Words used in the regulations in this part in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this part, unless the context requires otherwise, the following terms will be construed to mean:

Agency. The Agricultural Marketing Service agency of the United States Department of Agriculture.

Analyses. Microbiological, chemical, or physical tests performed on a commodity.

Applicant. Any person or organization requesting services provided by the Science and Technology (S&T) programs.

Legal holidays. Those days designated as legal public holidays specified by Congress in paragraph (a) of section 6103, title 5 of the United States Code and any other day declared to be a holiday by Federal Statute or Executive Order. Under section 6103 and Executive Order 10357, as amended, if the specified legal public holiday falls on a Saturday, the preceding Friday shall be considered the holiday, or if the specified legal holiday falls on a Sunday, the following Monday shall be considered to be the holiday.


§ 91.3 Authority.

The Deputy Administrator is charged with the administration of this subchapter.


Subpart B—General Services

§ 91.4 Kinds of services.

(a) Analytical tests. Analytical laboratory testing services under the regulations in this subchapter consist of microbiological, chemical, and certain other analyses, requested by the applicant and performed on tobacco, seed, dairy, egg, fruit and vegetable, meat and poultry products, and related processed products. Analyses are performed to determine if products meet Federal specifications or specifications defined in purchase contracts and cooperative agreements. Laboratory analyses are also performed on egg products as part of the mandatory Egg Products Inspection Program under the management
§ 91.5 Where services are offered.

(a) Services are offered to applicants at the Science and Technology laboratories and facilities as listed below.

(1) Science and Technology Programs National Science Laboratory. A variety of proximate for composition, chemical, physical, microbiological and biomolecular (DNA-based) tests and laboratory analyses performed on fruits and vegetables, poultry, dairy and dairy products, juices, fish, vegetative seed and oilseed, honey, meat and meat products, fiber products and processed foods are performed at the Science and Technology Programs (S&T) laboratory located at: USDA, AMS, Science and Technology Programs, National Science Laboratory (NSL), 801 Summit Crossing Place, Suite B, Gastonia, North Carolina 28054–2193.

(2) Science and Technology (S&T) Programs Science Specialty Laboratories. The Science specialty laboratories performing aflatoxin and other testing on peanuts, peanut products, dried fruits, grains, edible seeds, tree nuts, shelled corn products, oilseed products, olive oil, vegetable oils, juices, citrus products, and other commodities are located as follows:

(i) USDA, AMS, Science & Technology, Citrus Laboratory, 98 Third Street, SW., Winter Haven, Florida 33880–2905.

(ii) USDA, AMS, Science & Technology, Science Specialty Laboratory, 6567 Chancey Mill Road, Blakely, Georgia 39823–2785.

(3) Program laboratories. Laboratory services are available in all areas covered by cooperative agreements providing for this laboratory work and entered on behalf of the Department with cooperating Federal or State laboratory agencies pursuant to Act(s) of Congress. Also, services may be provided in other areas not covered by a cooperative agreement if the Administrator determines that it is possible to provide such laboratory services.

(4) Other alternative laboratories. Laboratory analyses may be conducted at alternative Science and Technology Programs laboratories and can be reached from any commodity market in which a laboratory facility is located to the extent laboratory personnel are available.

(5) The Plant Variety Protection (PVP) Office. The PVP office and plant examination facility of the Science and Technology programs issues certificates of protection to developers of novel varieties of plants which reproduce sexually. The PVP office is located as follows: USDA, AMS, Science & Technology Programs, Plant Variety Protection Office, National Agricultural Library Building, Room 401, 10301 Baltimore Boulevard, Beltsville, MD 20705–2351.

(6) Science and Technology Programs headquarters offices. The examination, licensure, quality assurance reviews, laboratory approval/certification and consultation services are provided by headquarters staff located in Washington, DC. The main headquarters office is located as follows: USDA, AMS, Science and Technology Programs, Office of the Deputy Administrator, Room 1092 South Agriculture Bldg., Mail Stop 0270, 1400 Independence Ave., SW., Washington, DC 20250–0270.

(7) Statistics Branch Office. The Statistics Branch office of Science and Technology Programs (S&T) provides statistical services to the Agency and other agencies within the USDA. In addition, the Statistics Branch office
generates sample plans and performs consulting services for research studies in joint efforts with or in a leading role with other program areas of AMS or of the USDA. The Statistics Branch office is located as follows: USDA, AMS, S&T Statistics Branch, Room 0603 South Agriculture Bldg., Mail Stop 0223, 1400 Independence Ave., SW., Washington, DC 20250–0223.

(8) Technical Services Branch Office. The Technical Services Branch office of Science and Technology (S&T) provides technical support services to all Agency programs and other agencies within the USDA. In addition, the Technical Services Branch office provides certification and approval services of private and State government laboratories as well as oversees quality assurance programs; import and export certification of laboratory tested commodities. The Technical Services Branch mailing address is as follows: USDA, AMS, S&T Technical Services Branch, South Agriculture Bldg., Mail Stop 0272, 1400 Independence Ave., SW., Washington, DC 20250–0272. The Technical Services Branch office is located as follows: USDA, AMS, Science and Technology Technical Services Branch, Room 0604 South Agriculture Bldg., 1400 Independence Ave., SW., Washington, DC 20250.

(9) Monitoring Programs Office. Services afforded by the Pesticide Data Program (PDP) and Microbiological Data Program (MDP) are provided by USDA, AMS, Science and Technology Monitoring Programs Office, 8609 Sudley Road, Suite 206, Manassas, VA 20110–8411.

(10) Pesticide Records Branch Office. Services afforded by the Federal Pesticide Record Keeping Program for restricted-use pesticides by private certified applicators are provided by USDA, AMS, Science and Technology, Pesticide Records Branch, 8609 Sudley Road, Suite 203, Manassas, VA 20110–8411.

(b) The addresses of the various laboratories and offices appear in the pertinent parts of this subchapter. A prospective applicant may obtain a current listing of addresses and telephone numbers of Science and Technology Programs laboratories, offices, and facilities by addressing an inquiry to the Administrative Officer, Science and Technology Programs, Agricultural Marketing Service, United States Department of Agriculture (USDA), 1400 Independence Ave., SW., Room 0725 South Agriculture Building, Mail Stop 0271, Washington, DC 20250–0271.

(75 FR 17287, Apr. 6, 2010)

§ 91.6 Availability of services.

(a) Services may be furnished whenever a Science and Technology staff is available and the facilities and conditions are satisfactory for the conduct of such service.

(b) Laboratories may provide limited service on Saturdays and Sundays at a premium fee. Weekend service may be obtained by contacting the laboratory director or supervisor.

(c) Holiday and overtime laboratory service may be obtained with a minimum 24 hour advance notice, at a premium fee, by any prospective applicant through the laboratory director or supervisor.


Subpart C—Application for Services

§ 91.7 Nondiscrimination.

All services under these regulations are provided to applicants without discrimination as to race, color, handicapped or disabled condition, religion, sex, age, or national origin.

§ 91.8 Who may apply.

An application for service may be made by any individual or interested party including, but not limited to, the United States and any instrumentality or agency thereof, any State, county, municipality, or common carrier, and any authorized agent on behalf of the foregoing.

§ 91.9 How to make an application.

(a) Voluntary. An application for analysis and testing may be made by contacting the director or supervisor of the Science and Technology laboratory where the service is provided, or by contacting the Technical Services Branch Chief at Science and Technology Headquarters, Washington, DC.
§ 91.10 Information required in connection with an application.

(a) An application for laboratory service shall be made in the English language and may be made orally (in person or by telephone), in writing, or by facsimile. If an application for laboratory service is made orally, written confirmation may be required by the laboratory involved.

(b) In connection with each application for a laboratory service, information that may be necessary to perform analyses on the processed product(s) shall also be furnished. The information shall include, but is not limited to, the name of the product, name and address of the packer or plant where such product was packed, the location of the product, its lot or load number, codes or other identification marks, the number of containers, the type and size of the containers, the analytical test requested, and the size of the sample. In addition, information regarding analysis of the lot by any federal agency previous to the application and the purpose of the desired laboratory service may be requested.

§ 91.11 Filing of an application.

An application for a laboratory service shall be regarded as filed only when made in accordance with the regulations in this part.

§ 91.12 Record of filing time and laboratory tests.

A record showing the date of receipt for each application for a laboratory service or an appeal of a laboratory service shall be maintained. In addition, the requested laboratory analyses shall be recorded at the time of sample receipt.

§ 91.13 When an application may be rejected.

(a) An application for a laboratory service may be rejected by the Administrator when deemed appropriate as follows:

(1) For non-compliance by the applicant with the regulations in this part,

(2) For non-payment of previous laboratory services rendered,

(3) When the sample is not properly identified by a code or other marks,

(4) When the samples are received in an unsatisfactory condition and are rejected for analysis,

(5) When there is evidence or knowledge of tampering with the sample,

(6) When it appears that to perform the analytical testing or laboratory service specified in this part would not be to the best interests of the public welfare or of the Government, or

(7) When it appears to the Administrator that prior commitments of the Department necessitate rejection of the application.

(b) Each such applicant shall be promptly notified by registered mail of the reasons for the rejection.

(c) A written petition for reconsideration of such rejection may be filed by the applicant with the Administrator if postmarked or delivered within 10 days after the receipt of notice of the rejection. Such petition shall state specifically the errors alleged to have been made by the Administrator in rejecting the application. Within 20 days following the receipt of such a petition for reconsideration, the Administrator shall approve the application or notify the applicant by registered mail of the reasons for the rejection thereof.

§ 91.14 When an application may be withdrawn.

An application for a laboratory service may be withdrawn by the applicant at any time before the analytical testing is performed; Provided, That, the applicant shall pay, at the hourly rate prescribed in §91.37, for the time incurred by the scientist or laboratory technician, in connection with such application and any travel expenses, telephone, facsimile, mailing, telegraph or
other expenses, which have been incurred by the laboratory servicing office, in connection with such application.

Subpart D—Laboratory Service

§ 91.15 Basis of a laboratory service.

Analytical testing and laboratory determination for analyte or quality constituent shall be based upon the appropriate standards promulgated by the U.S. Department of Agriculture, applicable standards prescribed by the laws of the State where the particular product was produced, specifications of any governmental agency, written buyer and seller contract specifications, or any written specifications by an applicant which is approved by the Administrator; Provided, That, if such product is regulated pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), or the comparable laws of any State, such testing and determination shall be on the basis of the standards, if any, prescribed in, or pursuant to, the marketing order and/or agreement effective thereunder.

§ 91.16 Order of a laboratory service.

Laboratory service shall be performed, insofar as possible, in the order in which applications are made except that precedence may be given to any such applications which are made by the United States (including, but not being limited to, any instrumentality or agency thereof) and to any application for an appeal inspection.

§ 91.17 Postponing a laboratory service.

If the scientist determines that it is not possible to accurately analyze or make a laboratory determination of a sample immediately after receipt because standard materials, laboratory equipment and supplies need replacement, or for any other substantial reason, the scientist may postpone laboratory service for such period as may be necessary.

§ 91.18 Financial interest of a scientist.

No scientist shall perform a laboratory analysis on any product in which he is directly or indirectly financially interested.

Subpart E—Samples

§ 91.19 General requirements of suitable samples.

(a) Samples must be representative of the product tested and provided in sufficient quantity for the analyses requested.

(b) Each sample must be identified with the following information:

(1) Product type (specific description);

(2) Lot number or production date;

(3) Analyses desired;

(4) Date/time collected;

(5) Storage conditions prior to shipping;

(6) Name of applicant;

(7) Name of sampler;

(8) Any other information which is required by the specific program under which analysis or test is performed.

§ 91.20 Shipping.

(a) Samples must be submitted to the laboratory in a condition (including temperature) that does not compromise the quality and validity of analytical results.

(b) All samples must be submitted in sealed, leakproof containers.

(c) Containers for perishable refrigerated samples should contain ice or ice packs to maintain temperatures of 0° to 5° C, unless a different temperature is required for the sample to be tested.

(d) Containers for frozen samples should contain dry ice or other effective methods of maintaining samples in a frozen state.

(e) The applicant is responsible for providing shipping containers and paying shipping costs for fee basis tests.

(f) A courier charge may apply for the shipment of some samples.

§ 91.21 Protecting samples.

Laboratory personnel shall protect each sample from manipulation, substitution, and improper or careless handling which would deprive the sample of its representative character from the time of receipt in the laboratory until the analysis is completed and the sample has been discarded.
§ 91.22 Disposition of analyzed sample.

(a) Excess samples not used in analyses will be placed in proper storage for a maximum period of 30 days after reporting results of tests.

(b) Any sample of a processed commodity that has been used for a laboratory service may be returned to the applicant at his or her request and expense; otherwise, it shall be destroyed or disposed of to a charitable institution.

Subpart F—Method Manuals

§ 91.23 Analytical methods.

Most analyses are performed according to approved procedures described in manuals of standardized methodology. These standard methods are the specific methods used. Alternatively, equivalent methods prescribed in cooperative agreements are used. The manuals of standard methods most often used by the Science and Technology laboratories are listed as follows:


(b) ASTA’s Analytical Methods Manual, American Spice Trade Association (ASTA), 560 Sylvan Avenue, P.O. Box 1267, Englewood Cliffs, New Jersey 07632.

(c) Compendium Methods for the Microbiological Examination of Foods, Carl Vanderzant and Don Splittstoesser (Editors), American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005.


(e) FDA Bacteriological Analytical Manual (BAM), AOAC INTERNATIONAL, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877–2417.

(f) Manual of Analytical Methods for the Analysis of Pesticide Residues in Human and Environmental Samples, EPA 600/9–80–038, U.S. Environmental Protection Agency (EPA) Chemical Exposure Research Branch, EPA Office of Research and Development (ORD), 26 West Martin Luther King Drive, Cincinnati, Ohio 45268.

(g) Official Methods and Recommended Practices of the American Oil Chemists’ Society (AOCS), American Oil Chemists’ Society, P.O. Box 3489, 2211 West Bradley Avenue, Champaign, Illinois 61821–1827.

(h) Official Methods of Analysis of AOAC INTERNATIONAL, Volumes I & II, AOAC INTERNATIONAL, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877–2417.

(i) Standard Analytical Methods of the Member Companies of Corn Industries Research Foundation, Corn Refiners Association (CRA), 1701 Pennsylvania Avenue, NW., Washington, DC 20006.


(k) Standard Methods for the Examination of Water and Wastewater, American Public Health Association (APHA), the American Water Works Association (AWWA) and the Water Pollution Control Federation, AWWA Bookstore, 6666 West Quincy Avenue, Denver, CO 80235.


(m) U.S. Army Natick Research, Development and Engineering Center’s Military Specifications, approved analytical test methods noted therein, Code NPP–9, Department of Defense Single Stock Point (DODSSP) for Military Specifications, Standards, Building 4D, 700 Robbins Avenue, Philadelphia, PA 19111–5094.

(n) U.S. Food and Drug Administration, Pesticide Analytical Manuals (PAM), Volumes I and II, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), 200 C Street, SW., Washington, DC 20204
Subpart G—Reporting

§ 91.24 Reports of test results.

(a) Results of analyses are provided, in writing, by facsimile, by e-mail or other electronic means to the applicant.

(b) Results of test analyses and laboratory determinations provided by AMS laboratory services only apply to the submitted samples and do not represent the quality, condition or disposition of the lot from which each sample was taken.

(c) Applicants may call the appropriate Science and Technology laboratory for interim or final results prior to issuance of the formal report. The advance results may be telegraphed, e-mailed, telephoned, or sent by facsimile to the applicant. Any additional expense for advance information shall be borne by the requesting party.

(d) A letter report in lieu of an official certificate of analysis may be issued by a laboratory representative when such action appears to be more suitable than a certificate: Provided, that, issuance of such report is approved by the Deputy Administrator.

§ 91.25 Certificate requirements.

Certificates of analysis and other memoranda concerning laboratory service and the reporting of results should have the following requirements:

(a) Certificates of analysis shall be on standard printed forms approved by the Deputy Administrator;

(b) Shall be printed in English;

(c) Shall have results typewritten, computer generated, or handwritten in ink and be clearly legible;

(d) Shall show the results of laboratory tests in a uniform, accurate, and concise manner with abbreviations identified on the form;

(e) Shall show the information required by §§ 91.26 through 91.29; and

(f) Show only such other information and statements of fact as are provided in the instructions authorized by the Deputy Administrator.

§ 91.26 Issuance of certificates.

(a) The person signing and issuing the certificate of analysis shall be one of the following:

(1) The scientist who performed the analysis;

(2) Another technician of the laboratory facility, who has been given power of attorney by the scientist who performed the analytical testing and been authorized by the Deputy Administrator to affix the scientist’s signature to a certificate. The power of attorney shall be on file with the employing office or laboratory of the Science and Technology program;

(3) A person designated as the “laboratory director in charge,” when the certificate represents composite analyses by several technicians.

(b) The laboratory certificate shall be prepared in accordance with the facts set forth in the official memorandum made by the scientist or technicians in connection with the analysis.

(c) Whenever a certificate is signed by a person under a power of attorney, the certificate should so indicate. The signature of the holder of power shall appear under the name of the scientist who personally analyzed the sample, and whenever a certificate issued is signed by a scientist in charge, that title must appear in connection with the signature.

§ 91.27 Corrections to certificates prior to issuance.

(a) The accuracy of the statements and information shown on certificates of analysis must be verified by the individual whose name or signature, or both, is shown on the certificate or by the authorized agent who affixed the name or signature, or both. When a name or signature, or both, is affixed by an authorized agent, the initials of the agent shall appear directly below or following the name, or signature of the person. Errors found during this...
process shall be corrected according to this section.

(b) Only official personnel or their authorized agents may make corrections, additions, or other changes to certificates.

(c) No corrections, additions, or other changes shall be made which involve identification, quality, or quantity. If such errors are found, a new certificate shall be prepared and issued and the incorrect certificate marked “Void.” Otherwise, errors may be corrected, provided there is evidence of satisfactory correction procedures as follows:

(1) The corrections are neat and legible;

(2) Each correction is initialed by the individual who corrects the certificate; and

(3) The corrections and initials are shown on the original and all copies.

§ 91.28 Issuance of corrected certificates or amendments for analysis reports.

(a) A corrected certificate of analysis or an amended letter report may be issued by the laboratory representative who issued the original certificate or report after distribution of the form if errors, such as incorrect dates, analytical results, or test determination statements, lot numbers, or errors in any other pertinent information require the issuance of a corrected certificate or an amended report.

(b) Whenever a corrected certificate or amended report is issued, such certificate or report shall supersede the original form which was issued in error. The superseded certificate or incorrect report shall become null and void after the issuance of the corrected certificate or the amended analysis report.

(c) The corrected certificates or amended reports shall show the following:

(1) The terms “Corrected Original” and “Corrected Copy”;

(2) A statement identifying the superseded certificate or incorrect letter report and the corrections;

(3) A new serial number or new date of issuance; and

(4) The same statements and information, including permissive statements, that were shown on the incorrect certificate or the incorrect report, along with the correct statement or information, shall be shown on the corrected form.

(d) If all copies of the incorrect certificate or incorrect report can be obtained, then the superseded form shall be marked “Void” when submitted.

(e) Corrected certificates or amended letter reports cannot be issued for a certificate that has been superseded by another certificate, or superseded on the basis of a subsequent analysis or an additional laboratory test determination.

§ 91.29 Issuance of duplicate certificates or reissuance of an analysis report.

(a) Upon request by an applicant, a duplicate certificate or an additional report may be issued for a lost, destroyed, or otherwise not obtainable original form.

(b) The duplicate certificate or the reissuance of an analysis report shall be at the expense of the applicant.

(c) Requests for duplicate certificates or additional analysis reports shall be filed as follows:

(1) In writing;

(2) By the applicant who requested the service covered by the lost, destroyed, or otherwise not obtainable original form; and

(3) With the office that issued the initial certificate or original laboratory analysis report.

(d) The duplicate certificates or reissued analysis reports shall show the following:

(1) The terms “Duplicate Original,” and the copies shall show “Duplicate Copy,”

(2) A statement that the certificate or letter report was issued in lieu of a lost or destroyed or otherwise not obtainable certificate or laboratory analysis report; and

(3) The same statements and information, including permissive statements, that were shown on the original certificate or the initial analysis report shall be shown on the duplicate form.

(e) Duplicate certificates or duplicate analysis reports shall be issued as promptly as possible and distributed as
the original certificates or original analysis reports and their copies.
(f) Duplicate certificates shall not be issued for certificates that have been superseded.

§ 91.30 Maintenance and retention of copies of certificates or analysis reports.
(a) At least one copy of each certificate or analysis report shall be filed in the laboratory for a period of not less than 3 years either from the date of issuance of the document, from the date of voiding a certificate, or from the date last payment is made by the applicant for a reported laboratory determination, whichever is later.
(b) Whenever any document, because of its condition, becomes unsuitable for its intended or continued use, the laboratory personnel shall make a copy of the original document.
(c) True copies shall be retained as photocopies, microfilm, microfiche, or other accurate reproductions and durable forms of the original document. Where reduction techniques, such as microfilming are used, suitable reader and photocopying equipment shall be readily available. Such reproductions shall be treated and considered for all purposes as though they were the original documents.
(d) All documents required to be maintained under this part shall be kept confidential and shall be disclosed only to the applicants or other persons with the applicants’ knowledge and permission. Only such information as the Administrator deems relevant shall be disclosed to the public without the applicants’ permission, and then, only in a suit or administrative hearing brought at the direction, or on the request, of the Administrator, or to which the Administrator or any other officer of the United States is a party.

Subpart H—Appeal of Laboratory Services

§ 91.31 When an appeal of a laboratory service may be requested.
(a) An application for an appeal of a laboratory service may be made by any interested party who is dissatisfied with the results of an analysis as stated in a certificate or laboratory report, if the lot of the commodity can be positively identified by the laboratory service as the lot from which originally drawn samples were previously analyzed.
(b) An application for an appeal of a laboratory service shall be made within thirty (30) days following the day on which the previous analysis was performed. However, upon approval by the Deputy Administrator, the filing time for an appeal application may be extended.

§ 91.32 Where to file for an appeal of a laboratory service and information required.
(a) Application for an appeal of a laboratory service may be filed with the supervisor in the office or the director of the laboratory facility that issued the certificate or laboratory report on which the appeal analysis covering the commodity product is requested.
(b) The application for an appeal of a laboratory service shall state the location of the lot of the commodity product and the reasons for the appeal; and date and serial number of the certificate covering the laboratory service of the commodity product on which the appeal is requested. In addition, such application shall be accompanied by the original and all available copies of the certificate or laboratory report.
(c) Application for an appeal of a laboratory service may be made orally (in person or by telephone), in writing, by e-mail, by facsimile, or by telegraph. If made orally, written confirmation shall be made promptly.

§ 91.33 When an application for an appeal of a laboratory service may be withdrawn.
An application for an appeal of a laboratory service may be withdrawn by the applicant at any time before the appealed laboratory service is performed; Provided, That, the applicant shall pay, at the hourly rate prescribed in §91.37, for the time incurred by the laboratory personnel, any travel, telephone, telegraph, or other expenses
which have been incurred by the laboratory service in connection with such application.

§ 91.34 When an appeal of a laboratory service may be refused.

An application for an appeal of a laboratory service may be refused if:

(a) The reasons for the appealed laboratory service are frivolous or not substantial;

(b) The quality or condition of the commodity product has undergone a material change since the laboratory service covering the commodity product on which the appealed laboratory service is requested;

(c) The lot in question is not, or cannot be made accessible for sampling;

(d) The lot relative to which the appealed laboratory service is requested cannot be positively identified as the lot from which samples were previously drawn and originally analyzed; or

(e) There is noncompliance with the regulations in this part. Such applicant shall be notified promptly of the reason for such refusal.

§ 91.35 Who shall perform an appealed laboratory service.

An appealed laboratory service shall be performed, whenever possible, by another individual or other individuals than the scientist(s) or the technician(s) that performed the original analytical determination.

§ 91.36 Appeal laboratory certificate.

(a) An appeal laboratory certificate shall be issued showing the results of such appealed analysis. This certificate shall supersede the laboratory certificate previously issued for the commodity product involved.

(b) Each appeal laboratory certificate shall clearly identify the number and date of the laboratory certificate which it supersedes. The superseded certificate shall become null and void upon the issuance of the appealed laboratory certificate and shall no longer represent the analytical results of the commodity product.

(c) The individual issuing an appeal laboratory certificate shall forward notice of such issuance to such persons as he or she considers necessary to prevent misuse of the superseded certificate if the original and all copies of such superseded certificate have not previously been delivered to the individual issuing the appeal certificate.

(d) The provisions in the regulations in this part concerning forms and certificates, issuance of certificates, and retention and disposition of certificates shall apply to appeal laboratory certificates, except that copies of such appeal certificates shall be furnished to all interested parties who received copies of the superseded certificate.

Subpart I—Fees and Charges

§ 91.37 Standard hourly fee rate for laboratory testing, analysis, and other services.

(a) The standard hourly fee rate in this section for the individual laboratory analyses cover the costs of Science and Technology laboratory services, including issuance of certificates and personnel and overhead costs other than the commodity inspection fees referred to in 7 CFR 52.42 through 52.46, 52.48 through 52.51, 55.510 through 55.530, 55.560 through 55.570, 58.38 through 58.43, 58.45 through 58.46, 70.71 through 70.72, and 70.75 through 70.78. The hourly fee rates in this part 91 shall apply to all commodity and processed commodity products. The new fiscal year for Science and Technology Programs commences on October 1 of each calendar year. The rate for laboratory services is $78.00 per hour in fiscal year 2010, $81.00 per hour in fiscal year 2011, and $83.00 per hour in fiscal year 2012.

(b) Printed updated schedules of the laboratory testing fees for processed fruits and vegetables (7 CFR part 93), poultry and egg products (7 CFR part 94), and meat and meat products (7 CFR part 98) will be available for distribution to Science and Technology’s constituents and stakeholders by the individual Laboratory Directors of Science and Technology laboratories listed in §91.5. These single test laboratory fee schedules are based upon the applicable hourly fee rate stated in paragraph (a) of this section.

(c) Except as otherwise provided in this section, charges will be made at the applicable hourly rate stated in paragraph (a) of this section for the time required to perform the service. A
charge will be made for service pursuant to each request or certificate issued.

(d) When a laboratory test service is provided for AMS by a commercial or State government laboratory, the applicant will be assessed a fee which covers the costs to the Science and Technology program for the service provided.

(e) When Science and Technology staff provides applied and developmental research and training activities for microbiological, physical, chemical, and biomolecular analyses on agricultural commodities the applicant will be charged a fee on a reimbursable cost to AMS basis.

[75 FR 17288, Apr. 6, 2010]

§ 91.38 Additional fees for appeal of analysis.

(a) The applicant for appeal sample testing will be charged a fee at the hourly rate for laboratory service that appears in this paragraph. The new fiscal year for Science and Technology Programs commences on October 1 of each calendar year. The appeal rate for laboratory service is $93.00 per hour in fiscal year 2010, $96.00 per hour in fiscal year 2011, and $99.00 per hour in fiscal year 2012.

(b) The appeal fee will not be waived for any reason if analytical testing was completed in addition to the original analysis.

[75 FR 17288, Apr. 6, 2010]

§ 91.39 Premium hourly fee rates for overtime and legal holiday service.

(a) When analytical testing in a Science and Technology facility requires the services of laboratory personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime work. When analytical testing in a Science and Technology facility requires the services of laboratory personnel on a Federal holiday or a day designated in lieu of such a holiday, such services are considered holiday work. Laboratory analyses initiated at the request of the applicant to be rendered on Federal holidays, and on an overtime basis will be charged fees at hourly rates for laboratory service that appear in this paragraph. The new fiscal year for Science and Technology Programs commences on October 1 of each calendar year. The laboratory analysis rate for overtime service is $93.00 per hour in fiscal year 2010, $96.00 per hour in fiscal year 2011, and $99.00 per hour in fiscal year 2012. The laboratory analysis rate for Federal holiday or designed holiday service is $108.00 per hour in fiscal year 2010, $111.00 per hour in fiscal year 2011, and $115.00 per hour in fiscal year 2012.

(b) Information on legal holidays or what constitutes overtime service at a particular Science and Technology laboratory is available from the Laboratory Director or facility manager.

[75 FR 17288, Apr. 6, 2010]

§ 91.40 Fees for courier service and facsimile of the analysis report.

(a) The Science and Technology laboratories have a courier charge per trip to retrieve the sample package. The courier service charge is determined from the established single standard mileage rate and from the total authorized distance based on the shortest round trip route from laboratory to sample retrieval site. Pursuant to the requirements of paragraph (a) (1) of §5704 of Title 5, United States Code (U.S.C.), the automobile reimbursement rate cannot exceed the single standard mileage rate established by the Internal Revenue Service (IRS).

(b) The faxing of laboratory analysis reports or certificates is an optional service for each S&T facility offered at a fee specified in table 8 in §91.37.

[65 FR 64314, Oct. 26, 2000]

§ 91.41 Charges for demonstrations and courses of instruction.

Charges, not in excess of the cost thereof and as approved by the Deputy Administrator, may be made for demonstrations, samples, or courses of instruction when such are furnished upon request.


§ 91.42 Billing.

(a) Each billing cycle will end on the 25th of the month. The applicant will
§ 91.43 Payment of fees and charges.

(a) Fees and charges for services shall be paid by the applicant, by check or money order payable, to the “Agricultural Marketing Service, USDA” and sent to the office indicated on the bill.

(b) Fees and charges for services under a cooperative agreement with a State or other AMS programs or other governmental agency will be paid in accordance with the terms of the cooperative agreement.

(c) As necessary, the Deputy Administrator may require that fees shall be paid in advance of the performance of the requested service. Any fees paid in excess of the amount due shall be used to offset future billings, unless a request for a refund is made by applicant.


§ 91.44 Charges on overdue accounts and issuance of delinquency notices.

(a) Accounts are considered overdue if payment is late with the National Finance Center (NFC). The timeliness of a payment will be based on the postmark date of the payment or the date of receipt by the NFC if no postmark date is present or legible. Bills are payable upon receipt and become delinquent 30 days from date of billing.

(b) Any amount due not paid by the due date will be increased by a late payment charge. The actual assessed rate applied to overdue accounts is set quarterly by the Department of the Treasury. This amount is one-twelfth of one year’s late penalty interest rate computed at the prescribed rate.

(c) Overtime or holiday laboratory service will not be performed for any applicant with a notice of delinquency.

(d) Applicants with three notices of delinquency may be required of any person failing to pay in claim after issuance of such notice of delinquency.

(e) The Deputy Administrator of S&T program and personnel of the USDA, NFC Billings and Collections Branch (address as listed in §91.42) will take such actions as may be necessary to collect any delinquent amounts due for accounts in claim status.

[72 FR 15021, Mar. 30, 2007]

§ 91.45 Charges for laboratory services on a contract basis.

(a) Irrespective of hourly fee rates and charges prescribed in §91.37, or in other sections of this subchapter E, the Deputy Administrator may enter into contracts with applicants to perform continuous laboratory services or other types of laboratory services pursuant to the regulations in this part and other requirements, as prescribed by the Deputy Administrator in such contract. In addition, the charges for such laboratory services, provided in such contracts, shall be on such basis as will reimburse the Agricultural Marketing Service of the Department for the full cost of rendering such laboratory services, including an appropriate overhead charge to cover administrative overhead expenses as may be determined by the Administrator.

(b) Irrespective of hourly fee rates and charges prescribed in this subpart I, or in other parts of this subchapter E, the Deputy Administrator may enter into a written Memorandum of Understanding (MOU) or agreement with any administrative agency or governing party for the performance of
Agricultural Marketing Service, USDA Laboratory services pursuant to said agreement or order on a basis that will reimburse the Agricultural Marketing Service of the Department for the full cost of rendering such laboratory service, including an appropriate overhead administrative overhead charge.

(c) The conditions and terms for renewal of such Memorandum of Understanding or agreement shall be specified in the contract.

[65 FR 64315, Oct. 26, 2000]

Subpart J—Designation of Approved Symbols for Identification of Commodities Officially Tested By AMS

SOURCE: 68 FR 69946, Dec. 16, 2003, unless otherwise noted.

§ 91.100 Scope.

Two approved information symbols in the form of AMS shields are available to indicate official testing by an AMS laboratory. The two approved AMS shields with the words “USDA AMS TESTED” and “USDA LABORATORY TESTED FOR EXPORT” are added to the USDA symbol inventory to enhance the acceptance of AMS tested agricultural commodities on a national or international basis.

§ 91.101 Definitions.

Words used in the regulations in this part in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this part, unless the context requires otherwise, the following terms will be construed to mean:

AMS. The abbreviation for the Agricultural Marketing Service (AMS) agency of the United States Department of Agriculture.

Export. To send or transport a product originally created or manufactured in the United States of America to another country in the course of trade.

Laboratory. An AMS Science and Technology (S&T) laboratory listed in §91.5 that performs the official analyses.

Test. To perform chemical, microbiological, or physical analyses on a sample to determine presence and levels or amounts of a substance or living organism of interest.

USDA. The abbreviation for the United States Department of Agriculture.

§ 91.102 Form of official identification symbols.

Two information symbols in the form of AMS shields indicate commodity testing at an AMS laboratory listed in §91.5 of this part. The AMS shield set forth in figure 1 of this section, containing the words “USDA AMS TESTED”, and the shield set forth in figure 2, containing the words “USDA LABORATORY TESTED FOR EXPORT” have been approved by the USDA Office of Communications to be added to the USDA/AMS inventory of symbols. Each example of an AMS shield has a black and white background; however the standard red, white and blue colors are approved for the shields. They are approved for use with AMS materials. Shields with the same wording that are similar in form and design to the examples in figures 1 and 2 of this section may also be used.
PART 93—PROCESSED FRUITS AND VEGETABLES

Subpart A—Citrus Juices and Certain Citrus Products

Sec.  
93.1 General.  
93.2 Definitions.  
93.3 Analyses available and location of laboratory.  
93.4 Analytical methods.  
93.5 Fees for citrus product analyses set by cooperative agreement.

Source: 61 FR 51351, Oct. 2, 1996, unless otherwise noted.
method outlined in the Official Methods of Analysis of AOAC INTERNATIONAL, Volumes I & II.

Brix value/acid ratio. The ratio of the Brix value of the juice or citrus product, in degrees Brix, to the grams of anhydrous citric acid per 100 grams of juice or citrus product.

Brix/acid ratio. The ratio of the degrees Brix of the juice to the grams of anhydrous citric acid per 100 grams of the juice.

Citrus. All plants, edible parts and commodity products thereof, including pulp and juice of any orange, lemon, lime, grapefruit, mandarin, tangerine, kumquat or other tree or shrub in the genera *Citrus*, *Fortunella*, or *Poncirus* of the plant family Rutaceae.

Recoverable oil. The percent of oil by volume, determined by the bromate titration method after distillation and acidification as described in the current edition of the Official Methods of Analysis of AOAC INTERNATIONAL, Volumes I & II.

Subpart B—Peanuts, Tree Nuts, Corn and Other Oilseeds

§ 93.10 General.

Chemical analyses are performed to detect the presence of aflatoxin in lots of shelled peanuts and peanut products, as well as in other nuts and agricultural products. In addition, proximate chemical analyses for quality determination are performed on oilseeds.
§ 93.11 Definitions.

Words used in the regulations in this subpart in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this subpart, unless the context requires otherwise, the following terms will be construed to mean:

**Aflatoxin.** A toxic metabolite produced by the molds *Aspergillus flavus*, *Aspergillus parasiticus*, and *Aspergillus nomius*. The aflatoxin compounds fluoresce when viewed under UV light as follows: aflatoxin B$_1$ and derivatives with a blue fluorescence, aflatoxin B$_2$ with a blue-violet fluorescence, aflatoxin G$_1$ with a green fluorescence, aflatoxin G$_2$ with a green-blue fluorescence, aflatoxin M$_1$ with a blue-violet fluorescence, and aflatoxin M$_2$ with a violet fluorescence. These closely related molecular structures are referred to as aflatoxin B$_1$, B$_2$, G$_1$, G$_2$, M$_1$, M$_2$, GM$_1$, B$_{2a}$, G$_{2a}$, Ro, B$_1$, 1-OCH$_3$B$_2$, and 1-CH$_3$G$_2$.

**Peanut Administrative Committee (PAC).** The committee established under the United States Department of Agriculture Marketing Agreement for Peanuts, 7 CFR part 998, which administers the terms and provisions of this Agreement, including the aflatoxin control program for domestically produced raw peanuts, for peanut shellers. The Peanut Administrative Committee (PAC) headquarters are at 2337 Lafayette Plaza Drive Suite A; Albany, Georgia 31707.

**Peanut Marketing Agreement.** The agreement concerning the regulations and instructions set forth since July 12, 1965, by the Peanut Administrative Committee for the marketing of peanuts entered into by handlers of domestically produced raw peanuts, for peanut shellers. The Peanut Administrative Committee (PAC) headquarters are at 2337 Lafayette Plaza Drive Suite A; Albany, Georgia 31707.

§ 93.12 Analyses available and locations of laboratories.

(a) **Aflatoxin testing services.** The aflatoxin analyses for peanuts, peanut products, dried fruits, grains, edible seeds, tree nuts, shelled corn products, cottonseed, oilseed products and other commodities are performed at the following 6 locations for AMS Science and Technology (S&T) Aflatoxin Laboratories:

1. USDA, AMS, S&T
   1211 Schley Avenue, Albany, GA 31707.
2. USDA, AMS, S&T
   c/o Golden Peanut Company, Mail: P.O. Box 279, 301 West Pearl Street, Aulander, NC 27805.
3. USDA, AMS, S&T
   610 North Main Street, Blakely, GA 31723.
4. USDA, AMS, S&T
   107 South Fourth Street, Madill, OK 73446.
5. USDA, AMS, S&T
   c/o Cargill Peanut Products, Mail: P.O. Box 272, 715 North Main Street, Dawson, GA 31742–0272.
6. USDA, AMS, S&T
   Mail: P.O. Box 1130, 308 Culloden Street, Suffolk, VA 23434.

(b) **Peanuts, peanut products, and oilseed testing services.** (1) The Science and Technology (S&T) Aflatoxin Laboratories at Madill, Oklahoma and Blakely, Georgia will perform other analyses for peanuts, peanut products, and a variety of oilseeds. The analyses for oilseeds include testing for free fatty acids, ammonia, nitrogen or protein, moisture and volatile matter, foreign matter, and oil (fat) content.

(2) All of the analyses described in paragraph (b)(1) of this section performed on a single seed sample are billed at the rate of one hour per sample. Any single seed analysis performed on a single sample is billed at the rate of one-half hour per sample. The standard hourly rate shall be as specified in §91.37(a) of this subchapter.

(c) **Vegetable oil testing services.** The analyses for vegetable oils are performed at the USDA, AMS, Science and Technology (S&T) Midwestern Laboratory, 3570 North Avondale Avenue, Chicago, IL 60618–5391. The analyses for vegetable oils will include the flash point test, smoke point test, acid
value, peroxide value, phosphorus in oil, and specific gravity. The fee charged for any single laboratory analysis for vegetable oils shall be obtained from the Midwestern Laboratory Director and it is based on the hourly fee rates and charges as specified in 7 CFR part 91, subpart I.

§ 93.13 Analytical methods.

Official analyses for peanuts, nuts, corn, oilseeds, and related vegetable oils are found in the following manuals:


(b) ASTA’s Analytical Methods Manual, American Spice Trade Association (ASTA), 560 Sylvan Avenue, P.O. Box 1267, Englewood Cliffs, New Jersey 07632.

(c) Analyst’s Instruction for Aflatoxin (August 1994), S&T Instruction No. 1, USDA, Agricultural Marketing Service, Science and Technology, 3521 South Agriculture Building, 1400 Independence Avenue, SW., P.O. Box 96456, Washington, DC 20090–6456.

(d) Official Methods and Recommended Practices of the American Oil Chemists’ Society (AOCS), American Oil Chemists’ Society, P.O. Box 3489, 2211 West Bradley Avenue, Champaign, Illinois 61821–1827.

(e) Official Methods of Analysis of AOAC INTERNATIONAL, Volumes I & II, AOAC INTERNATIONAL, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877–2417.

(f) Standard Analytical Methods of the Member Companies of Corn Industries Research Foundation, Corn Refiners Association (CRA), 1701 Pennsylvania Avenue, NW., Washington, DC 20006.


[65 FR 63317, Oct. 26, 2000]

§ 93.14 Fees for aflatoxin analysis and fees for testing of other mycotoxins.


(b) The charge for the aflatoxin testing of raw peanuts under the Peanut Marketing Agreement for subsamples 1–AB, 2–AB, 3–AB, and 1–CD is a set cost per pair of analyses and shall be set by cooperative agreement between the Peanut Administrative Committee and AMS Science and Technology program.

[65 FR 63317, Oct. 26, 2000]

§ 93.15 Fees for analytical testing of oilseeds.

The fee charged for any laboratory analysis for oilseeds shall be obtained from the Laboratory Director for aflatoxin laboratories at the Dothan administrative office as listed in 7 CFR 93.14(a).

[65 FR 63318, Oct. 26, 2000]

PART 94—POULTRY AND EGG PRODUCTS

Subpart A—Mandatory Analyses of Egg Products

Sec.
94.1 General.
94.2 Definitions.
94.3 Analyses performed and locations of laboratories.
94.4 Analytical methods.
94.5 Charges for laboratory service.

Subpart B—Voluntary Analyses of Egg Products

94.100 General.
94.101 Definitions.
94.102 Analyses available.
94.103 Analytical methods.
94.104 Fees and charges.
§ 94.1

Subpart C—Salmonella Laboratory
Recognition Program

94.200 [Reserved]

Subpart D—Processed Poultry Products

94.300 General.
94.301 Definitions.
94.302 Analyses available and locations of laboratories.
94.303 Analytical methods.
94.304 Fees and charges.


SOURCE: 58 FR 42428, Aug. 9, 1993, unless otherwise noted.


Subpart A—Mandatory Analyses of Egg Products

§ 94.1 General.

Microbiological, chemical, and physical analysis of liquid, frozen, and dried egg products is performed under authority of the Egg Products Inspection Act (21 U.S.C. 1031–1056).

§ 94.2 Definitions.

Words used in the regulations in this subpart in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this subpart, unless the context requires otherwise, the following terms will be construed to mean:

\textbf{Egg.} The shell egg of the domesticated chicken, turkey, duck, goose, or guinea. Some of the terms applicable to shell eggs are defined by the AMS Poultry Programs in 7 CFR 57.5.

\textbf{Egg product.} Any dried, frozen, or liquid eggs, with or without added ingredients. However, products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry may be exempted as not being egg products are specified by the AMS Poultry Programs in 7 CFR 57.5.

\textbf{Mandatory sample.} An official sample of egg product(s) taken for testing under authority of the Egg Products Inspection Act (21 U.S.C. 1031–1056) for analysis by a United States Department of Agriculture, Agricultural Marketing Service, Science and Technology laboratory at government expense. A mandatory sample shall include an egg product sample to be analyzed for microbiological, chemical, or physical attributes. A mandatory egg product sample analyzed for the presence of Salmonella is also referred to as a confirmation sample as specified by the Food Safety and Inspection Service agency of USDA in 9 CFR 590.580, paragraph (d).

\textbf{Official plant.} Any plant, as determined by the Secretary, at which the U.S. Department of Agriculture maintains inspection of the processing of egg products under the authority of the Egg Products Inspection Act.

\textbf{Pasteurize.} The subjecting of each particle of egg products to heat or other treatments to destroy harmful viable microorganisms by such processes as may be prescribed by the regulations in the EPIA.

\textbf{Pesticide chemical, food additive, color additive, and raw agricultural commodity.} These terms shall have the same meaning for purposes of this subpart as under sections 408, 409, and 706 of the Federal Food, Drug, and Cosmetic Act.

\textbf{Plant.} Any place of business where egg products are processed.

\textbf{Processing.} Manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products at official plants.


§ 94.3 Analyses performed and locations of laboratories.

(a) Samples drawn by a USDA egg products inspector will be analyzed by AMS Science and Technology (S&T) personnel for microbiological, chemical, and physical attributes. The analytical results of these samples will be reported to the resident egg products
Agricultural Marketing Service, USDA

§ 94.5

(b) Mandatory egg product samples for Salmonella are required and are analyzed in S&T laboratories to spot check and confirm the adequacy of USDA approved and recognized laboratories for analyzing routine egg product samples for Salmonella.

(c) Mandatory egg product samples for chlorinated hydrocarbons are required and are submitted by the plant inspectors on a random basis. These samples screen for pesticide residues and industrial chemical contaminants in egg products.

(d) Samples are drawn by a USDA egg products inspector to determine potential adulteration. These egg product samples may be analyzed for extraneous material, color, color additive, pesticide, heavy metal, microorganism, dextrin, or other substance.

(e) The AMS Science and Technology’s Eastern Laboratory shall conduct the majority of laboratory analyses for egg products. The analyses for mandatory egg product samples are performed at the following USDA location: USDA, AMS, Science & Technology, Eastern Laboratory (Microbiology), 2311-B Aberdeen Boulevard, Gastonia, NC 28054-0614.

§ 94.4 Analytical methods.

The majority of analytical methods used by the USDA laboratories to perform mandatory analyses for egg products are listed as follows:

(a) Compendium Methods for the Microbiological Examination of Foods, Carl Vanderzant and Don Splittstoesser (Editors), American Public Health Association, 1015 Fifteenth Street, NW, Washington, DC 20005.


(c) FDA Bacteriological Analytical Manual (BAM), AOAC INTERNATIONAL, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2417.

(d) Manual of Analytical Methods for the Analysis of Pesticide Residues in Human and Environmental Samples, EPA 600/9–80–038, U.S. Environmental Protection Agency (EPA) Chemical Exposure Research Branch, EPA Office of Research and Development (ORD), 26 West Martin Luther King Drive, Cincinnati, Ohio 45268.

(e) Official Methods of Analysis of AOAC INTERNATIONAL, Volumes I & II, AOAC INTERNATIONAL, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877–2417.

(f) Standard Methods for the Examination of Dairy Products, American Public Health Association, 1015 Fifteenth Street, NW, Washington, DC 20005.

(g) Standard Methods for the Examination of Water and Wastewater, American Public Health Association (APHA), the American Water Works Association (AWWA) and the Water Pollution Control Federation, AWWA Bookstore, 6666 West Quincy Avenue, Denver, CO 80235.


(i) U.S. Food and Drug Administration, Pesticide Analytical Manuals (PAM), Volumes I and II, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), 200 C Street, SW, Washington, DC 20204 (available from National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161).

§ 94.5 Charges for laboratory service.

The costs for analysis of mandatory egg product samples at Science and Technology Division laboratories shall be paid by annually appropriated and designated funds allocated to the egg products inspection program. The costs for any other mandatory laboratory analyses and testing of an egg product’s identity and condition, necessitated by the Egg Products Inspection
Act, shall also be paid by such program funding.

Subpart B—Voluntary Analyses of Egg Products

§ 94.100 General.

Analyses for voluntary egg product samples may be requested to certify that specifications regarding stated identity, quality, and wholesomeness are met; to test routinely for the presence of Salmonella; and to ensure laboratory quality control with testing activities.

§ 94.101 Definitions.

Words used in the regulations in this subpart in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this part, unless the context requires otherwise, the following terms will be construed to mean:

Certification sample. An egg product sample submitted by an applicant for chemical, physical, or microbiological analyses and tests at a Science and Technology Division laboratory. This voluntary sample is analyzed or tested by the Division’s analyst or scientist to certify that an egg product lot meets applicable specifications for identity, quality, and wholesomeness.

Surveillance sample. This is a 100 gram sample for Salmonella analysis that is drawn by the USDA egg product inspector from each lot of egg product processed at an official plant. This sample may be analyzed by a Science and Technology Division laboratory, or by a laboratory approved and recognized by the Division to analyze for Salmonella in egg products.

Unofficial sample. These samples of egg products are drawn by plant personnel upon the request of plant management. Analyses of these samples are usually conducted for the plant’s refractometer correlation, bacteriological evaluation of production techniques, or quality control of procedures. Official plant or Science and Technology Division laboratories can analyze these samples.

§ 94.102 Analyses available.

A wide array of analyses for voluntary egg product samples is available. Voluntary egg product samples include surveillance, certification, and unofficial samples. The physical and chemical tests for voluntary egg products include analyses for total ash, fat by acid hydrolysis, moisture, salt, protein, beta-carotene, catalase, cholesterol, NEPA color, density, total solids, aflatoxin, daminozide and amitraz residues, BHA, and BHT; alcohol, chlorinated hydrocarbon and fumigant residues, dextrin, heavy and light filth, glucose, glycerol, and gums. In addition, egg products can be analyzed for high sucrose content, pH, heavy metals and minerals, monosodium dihydrogen phosphate, monosodium glutamate, nitrites, oxygen, palatability and odor, phosphorus, propylene glycol, SLS, and zeolex. There are also tests for starch, total sugars, sugar profile, whey, standard plate count, direct microscopic count, Campylobacter, coliforms, presumptive Escherichia coli, Listeria monocytogenes, proteolytic count, psychrotrophic bacteria, Salmonella, Staphylococcus, thermoduric bacteria, and yeast with mold count.

§ 94.103 Analytical methods.

The analytical methods used by the Science and Technology Division laboratories to perform voluntary analyses for egg products shall be the same as listed in §94.4.

§ 94.104 Fees and charges.

(a) The fee charged for any single laboratory analysis of voluntary egg product samples shall be obtained from the schedules of charges in paragraph (a) of §91.37 of this subchapter.

(b) The charge for any requested laboratory analysis not listed shall be based on the standard hourly rate specified in §91.37, paragraph (b).
§ 94.300 General.

Laboratory services of processed poultry products are conducted to derive their analytical attributes used to determine the compliance of the product with applicable specifications.

§ 94.301 Definitions.

Words used in the regulations in this subpart in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this subpart, unless the context requires otherwise, the following terms will be construed to mean:

Dark meat. Refers to the skinless and deboned drumstick, thigh, and back portions of poultry.

Light meat. Refers to the skinless and deboned breast and wing portions of poultry.

Poultry. Any kind of domesticated bird, including, but not limited to, chicken, turkey, duck, goose, pigeon, and guinea.

Poultry product. Any ready-to-cook poultry carcass or part therefrom or any specified poultry food product.

§ 94.302 Analyses available and locations of laboratories.

(a) The Science and Technology Division laboratories will analyze processed poultry products for moisture, fat, salt, protein, nitrites, and added citric acid.

(b) Deboned poultry for roasting will have the individual dark meat, light meat, and skin portions tumbled separately in the natural juices prior to grinding. The skin, light meat, and dark meat portion weight percentages of the total product are determined. The ground skin, ground dark meat, and ground light meat portions will be analyzed separately for moisture, protein, salt, and fat. Moisture to protein ratios will be reported also for the individual portions of poultry.

(c) Canned boned poultry for a variety of USDA programs will be tested as a total can composite of the canned product for moisture, fat, salt, and protein analyses. Additional poultry commodities and related products for specific USDA sponsored programs will be tested for different chemical and physical attributes.

(d) Microbiological analyses, as the Salmonella determination, are available for poultry products.

(e) The majority of analyses for processed poultry products shall be performed at the Science and Technology Division Eastern Laboratory, as indicated in paragraph (e) of § 94.3.

§ 94.303 Analytical methods.

The analytical methods used by the USDA laboratories to perform analyses for processed poultry products are found in the latest edition of the Official Methods of Analysis of AOAC INTERNATIONAL, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877–2417.

§ 94.304 Fees and charges.

(a) The fee charged for any single laboratory analysis of processed poultry products shall be obtained from the schedules of charges in paragraph (a) of § 91.37 of this subchapter.

(b) The laboratory analyses for processed poultry products shall result in an additional fee, found in Table 7 of § 91.37 of this subchapter, for sample preparation or grinding.

(c) The charge for any requested laboratory analysis of processed poultry products not listed shall be based on the standard hourly rate specified in § 91.37 (b) of this subchapter.
§ 97.1 General.

Certificates of protection are issued by the Plant Variety Protection office...
Agricultural Marketing Service, USDA § 97.2

for new, distinct, uniform, and stable varieties of sexually reproduced or tubor propagated plants. Each certificate of plant variety protection certifies that the breeder has the right, during the term of the protection, to prevent others from selling the variety, offering it for sale, reproducing it, importing or exporting it, conditioning it, stocking it, or using it in producing a hybrid or different variety from it, as provided by the Act.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17189, Apr. 4, 1995]

DEFINITIONS

§ 97.2 Meaning of words.

Words used in the regulations in this part in the singular form will import the plural, and vice versa, as the case may demand. The definitions of terms contained in the Act shall apply to such terms when used in this part. As used throughout the regulations in this part, unless the context requires otherwise, the following terms will be construed to mean:

Abandoned application. An application which has not been pursued to completion within the time allowed by the Office or has been voluntarily abandoned.

Act. The Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

Administrator. The Administrator of the Agricultural Marketing Service of the U.S. Department of Agriculture, or any other officer or employee of the Department of Agriculture to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his or her stead.

Applicant. The person who applied for a certificate of plant variety protection.

Application. An application for plant variety protection under the Act.

Assignee. A person to whom an owner assigns his/her rights in whole or in part.

Board. The Plant Variety Protection Board appointed by the Secretary.

Certificate. A certificate of plant variety protection issued under the Act by the Office.

Certified seed. Seed which has been determined by an official seed certifying agency to conform to standards of genetic purity and identity as to variety, which standards have been approved by the Secretary.

Commissioner. The Examiner in Chief of the Office.

Decision and order. Includes the Secretary’s findings of fact; conclusions with respect to all material issues of fact and law, as well as the reasons or basis therefor; and order.

Examiner. An employee of the Plant Variety Protection Office who determines whether a certificate is entitled to be issued. The term shall, in all cases, include the Commissioner.

Foreign application. An application for plant variety protection filed in a foreign country.

Hearing Clerk. The Hearing Clerk, U.S. Department of Agriculture, Washington, DC.

Hearing Officer. An Administrative Law Judge, U.S. Department of Agriculture, or other officer or employee of the Department of Agriculture, duly assigned to preside at a hearing held pursuant to the rules of this part.

Office or Plant Variety Protection Office. The Plant Variety Protection Office, Science and Technology Programs, AMS, USDA.


Owner. A breeder who developed or discovered and developed a variety for which plant variety protection may be applied for under the Act, or a person to whom the rights to such variety have been assigned or transferred.

Person. An individual, partnership, corporation, association, government agency, or other business or governmental entity.

Secretary. The Secretary of Agriculture of the United States or any other officer or employee of the U.S. Department of Agriculture, to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated to act in his or her stead.

Seed certifying agency. It shall be defined as set forth in the Federal Seed Act (53 Stat. 1275).

Sale for other than seed purposes. The transfer of title to and possession of the seed by the owner to a grower or other person, for reproduction for the
§ 97.3 Plant Variety Protection Board.

(a) The Plant Variety Protection Board shall consist of 14 members appointed for a 2-year term. The Board shall be appointed every 2 years and shall consist of individuals who are experts in various areas of varietal development. The membership of the Board, which shall include farmer representation, shall be drawn approximately equally from the private or seed industry sector and from the government or public sector. No member shall be eligible to act on any matter involving any appeal or questions under section 44 of the Act, in which the member or his or her employer has a direct financial interest.

(b) The functions of the Board are to:

(1) Advise the Secretary concerning adoption of rules and regulations to facilitate the proper administration of the Act;

(2) Make advisory decisions on all appeals from the examiner or Commissioner;

(3) Advise the Secretary on the declaration of a protected variety open to use in the public interest; and

(4) Advise the Secretary on any other matters under the regulations in this part.

(c) The proceedings of the Board shall be conducted in accordance with the Federal Advisory Committee Act, Administrative Regulations of the U.S. Department of Agriculture (7 CFR part 25), and such additional operating procedures as are adopted by members of the Board.

§ 97.5 General requirements.

(a) Protection under the Act shall be afforded only as follows:

(1) Nationals and residents of the United States shall be eligible to receive all of the protection under the Act.

(2) Nationals and residents of Member States of the International Union for the Protection of New Varieties of Plants (including states which are members of an intergovernmental organization which is a UPOV member) shall be eligible to receive the same protection under the Act as is provided to nationals of the United States.

(3) Persons who are not entitled to protection under paragraph (a)(1) or (2) of this section, and who are nationals of a foreign state which is not a member of the International Union for the Protection of New Varieties of Plants, shall be entitled to only so much of the protection provided under the Act, as is afforded by such foreign state to nationals of the United States, for the same genus and species under the laws of such foreign state in effect at the time that the application for protection under the Act is filed, except where further protection under the Act must be provided in order to avoid the violation of a treaty to which the United States is a party.

(b) Applications for certificates shall be made to the Plant Variety Protection Office. An application shall consist of:

(1) A completed application form, except that the section specifying that seed of the variety shall be sold by variety name only, as a class of certified seed, need not be completed at the time of application.

(2) A completed set of the exhibits, as specified in the application form, unless the examiner waives submission of certain exhibits as unnecessary, based on other claims and evidence presented in connection with the application.

(3) Language and legibility: (i) Applications and exhibits must be in the English language and legibly written, typed or printed.

(ii) Any interlineation, erasure, cancellation, or other alteration must be made in permanent ink before the application is signed and shall be clearly initialed and dated by the applicant to indicate knowledge of such fact at the time of signing.
§ 97.7 Deposit of Voucher Specimen.

(a) Voucher specimen types. As regards the deposit of voucher specimen material for purposes of plant variety protection applications under 7 U.S.C. 2321 et seq., the term voucher specimen shall include material that is capable of self-replication either directly or indirectly. Representative examples include seeds, plant tissue cells, cell lines, and plots of vegetative material of self-incompatible parental lines of hybrids. Seed samples should not be treated with chemicals or coatings.

(b) Need to make a deposit. Applications for plant variety protection require deposit of a voucher specimen of the variety. The deposit shall be acceptable if made in accordance with these regulations. Sample packages shall meet the packaging and deposit requirements of the depository. Samples and correspondence about samples shall be identified, minimally, by:

1. The application number assigned by the Office;
2. The crop kind, genus and species, and variety denomination; and
3. The name and address of the depositor.

(c) Acceptable depository. A deposit shall be recognized for the purposes of these regulations if made in:

(1) A declaration that at least 3,000 seeds of the viable basic seed required to reproduce the variety will be deposited in a public depository approved by the Commissioner and will be maintained for the duration of the certificate; or
(2) With the application for a tuber propagated variety, a declaration that a viable cell culture will be deposited in a public depository approved by the Commissioner and will be maintained for the duration of the certificate; or
(3) With the application for a hybrid from self-incompatible parents, a declaration that a plot of vegetative material for each parent will be established in a public depository approved by the Commissioner and will be maintained for the duration of the certificate.

§ 97.6 Application for certificate.

(a) An application for a plant variety protection certificate shall be signed by, or on behalf, of the applicant.

(b) The application shall state the full name, including the full first name and the middle initial or name, if any, and the capacity of the person executing it.

(c) The fees for filing an application, and search or examination, shall be submitted with the application in accordance with §§97.175 through 97.178.

(d) The applicant shall submit with the application:

(1) A declaration that at least 3,000 seeds of the viable basic seed required to reproduce the variety will be deposited in a public depository approved by the Commissioner and will be maintained for the duration of the certificate; or
(2) With the application for a tuber propagated variety, a declaration that a viable cell culture will be deposited in a public depository approved by the Commissioner and will be maintained for the duration of the certificate; or
(3) With the application for a hybrid from self-incompatible parents, a declaration that a plot of vegetative material for each parent will be established in a public depository approved by the Commissioner and will be maintained for the duration of the certificate.

(1) The National Center for Genetic Resources Preservation, ARS, USDA, 1111 South Mason Street, Fort Collins, CO 80521–4500, or

(2) Any other depository recognized to be suitable by the Office. Suitability will be determined by the Commissioner on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for plant variety protection purposes. The Commissioner may seek the advice of impartial consultants on the suitability of a depository. The depository must:

(i) Have a continuous existence;

(ii) Exist independent of the control of the depositor;

(iii) Possess the staff and facilities sufficient to examine the viability and quantity of a deposit, and store the deposit in a manner which ensures that it is kept viable and uncontaminated;

(iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;

(v) Be impartial and objective;

(vi) Refrain from distributing samples while the application is being examined and during the term of protection but, after control of the sample is transferred by the Office to the depository, furnish samples of the deposited material in an expeditious and proper manner;

(vii) Have the capability to destroy samples or return samples to the Office when requested by the Office; and

(viii) Promptly notify the Office of low viability or low quantity of the sample.

(3) A depository seeking status under paragraph (c)(2) of this section must direct a communication to the Commissioner which shall:

(i) Indicate the name and address of the depository to which the communication relates;

(ii) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (c)(2) of this section, including information on its legal status, scientific standing, staff, and facilities;

(iii) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;

(iv) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds; and

(v) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (c)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

(4) A depository having status under paragraph (c)(2) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material by directing a communication to the Commissioner in accordance with paragraph (c)(3) of this section. If a previous communication under paragraph (c)(3) of this section is of record, items in common with the previous communication may be incorporated by reference.

(5) Once a depository is recognized to be suitable by the Commissioner or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Journal of the Plant Variety Protection Office or by other methods typically used for dissemination of information related to the procedures of the Office.

(d) Time of making an original deposit. An original deposit of materials for seed-reproduced plants shall be made within three months of the filing date of the application or prior to issuance of the certificate, whichever occurs first. A waiver may be granted for good cause, such as delays in obtaining a phytosanitary certificate for the importation of voucher sample materials. When the original deposit is made, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the voucher specimen material which is deposited is the variety specifically identified in the application as filed. Such statement must be filed in the application and must contain the identifying information listed in paragraph (b) of this section and:

(1) The name and address of the depository;

(2) The date of deposit;
§ 97.8 Specimen requirements.

(a) The applicant may be required by the examiner to furnish representative specimens of the variety, or its flower, fruit, or seeds, in a quantity and at a specified stage of growth, as may be necessary to verify the statements in the application. Such specimens shall be packed and forwarded in conformity with instructions furnished by the examiner. If the applicant requests the examiner to inspect plants in the field before a final decision is made, all such inspection costs shall be borne by the applicant by payment of fees sufficient to reimburse the Office for all costs, including travel, per diem or subsistence, and salary.

(b) Plant specimens submitted in support of an application shall not be removed from the Office except by an employee of the Office or other person authorized by the Secretary.

(c) Plant specimens submitted to the Office shall, except as provided below, and upon request, be returned to the applicant at his or her expense after the specimens have served their intended purpose. The Commissioner, upon a finding of good cause, may require that certain specimens be retained in the Office for indefinite periods of time. Specimens which are not returned or not retained as provided above shall be destroyed.

§ 97.8 Specimen requirements.

(a) The applicant may be required by the examiner to furnish representative specimens of the variety, or its flower, fruit, or seeds, in a quantity and at a specified stage of growth, as may be necessary to verify the statements in the application. Such specimens shall be packed and forwarded in conformity with instructions furnished by the examiner. If the applicant requests the examiner to inspect plants in the field before a final decision is made, all such inspection costs shall be borne by the applicant by payment of fees sufficient to reimburse the Office for all costs, including travel, per diem or subsistence, and salary.

(b) Plant specimens submitted in support of an application shall not be removed from the Office except by an employee of the Office or other person authorized by the Secretary.

(c) Plant specimens submitted to the Office shall, except as provided below, and upon request, be returned to the applicant at his or her expense after the specimens have served their intended purpose. The Commissioner, upon a finding of good cause, may require that certain specimens be retained in the Office for indefinite periods of time. Specimens which are not returned or not retained as provided above shall be destroyed.
§ 97.9 Drawings and photographs.

(a) Drawings or photographs submitted with an application shall disclose the distinctive characteristics of the variety.

(b) Drawings or photographs shall be in color when color is a distinguishing characteristic of the variety, and the color shall be described by use of Nickerson’s or other recognized color chart.

(c) Drawings should be sent flat, or may be sent in a suitable mailing tube, in accordance with instructions furnished by the Commissioner.

(d) Drawings or photographs submitted with an application shall be retained by the Office as part of the application file.

§ 97.10 Parts of an application to be filed together.

All parts of an application, including exhibits, should be submitted to the Office together, otherwise, each part shall be accurately and clearly referenced to the application.

§ 97.11 Application accepted and filed when received.

(a) An application, if materially complete when initially submitted, shall be accepted and filed to await examination.

(b) If any part of an application is so incomplete, or so defective that it cannot be handled as a completed application for examination, as determined by the Commissioner, the applicant will be notified. The application will be held a maximum of 3 months for completion. Applications not completed at the end of the prescribed period will be considered abandoned. The application fee in such cases will not be refunded.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17189, Apr. 4, 1995]

§ 97.12 Number and filing date of an application.

(a) Applications shall be numbered and dated in sequence in the order received in the Office. Applicants will be informed in writing as soon as practicable of the number and effective filing date of the application.

(b) An applicant may claim the benefit of the filing date of a prior foreign application in accordance with section 55 of the Act. A certified copy of the foreign application shall be filed upon request made by the examiner. If a foreign application is not in the English language, an English translation, certified as accurate by a sworn or official translator, shall be submitted with the application.

§ 97.13 When the owner is deceased or legally incapacitated.

In case of the death of the owner or if the owner is legally incapacitated, the legal representative (executor, administrator, or guardian) or heir or assignee of the deceased owner may sign as the applicant. If an applicant dies between the filing of his or her application and the granting of a certificate thereon, the certificate may be issued to the legal representative, heir, or assignee, upon proper intervention.

§ 97.14 Joint applicants.

(a) Joint owners shall file a joint application by signing as joint applicants.

(b) If an application for certificate is made by two or more persons as joint owners, when they were not in fact joint owners, the application shall be amended prior to issuance of a certificate by filing a corrected application, together with a written explanation signed by the original applicants. Such statement shall also be signed by the assignee, if any.

(c) If an application has been made by less than all the actual joint owners, the application shall be amended by filing a corrected application, together with a written explanation, signed by all of the joint owners. Such statement shall also be signed by the assignee, if any.

(d) If a joint owner refuses to join in an application or cannot be found after diligent effort, the remaining owner may file an application on behalf of him or herself and the missing owner. Such application shall be accompanied by a written explanation and shall state the last known address of the missing owner. Notice of the filing of the application shall be forwarded by the Office to the missing owner at the last known address. If such notice is returned to the Office undelivered, or if
Agricultural Marketing Service, USDA

§ 97.19 Publication of pending applications.

Information relating to pending applications shall be published in the Official Journal periodically as determined by the Commissioner to be necessary in the public interest. With respect to each application, the Official Journal shall show:

(a) Application number and date of filing;

(b) The name of the variety or temporary designation;

(c) A certificate of protection issued if applicable;

(d) The names of the joint owners or the assignee if applicable;

(e) Where applicable, the names of the assignees or the legal owner.

§ 97.18 Applications handled in confidence.

(a) Pending applications shall be handled in confidence. Except as provided below, no information may be given by the Office respecting the filing of an application, the pendency of any particular application, or the subject matter of any particular application. Also, nor will access be given to or copies furnished of any pending application or papers relating thereto, without written authority of the applicant, or his or her assignee or attorney or agent. Exceptions to the above may be made by the Commissioner in accordance with 5 U.S.C. 552 and §1.4 of this title, and upon a finding that such action is necessary to the proper conduct of the affairs of the Office, or to carry out the provisions of any Act of Congress, or as provided in sections 56 or 57 of the Act and §97.19.

(b) Abandoned applications shall not be open to public inspection. However, if an abandoned application is directly referred to in an issued certificate and is available, it may be inspected or copies obtained by any person on written request, and with written authority received from the applicant. Abandoned applications shall not be returned.

(c) Decisions of the Commissioner on abandoned applications not otherwise open to public inspection (see paragraph (b) of this section) may be published or made available for publication at the Commissioner's discretion. When it is proposed to release such a decision, the applicant shall be notified directly or through the attorney or agent of record, and a time, not less than 30 days, shall be set for presenting objections.

§ 97.17 Papers of completed application to be retained.

The papers submitted with a completed application shall be retained by the Office except as provided in §97.23(c). After issuance of a certificate of protection the Office will furnish copies of the application and related papers to any person upon payment of the specified fee.

§ 97.16 Amendment by applicant.

An application may be amended before or after the first examination and action by the Office, after the second or subsequent examination or reconsideration as specified in §97.107, or when and as specifically required by the examiner. Such amendment may include a specification that seed of the variety be sold by variety name only as a class of certified seed, if not previously specified or if previously declined. Once an affirmative specification is made, no amendment to reverse such a specification will be permitted unless the variety has not been sold and labeled or publication made in any manner that the variety is to be sold by variety name, only as a class of certified seed.

§ 97.15 Assigned varieties and certificates.

In case the whole or a part interest in a variety is assigned, the application shall be made by the owner or one of the persons identified in §97.13. However, the certificate may be issued to the assignee, or jointly to the owner and the assignee, when a part interest in a variety is assigned.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17189, Apr. 4, 1995]

§ 97.14 Amendments to applications.

An application may be amended before or after the first examination and action by the Office, as provided in §97.107, or when and as specifically required by the examiner. Such amendment may include a specification that seed of the variety be sold by variety name only as a class of certified seed, if not previously specified or if previously declined. Once an affirmative specification is made, no amendment to reverse such a specification will be permitted unless the variety has not been sold and labeled or publication made in any manner that the variety is to be sold by variety name, only as a class of certified seed.

§ 97.13 Applications handled in confidence.

(a) Pending applications shall be handled in confidence. Except as provided below, no information may be given by the Office respecting the filing of an application, the pendency of any particular application, or the subject matter of any particular application. Also, nor will access be given to or copies furnished of any pending application or papers relating thereto, without written authority of the applicant, or his or her assignee or attorney or agent. Exceptions to the above may be made by the Commissioner in accordance with 5 U.S.C. 552 and §1.4 of this title, and upon a finding that such action is necessary to the proper conduct of the affairs of the Office, or to carry out the provisions of any Act of Congress, or as provided in sections 56 or 57 of the Act and §97.19.

(b) Abandoned applications shall not be open to public inspection. However, if an abandoned application is directly referred to in an issued certificate and is available, it may be inspected or copies obtained by any person on written request, and with written authority received from the applicant. Abandoned applications shall not be returned.

(c) Decisions of the Commissioner on abandoned applications not otherwise open to public inspection (see paragraph (b) of this section) may be published or made available for publication at the Commissioner's discretion. When it is proposed to release such a decision, the applicant shall be notified directly or through the attorney or agent of record, and a time, not less than 30 days, shall be set for presenting objections.

§ 97.12 Papers of completed application to be retained.

The papers submitted with a completed application shall be retained by the Office except as provided in §97.23(c). After issuance of a certificate of protection the Office will furnish copies of the application and related papers to any person upon payment of the specified fee.
§ 97.20 Abandonment for failure to respond within the time limit.

(a) Except as otherwise provided in §97.104, if an applicant fails to advance actively his or her application within 30 days after the date when the last request for action was mailed to the applicant by the Office, or within such longer time as may be fixed by the Commissioner, the application shall be deemed abandoned. The application fee in such cases will not be refunded.

(b) The submission of an amendment to the application, not responsive to the last request by the Office for action, and any proceedings relative thereto, shall not operate to save the application from abandonment.

(c) When the applicant makes a bona fide attempt to advance the application, and is in substantial compliance with the request for action, but has inadvertently failed to comply with some procedural requirement, opportunity to comply with the procedural requirement shall be given to the applicant before the application shall be deemed abandoned. The Commissioner may set a period, not less than 30 days, to correct any deficiency in the application.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17189, Apr. 4, 1995; 61 FR 248, Jan. 4, 1996]

§ 97.21 Extension of time for a reply.

The time for reply by an applicant to a request by the Office for certain action, shall be extended by the Commissioner only for good and sufficient cause, and for a specified reasonable time. A request for extension and appropriate fee shall be filed on or before the specified time for reply. In no case shall the mere filing of a request for extension require the granting of an extension or state the time for reply.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17189, Apr. 4, 1995]

§ 97.22 Revival of an application abandoned for failure to reply.

An application abandoned for failure on the part of the applicant to advance actively his or her application to its completion, in accordance with the regulations in this part, may be revived as a pending application within 3 months of such abandonment, upon a finding by the Commissioner that the failure was inadvertent or unavoidable and without fraudulent intent. A request to revive an abandoned application shall be accompanied by a written statement showing the cause of the failure to respond, a response to the last request for action, and by the specified fee.

[58 FR 42435, Aug. 9, 1993, as amended at 61 FR 248, Jan. 4, 1996]

§ 97.23 Voluntary withdrawal and abandonment of an application.

(a) An application may be voluntarily withdrawn or abandoned by submitting to the Office a written request for withdrawal or abandonment, signed by the applicant or his or her attorney or agent of record, if any, or the assignee of record, if any.

(b) An application which has been voluntarily abandoned may be revived within 3 months of such abandonment by the payment of the prescribed fee and a showing that the abandonment occurred without fraudulent intent.

(c) An original application which has been voluntarily withdrawn shall be returned to the applicant and may be reconsidered only by resubmission and payment of a new application fee.

(d) Transitional provision. An applicant whose application is pending on April 4, 1995, may notify the Plant Variety Protection Office in writing that he or she wishes to withdraw the application and refile it under the Plant Variety Protection Act as amended in
Agricultural Marketing Service, USDA

§ 97.104 Application or certificate abandoned.

(a) After the notice of allowance has been issued, the prescribed fee is received by the Office, and the applicant has clearly specified whether or not the variety shall be sold by variety name only as a class of certified seed, the certificate shall be promptly issued. Once an election is made and a certificate issued specifying that seed of the variety shall be sold by variety name only as a class of certified seed, no waiver of such rights shall be permitted by amendment of the certificate.

(b) The certificate shall be delivered or mailed to the owner.

§ 97.103 Issuance of a certificate.

(a) When the notice of allowance has been issued, the prescribed fee is received by the Office, and the applicant has clearly specified whether the variety shall be sold by variety name only as a class of certified seed, the certificate shall be promptly issued.

(b) On request by the Office, the owner shall replenish the viable basic seed sample of the variety and shall pay the handling fee for replenishment. Upon request, the sample of seed which has been replaced shall be returned to the owner, otherwise it shall be destroyed. Failure to replenish viable basic seed within 3 months from the date of request shall result in the certificate being regarded as abandoned. No sooner than 1 year after the date of such request, notices of abandoned certificates shall be published in the Official Journal, indicating that the variety has become open for use by the public and, if previously specified to be sold by variety name as “certified seed only,” that such restriction no longer applies.

(c) If the allowance fee, the viable basic seed sample or the fee for delayed payment are submitted within 9 months of the final due date, it may be accepted by the Commissioner as though no abandonment had occurred. For good cause, the Commissioner may extend for a reasonable time the period for submitting a viable basic seed sample before declaring the certificate abandoned.

(d) A certificate may be voluntarily abandoned by the applicant or his or
§ 97.105 Denial of an application.

(a) If the variety is found by the examiner to be not new, distinct, uniform, and stable, the application shall be denied.

(b) In denying an application, the examiner shall cite the reasons the application was denied. When a reason involves the citation of certain material which is complex, the particular part of the material relied on shall be designated as nearly as practicable. The pertinence of each reason, if not obvious, shall be clearly explained.

(c) If prior domestic certificates are cited as a reason for denial, their numbers and dates and the names of the owners shall be stated. If prior foreign certificates or rights are cited, as a reason for denial, their nationality or country, numbers and dates, and the names of the owners shall be stated, and such other data shall be furnished, as may be necessary to enable the applicant to identify the cited certificates or rights.

(d) If printed publications are cited as a reason for denial, the author (if any), title, date, pages or plates, and places of publication, or place where a copy can be found shall be given.

(e) When a denial is based on facts known to the examiner, and upon request by the applicant, the denial shall be supported by the affidavit of the examiner. Such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.

(f) Abandoned applications may not be cited as reasons for denial.

§ 97.106 Reply by applicant; request for reconsideration.

(a) After an adverse action by the examiner, the applicant may respond to the denial and may request a reconsideration, with or without amendment of his or her application. Any amendment shall be responsive to the reason or reasons for denial specified by the examiner.

(b) To obtain a reconsideration, the applicant shall submit a request for reconsideration in writing and shall specifically point out the alleged errors in the examiner’s action. The applicant shall respond to each reason cited by the examiner as the basis for the adverse action. A request for reconsideration of a denial based on a faulty form or procedure may be held in abeyance by the Commissioner until the question of the variety being new, distinct, uniform, and stable is settled.

(c) An applicant’s request for a reconsideration must be a bona fide attempt to advance the case to final action. A general allegation by the applicant that certain language which he or she cites in the application or amendment thereto establishes the variety is new, distinct, uniform, and stable without specifically explaining how the language distinguishes the alleged new, distinct, uniform, and stable variety from the material cited by the examiner shall not be grounds for a reconsideration.

§ 97.107 Reconsideration and final action.

If, upon reconsideration, the application is denied by the Commissioner, the applicant shall be notified by the Commissioner of the reason or reasons for denial in the same manner as after the first examination. Any such denial shall be final unless appealed by the applicant to the Secretary. If the denial is sustained by the Secretary on appeal, the denial shall be final subject to appeal to the courts, as provided in § 97.500.
§ 97.108 Amendments after final action.

(a) After a final denial by the Commissioner, amendments to the application may be made to overcome the reason or reasons for denial. The acceptance or refusal of any such amendment by the Office and any proceedings relative thereto shall not relieve the applicant from the time limit set for an appeal or an abandonment for failure to reply.

(b) No amendment of the application can be made in an appeal proceeding. After decision on appeal, amendments can only be made in accordance with the decision.

[58 FR 42435, Aug. 9, 1993, as amended at 70 FR 28785, May 19, 2005]

CORRECTION OF ERRORS IN CERTIFICATE

§ 97.120 Corrected certificate—office mistake.

When a certificate is incorrect because of a mistake in the Office, the Commissioner may issue a corrected certificate stating the fact and nature of such mistake, under seal, without charge, to be issued to the owner and recorded in the records at the Office.

§ 97.121 Corrected certificate—applicant's mistake.

When a certificate is incorrect because of a mistake by the applicant of a clerical or typographical nature, or of minor character, or in the description of the variety (including, but not limited to, the use of a misleading variety name or a name assigned to a different variety of the same species), and the mistake is found by the Commissioner to have occurred in good faith and does not require a further examination, the Commissioner may, upon payment of the required fee and return of the original certificate, correct the certificate by issuing a corrected certificate, in accordance with section 85 of the Act. If the mistake requires a reexamination, a correction of the certificate shall be dependent on the results of the reexamination.

REISSUANCE OF CERTIFICATE

§ 97.122 Certified seed only election.

When an owner elects after a certificate is issued to sell the protected variety by variety name only as a class of certified seed, a new certificate may be issued upon return of the original certificate to the Office and payment of the appropriate fee.

ASSIGNMENTS AND RECORDING

§ 97.130 Recording of assignments.

(a) Any assignment of an application for a certificate, or of a certificate of plant variety protection, or of any interest in a variety, or any license or grant and conveyance of any right to use of the variety, may be submitted for recording in the Office in accordance with section 101 of the Act (7 U.S.C. 2531).

(b) No instrument shall be recorded which is not in the English language or which does not identify the certificate or application to which it relates.

(c) An instrument relating to title of a certificate shall identify the certificate by number and date, the name of the owner, and the name of the variety as stated in the certificate. An instrument relating to title of an application shall identify an application by number and date of filing, the name of the owner, and the name of the variety as stated in the application.

(d) If an assignment is executed concurrently or subsequent to the filing of an application, but before its number and filing date are ascertained, the assignment shall identify the application by the date of the application, the name of the owner, and the name of the variety.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17190, Apr. 4, 1995]

§ 97.131 Conditional assignments.

Assignments recorded in the Office are regarded as absolute assignments for Office purposes until canceled in writing by both parties to the assignment or by a decree of a court of competent jurisdiction. The Office shall not determine whether conditions precedent to the assignment, such as the payment of money, have been fulfilled.
§ 97.132 Assignment records open to public inspection.

(a) Assignment records relating to original or amended certificates shall be open to public inspection and copies of any recorded document may be obtained upon payment of the prescribed fee.

(b) Assignment records relating to any pending or abandoned application shall not be available for inspection except to the extent that pending applications are published as provided in section 57 of the Act and § 97.19, or where necessary to carry out the provisions of any Act of Congress. Copies of assignment records and information on pending or abandoned applications shall be obtainable only upon written authority of the applicant or his or her assignee, or attorney or agent of record, or where necessary to carry out the provisions of any Act of Congress. An order for a copy of an assignment shall give the proper identification of the assignment.

MARKING OR LABELING PROVISIONS

§ 97.140 After filing.

Upon filing an application for protection of a variety and payment of the prescribed fee, the owner, or his or her designee, may label the variety or containers of the seed of the variety or plants produced from such seed, substantially as follows: “Unauthorized Propagation Prohibited—(Unauthorized Seed Multiplication Prohibited)—U.S. Variety Protection Applied For.” Where applicable, “PVPA 1994” or “PVPA 1994—Unauthorized Sales for Reproductive Purposes Prohibited” may be added to the notice.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17190, Apr. 4, 1995; 61 FR 248, Jan. 4, 1996]

§ 97.142 For testing or increase.

An owner who contemplates filing an application and releases for testing or increase, seed of the variety or reproducible plant material of the variety, may label such plant material or containers of the seed or plant material substantially as follows: “Unauthorized Propagation Prohibited—For Testing (or Increase) Only.”

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17190, Apr. 4, 1995]

§ 97.143 Certified seed only.

(a) Upon filing an application, or amendment thereto, specifying seed of the variety is to be sold by variety name only as a class of certified seed, the owner, or his or her designee, may label containers of seed of the variety substantially as follows: “Unauthorized Propagation Prohibited—U.S. Variety Protection Applied for Specifying That Seed of This Variety Is To Be Sold By Variety Name Only as a Class of Certified Seed.”

(b) An owner who has received a certificate specifying that a variety is to be sold by variety name only, as a class of certified seed, may label containers of the seed of the variety substantially as follows: “Unauthorized Propagation Prohibited—To Be Sold By Variety Name Only as a Class of Certified Seed—U.S. Protected Variety.”

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17190, Apr. 4, 1995]

§ 97.144 Additional marking or labeling.

Additional clarifying information that is not false or misleading may be used by the owner, in addition to the above markings or labeling.

ATTORNEYS AND AGENTS

§ 97.150 Right to be represented.

An applicant may actively advance an application or may be represented by an attorney or agent authorized in writing.
§ 97.151 Authorization.

Only attorneys or agents specified by the applicant shall be allowed to inspect papers or take action of any kind, on behalf of the applicant, in any pending application or proceedings.

§ 97.152 Revocation of authorization; withdrawal.

An authorization of an attorney or agent may be revoked by an applicant at any time, and an attorney or agent may withdraw, upon application to the Commissioner. When the authorization is so revoked, or the attorney or agent has so withdrawn, the Office shall inform the interested parties and shall thereafter communicate directly with the applicant, or with such other attorney or agent as the applicant may appoint. An assignment will not of itself operate as a revocation of authorization previously given, but the assignee of the entire interest may revoke previous authorizations and be represented by an attorney or agent of his or her own selection.

§ 97.153 Persons recognized.

Unless specifically authorized as provided in § 97.151, no person shall be permitted to file or advance applications before the Office on behalf of another person.

§ 97.154 Government employees.

Officers and employees of the United States who are disqualified by statute (18 U.S.C. 203 and 205) from practicing as attorneys or agents in proceedings or other matters before government departments or agencies, shall not be eligible to represent applicants, except officers and employees whose official duties require the preparation and prosecution of applications for certificates of variety protection.

§ 97.155 Signatures.

Every document filed by an attorney or agent representing an applicant or party to a proceeding in the Office shall bear the signature of such attorney or agent, except documents which are required to be signed by the applicant or party.

§ 97.156 Addresses.

Attorneys and agents practicing before the Plant Variety Protection Office shall notify the Office in writing of any change of address. The Office shall address letters to any person at the last address received.

§ 97.157 Professional conduct.

Attorneys and agents appearing before the Office shall conform to the standards of ethical and professional conduct, generally applicable to attorneys appearing before the courts of the United States.

FEES AND CHARGES

§ 97.175 Fees and charges.

The following fees and charges apply to the services and actions specified below:

(a) Filing the application and notifying the public of filing—$518.00.
(b) Search or examination—$3,864.00.
(c) Submission of new application data, after notice of allowance, prior to issuance of certificate—$432.00.
(d) Allowance and issuance of certificate and notifying public of issuance—$768.00.
(e) Revive an abandoned application—$518.00.
(f) Reproduction of records, drawings, certificates, exhibits, or printed material (cost per page of material)—$1.80.
(g) Authentication (each page)—$1.80.
(h) Correcting or re-issuance of a certificate—$518.00.
(i) Recording an assignment, any revision of an assignment, or withdrawal or revocation of an assignment (per certificate or application)—$41.00.
(j) Copies of 8 × 10 photographs in color—$41.00.
(k) Additional fee for reconsideration—$518.00.
(l) Additional fee for late payment—$41.00.
(m) Fee for handling replenishment seed sample (applicable only for certificates issued after June 20, 2005)—$38.00.
(n) Additional fee for late replenishment of seed—$41.00.
(o) Filing a petition for protest proceeding—$4,118.00.
(p) Appeal to Secretary (refundable if appeal overturns the Commissioner’s decision)—$4,942.00.
§ 97.176 Fees payable in advance.

Fees and charges shall be paid at the time of making application or at the time of submitting a request for any action by the Office for which a fee or charge is payable and established in this part.

§ 97.177 Method of payment.

Checks or money orders shall be made payable to the Treasurer of the United States. Remittances from foreign countries must be payable and immediately negotiable in the United States for the full amount of the prescribed fee. Money sent by mail to the Office shall be sent at the sender’s risk.

§ 97.178 Refunds.

Money paid by mistake or excess payments shall be refunded, but a mere change of plans after the payment of money, as when a party decides to withdraw an application or to withdraw an appeal, shall not entitle a party to a refund. However, the examination or search fee shall be refunded if an application is voluntarily abandoned pursuant to §97.23(a) before a search or examination has begun. Amounts of $1 or less shall not be refunded unless specifically demanded.

§ 97.179 Copies and certified copies.

(a) Upon request, copies of applications, certificates, or of any records, books, papers, drawings, or photographs in the custody of the Office and which are open to the public, will be furnished to persons entitled thereto, upon payment of the prescribed fee.

(b) Upon request, copies will be authenticated by imprint of the seal of the Office and certified by the official, authorized by the Commissioner upon payment of the prescribed fee.

AVAILABILITY OF OFFICE RECORDS

§ 97.190 When open records are available.

Copies of records, which are open to the public and in the custody of the Office, may be examined in the Office during regular business hours upon approval by the Commissioner.

PROTEST PROCEEDINGS

§ 97.200 Protests to the grant of a certificate.

Opposition on the part of any person to the granting of a certificate shall be permitted while an application is pending and for a period not to exceed 5 years following the issuance of a certificate.

§ 97.201 Protest proceedings.

(a) Opposition shall be made by submitting in writing a petition for protest proceedings, which petition shall be supported by affidavits and shall show the reason or reasons for opposing the application or certificate. The petition and accompanying papers shall be filed in duplicate. If it appears to an examiner that a variety involved in a pending application or covered by a certificate may not be or may not have been entitled to protection under the Act, a protest proceeding may be permitted by the Commissioner.

(b) One copy of the petition and accompanying papers shall be served by the Office upon the applicant or owner, or his or her attorney or agent of record.

(c) An answer, by the applicant or owner of the certificate, or his or her assignee, in response to the petition, may be filed with the Commissioner within 60 days after service of the petition, upon such person. If no answer is filed within said period, the Commissioner shall decide the matter on the basis of the allegations set forth in the petition.
(d) If the petition and answer raise any issue of fact needing proof, the Commissioner shall afford each of the parties a period of 60 days in which to file sworn statements or affidavits in support of their respective positions.

(e) As soon as practicable after the petition or the petition and answer are filed, or after the expiration of any period for filing sworn statements or affidavits, the Commissioner shall issue a decision as to whether the protests are upheld or denied. The Commissioner may, following the protest proceeding, cancel any certificate issued and may grant another certificate for the same variety to a person who proves to the satisfaction of the Commissioner, that he or she is the breeder or discoverer. The decision shall be served upon the parties in the manner provided in §97.403.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17190, Apr. 4, 1995]

§ 97.301 Commissioner’s answer.

(a) The Commissioner may, within such time as may be directed by the Secretary, furnish a written statement to the Secretary in answer to the appellant’s petition, including such explanation of the reasons for the action as may be necessary and supplying a copy to the appellant.

(b) Within 20 days from the date of such answer, the appellant may file a reply statement directed only to such new points of argument as may be raised in the Commissioner’s answer.

§ 97.302 Decision by the Secretary.

(a) The Secretary, after receiving the advice of the Board, may affirm or reverse the decision of the Commissioner, in whole or in part.

(b) Should the decision of the Secretary include an explicit statement that a certificate be allowed, based on an amended application, the applicant shall have the right to amend his or her application in conformity with such statement and such decision shall be binding on the Commissioner.

§ 97.303 Action following the decision.

(a) Copies of the decision of the Secretary shall be served upon the appellant and the Commissioner in the manner provided in §97.403.

(b) When an appeal petition is dismissed, or when the time for appeal to the courts pursuant to the Act has expired and no such appeal or civil action has been filed, proceedings in the appeal shall be considered terminated as of the dismissal or expiration date, except in those cases in which the nature of the decision requires further action by the Commissioner. If the decision of the Secretary is appealed or a civil action has been filed pursuant to the Act, the decision of the Secretary will be stayed pending the outcome of the court appeal or civil action.

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17190, Apr. 4, 1995]
§ 97.400 Extensions of time.

Upon a showing of good cause, extensions of time not otherwise provided for may be granted by the Commissioner or, if an appeal has been filed by the Secretary for taking any action required in any priority, protest, or appeal proceeding.

§ 97.401 Miscellaneous provisions.

(a) Petitions for reconsideration or modification of the decision of the Commissioner in priority or protest proceedings shall be filed within 20 days after the date of the decision.

(b) The Commissioner may consider on petition any matter involving abuse of discretion in the exercise of an examiner’s authority, or such other matters as may be deemed proper to consider. Any such petition, if not filed within 20 days from the decision complained of, may be dismissed as untimely.

§ 97.402 Service of papers.

(a) Every paper required to be served on opposing parties and filed in the Office in any priority, protest, or appeal proceeding, must be served by the Secretary in the manner provided in § 97.403.

(b) The requirement in certain sections that a specified paper shall be served includes a requirement that all related supporting papers shall also be served. Proof of such service upon other parties to the proceeding must be made before the supporting papers will be considered by the Commissioner or Secretary.

§ 97.403 Manner of service.

Service of any paper under this part must be on the attorney or agent of the party if there be such, or on the party if there is no attorney or agent, and may be made in any of the following ways:

(a) By mailing a copy of the paper to the person served by certified mail, with the date of the return receipt controlling the date of service;

(b) By leaving a copy at the usual place of business of the person served with someone in his or her employ;

(c) When the person served has no usual place of business, by leaving a copy at his or her home with a member of the family over 14 years of age and of discretion; and

(d) Whenever it shall be found by the Commissioner or Secretary that none of the above modes of serving the paper is practicable, service may be by notice, published once in the Office Journal.

§ 97.500 Appeal to U.S. Courts.

Any applicant dissatisfied with the decision of the Secretary on appeal may appeal to the U.S. Court of Customs and Patent Appeals or the U.S. Courts of Appeals, or institute a civil action in the U.S. District Court as set forth in the Act. In such cases, the appellant or plaintiff shall give notice to the Secretary, state the reasons for appeal or civil action, and obtain a certified copy of the record. The certified copy of the record shall be forwarded to the Court by the Plant Variety Protection Office on order of, and at the expense of the appellant or plaintiff.  

[58 FR 42435, Aug. 9, 1993, as amended at 60 FR 17190, Apr. 4, 1995]

§ 97.600 Rules of practice.

Any proceedings instituted under section 128 of the Act for false marking shall be conducted in accordance with §§ 202.10 through 202.29 of this chapter (rules of practice under the Federal Seed Act) (7 U.S.C. 1551 et seq.), except that all references in those rules and regulations to “Examiner” shall be construed to be an Administrative Law Judge, U.S. Department of Agriculture, and not an “Examiner” as defined in the regulations under the Plant Variety Protection Act.

§ 97.700 Public interest in wide usage.

(a) If the Secretary has reason to believe that a protected variety should be declared open to use by the public in accordance with section 44 of the Act, the Secretary shall give the owner of the variety appropriate notice and an
opportunity to present views orally or in writing, with regard to the necessity for such action to be taken in the public interest.

(b) Upon the expiration of the period for the presentation of views by the owner, as provided in paragraph (a) of this section, the Secretary shall refer the matter to the Plant Variety Protection Board for advice, including advice on any limitations or rate of remuneration.

(c) Upon receiving the advice of the Plant Variety Protection Board, the Secretary shall advise the owner of the variety, the members of the Plant Variety Protection Board, and the public, by issuance of a press release, of any decision based on the provisions of section 44 of the Act to declare a variety open to use by the public. Any decision not to declare a variety open to use by the public will be transmitted only to the owner of the variety and the members of the Plant Variety Protection Board.

§ 97.900 Form of official identification symbol.

The symbol set forth in Figure 1, containing the words “Plant Variety Protection Office” and “U.S. Department of Agriculture,” shall be the official identification symbol of the Plant Variety Protection Office. This information symbol, used by the Plant Variety Protection Office on the seal on certificates of Plant Variety Protection, has been approved by the Office of Communications to be added to the USDA/AMS inventory of symbols. It is approved for use with AMS materials.

Figure 1. Official identification symbol of the Plant Variety Protection Office.
PART 98—MEALS, READY-TO-EAT (MREs), MEATS, AND MEAT PRODUCTS

Subpart A—MREs, Meats, and Related Meat Food Products

§ 98.1 General.

Analytical services of meat and meat food products are performed for fat, moisture, salt, protein, and other content specifications.

§ 98.2 Definitions.

Words used in the regulations in this subpart in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this subpart, unless the context requires otherwise, the following terms will be construed to mean:

Lard (Edible). The fat rendered from clean and sound edible tissues from swine.

Meat. This includes the edible part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, and which is intended for human food, with or without the accompanying and overlying fat, and the portions of bone, skin, tendon, nerve, and blood vessels which normally accompany the muscle tissue, and which are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Meat food product. Any article capable for use as human food (other than meat, prepared meat, or a meat by-product), which is derived or prepared wholly or in substantial part from meat or other portion of the carcass of any cattle, sheep, swine, or goats. An article exempted from definition as a meat food product by the Administrator, such as an organotherapeutic substance, meat juice, meat extract, and the like, which is used only for medicinal purposes and is advertised solely to the medical profession is not included.

MREs are for use by the DOD, DPSC as a component of operational food rations, and as an item of general issue by the military.

Meals, Ready-To-Eat (MRE). Meals, Ready-To-Eat are complete portions of one meal for one military person and are processed and packaged to destroy or retard the growth of spoilage-type microorganisms in order to extend product shelf life for 7 years. Composition analyses for MREs are covered by the reimbursable agreement in the Memorandums of Understanding (MOU’s) between AMS, USDA and the Defense Personnel Support Center, Department of Defense (DOD). These DOD, Defense Personnel Support Center (DPSC) contracts state certain military specifications for an acceptable one meal serving, retorted pouched or 18–24 serving hermetically-sealed tray packed meat, or meal product regarding satisfactory analyses for fat, salt, protein, moisture content, added stabilizer ingredient, and sometimes microbiological composition. MREs are for use by the DOD, DPSC as a component of operational food rations, and as an item of general issue by the military.

Specifications. Descriptions with respect to the class, grade, other quality, quantity or condition of products, approved by the Administrator, and
available for use by the industry regardless of the origin of the descriptions.

Tallow (Edible). The hard fat derived from USDA inspected and passed cattle, sheep, or goats.

Titer. The measure of the hardness or softness of the tested material as determined by the solidification point of fatty acids and expressed in degrees centigrade (°C).

### §98.3 Analyses performed and locations of laboratories.

(a) Tables 1 through 4 list the special laboratory analyses rendered by the Science and Technology as a result of an agreement with the Livestock and Seed Division. The payment for such laboratory services rendered at the request of an individual or third party served shall be reimbursed pursuant to the terms as specified in the cooperative agreement.

<table>
<thead>
<tr>
<th>TABLE 1—SCHEDULE ANALYSIS</th>
</tr>
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<tbody>
<tr>
<td><strong>Identity</strong></td>
</tr>
<tr>
<td>Schedule BC (Beef Chunks, Canned)</td>
</tr>
<tr>
<td>Schedule BJ (Beef with Natural Juices, Canned)</td>
</tr>
<tr>
<td>Schedule CS (Canned Meatball Stew)</td>
</tr>
<tr>
<td>Schedule GP (Frozen Ground Pork)</td>
</tr>
<tr>
<td>Schedule Pj (Pork with Natural Juices, Canned)</td>
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<tr>
<td>Schedule RB (beef for Reprocessing)</td>
</tr>
<tr>
<td>Schedule RG (beef Roasts and Ground Beef)</td>
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<tr>
<td>Schedule SB (Slab or Sliced Bacon)</td>
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<td>Schedule WS (Beef or Wafer Steaks)</td>
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<tr>
<th>TABLE 2—MICROBIOLOGICAL ANALYSIS</th>
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<tbody>
<tr>
<td><strong>Type of analysis</strong></td>
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<tr>
<td>Psychrotrophic Bacterial Plate Count</td>
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<table>
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<tr>
<th>TABLE 3—NONSCHEDULE ANALYSIS</th>
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<tbody>
<tr>
<td><strong>Identity</strong></td>
</tr>
<tr>
<td>Fed Specification PP–B–2120B (Ground Beef Products)</td>
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<tr>
<td>Fed Specification PP–B–81J (Sliced Bacon)</td>
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<tr>
<td>Fed Specification PP–L–809E (Luncheon Meat, Canned)</td>
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<td>Pork Sausage</td>
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<td>Mil–P–44131A (Pork Steaks, Flaked, Formed, Breaded)</td>
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<td>Milwaukee Public Schools (Breaded/Unbreaded Meat)</td>
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<td>Chili Con Carne Without Beans</td>
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<td>A–A–20047–B</td>
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<td>A–A–20136</td>
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<td>A–A–20148</td>
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<td>Mil–B–44133 (GL)</td>
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<td>Mil–B–44158A</td>
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<td>Mil–C–44239</td>
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<tr>
<td>Mil–H–44159B (GL)</td>
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<td>PP–F–02154 (Army GL)</td>
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<thead>
<tr>
<th>TABLE 4—lard and tallow analysis</th>
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</thead>
<tbody>
<tr>
<td><strong>Type of analysis</strong></td>
</tr>
<tr>
<td>Fat Analysis Committee (FAC) Color</td>
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<tr>
<td>Free Fatty Acids</td>
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<td>Insoluble Impurities</td>
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<td>Moisture and Volatile Matter</td>
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Table 4—Lard and Tallow Analysis—Continued

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<th>Type of analysis</th>
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<tr>
<td>Specific Gravity</td>
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<td>Titer Test</td>
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<tr>
<td>Unsaponifiable Material</td>
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</tbody>
</table>

(b) Meats, such as ground beef or ground pork, meat food products, and MREs, not covered by an agreement with Livestock and Seed Division, are analyzed for fat, moisture, salt, sulfur dioxide, nitrites, sulfites, ascorbates, citric acid, protein, standard plate counts, and coliform counts, among other analyses. These food product analyses are performed at any one of the Science and Technology (S&T) field laboratories as follows:

(1) USDA, AMS, Science and Technology, Midwestern Laboratory, 3570 North Avondale Avenue, Chicago, IL 60618.
(2) USDA, AMS, S&T Aflatoxin Laboratory, 107 South 4th Street, Madill, OK 73446.
(3) USDA, AMS, S&T, Eastern Laboratory, 2311–B Aberdeen Boulevard, Gastonia, NC 28054.


§ 98.5 Fees and charges.

(a) The fee charged for any single laboratory analysis of meat, meat food products, and MREs, not covered by an agreement with Livestock and Seed Division, is specified in the schedules of charges in paragraph (a) of §91.37 of this subchapter.

(b) The laboratory analyses of meat, meat food products, and MREs, not covered by a cooperative agreement, shall result in an additional fee, found in Table 7 of §91.37 of this subchapter, for sample preparation or grinding.

(c) The charge for any requested laboratory analysis of meat, meat food products, and MREs not listed shall be based on the standard hourly rate specified in §91.37, paragraph (b).

Subpart B—USDA Certification of Laboratories for the Testing of Trichinella in Horsemeat

§ 98.100 General.

A laboratory that has met the requirements for certification specified in this subpart shall receive an AMS Science and Technology certificate to approve its analysis for Trichinella spiralis in horsemeat. Certification would be granted to a qualified analyst or a laboratory based on having the proper training, facilities, and equipment. This AMS laboratory certification program will enable horsemeat exporters to comply with trichinella testing requirements of the European Community.


§ 98.101 Definitions.

Words used in the regulations in this part in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the
regulations in this part, unless the con-
text requires otherwise, the following
terms will be construed to mean:

European Community. The European
Community (EC) consists of the initial
12 European countries and the updated
and expanded membership of nations.
The original EC members are Belgium,
Britain, Denmark, France, Germany,
Greece, Ireland, Italy, Luxembourg,
Netherlands, Portugal and Spain.

Horsemeat. That U.S. inspected and
passed clean, wholesome muscle tissue
of horses, which is skeletal or which is
found in the tongue, in the diaphragm,
in the heart, or in the esophagus, with
or without the accompanying and over-
lying fat and the portions of sinews,
nerves, and blood vessels, which nor-
mally accompany the muscle tissue
and which are not separated from it in
the process of dressing.

Trichinella spiralis. A small parasitic
nematode worm which lives in the flesh
of various animals, including the horse.
When such infected meat is inade-
quately cooked and eaten by man, the
live worm multiplies within the body
and the larvae burrow their way into
the muscles, causing a disease referred
to as trichinosis.

§§ 98.102–98.600 [Reserved]

PART 99–109 [RESERVED]

PART 110—RECORDKEEPING ON
RESTRICTED USE PESTICIDES BY
CERTIFIED APPLICATORS; SUR-
VEYS AND REPORTS

Sec.
110.1 Scope.
110.2 Definitions.
110.3 Records, retention, and access to
records.
110.4 Demonstration of compliance.
110.5 Availability of records to facilitate
medical treatment.
110.6 Federal cooperation with States.
110.7 Penalties.
110.8 Rules of practice.
110.9 Miscellaneous.

AUTHORITY: 7 U.S.C. 136a(d)(1)(c), 136i–1,
and 450; 7 CFR 2.17, 2.50.

SOURCE: 58 FR 19022, Apr. 9, 1993, unless
otherwise noted.

§ 110.1 Scope.

This part sets forth the requirements
for recordkeeping on restricted use pes-
ticides by all certified applicators,
both private applicators and commer-
cial applicators.

§ 110.2 Definitions.

As used in this part, the following
terms shall be construed, respectively,
to mean:

Administrator. The Administrator of
the Agricultural Marketing Service,
United States Department of Agri-
culture, or any individual to whom the
Administrator delegates authority to
act in his or her behalf.

Authorized representative. Any person
who is authorized to act on behalf of
the Secretary or a State lead agency
for the purpose of surveying records re-
quired to be kept under this part and
enforcing this part.

Certification number. A number issued
by EPA or a State to an individual who
is authorized by EPA or the State to
use or supervise the use of any re-
stricted use pesticide.

Certified applicator. Any individual
who is certified by EPA or the State to
use or supervise the use of any re-
stricted use pesticide covered by that
individual’s certification.

Commercial applicator. A certified ap-
plicator, whether or not the individual
is a private applicator with respect to
some uses, who uses or supervises the
use of any restricted use pesticide for
any purpose on any property other
than as provided by the definition of
private applicator.

Comparable. With respect to the
records required to be kept under this
part, similar to those required under
EPA-approved State certification pro-
grams.

Complainant. The Administrator or
an official of a cooperating State that
deals with pesticide use or health or
environmental issues related to the
pesticide use, who institutes a pro-
ceeding pursuant to §110.8 of this part.

EPA. The United States Environ-
mental Protection Agency.

EPA registration number. The number
assigned to a product registered with
EPA in accordance with sections 3 or 24c of the Federal Insecticide, Fungicide, and Rodenticide Act and implementing regulations, and borne on the label of the product.

Indian governing body. The governing body of any tribe, band, or group of Indians subject to the jurisdiction of the United States and recognized by the United States as possessing power of self-government.

Licensed health care professional. A physician, nurse, emergency medical technician, or other qualified individual, licensed or certified by a State to provide medical treatment.

Medical emergency. A situation that requires immediate medical treatment or first aid to treat possible symptoms of pesticide poisoning or exposure.

Parties. Includes the Administrator or cooperating State agencies who institute proceedings against whom such proceedings are instituted, under §110.8 of this part.

Person. Any individual, corporation, company, association, firm, partnership, society, or other legal entity.

Presiding officer. Any individual designated in writing by the Administrator to preside at a proceeding conducted pursuant to §110.8 of this part.

Private applicator. A certified applicator who uses or supervises the use of any restricted use pesticide for purposes of producing any agricultural commodity:

1. On property owned or rented by the applicator or the employer of the applicator; or

2. If applied without compensation, other than trading of personal services between producers of agricultural commodities, on the property of another person.

Record. The legible recording of all required elements under section 110.3(a) (1) through (6) for the application of a federally restricted use pesticide.¹

Recordkeeping. The recording by the certified applicator, or the agent of the certified applicator, of the information required by §110.3(a) and (b) concerning each restricted use pesticide application, either electronically or manually in writing, and the maintenance of such records in a manner accessible to authorized representatives.

Respondent. The party proceeded against pursuant to §110.8 of this part.

Restricted use pesticide. A pesticide that is federally classified for restricted use under section 3(d)(1)(c) of the Federal Insecticide, Fungicide, and Rodenticide Act.

Secretary. The Secretary of Agriculture, United States Department of Agriculture, or any individual to whom the Secretary delegates authority to act in his or her behalf.

State. A State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States, or an Indian governing body.

State lead agency. The agency designated by a State to have access to the records required to be maintained under this part.

Supervise. To provide instruction and guidance in the application of restricted use pesticides and exercise control over an applicator of restricted use pesticides in accordance with standards prescribed by the EPA in 40 CFR part 171.

[58 FR 19022, Apr. 9, 1993, as amended at 60 FR 8123, Feb. 10, 1995]

§110.3 Records, retention, and access to records.

(a) Certified applicators of restricted use pesticides shall maintain records of the application of restricted use pesticides. Except as provided in paragraph (b) of this section, these records shall include the following information for each application:

1. The brand or product name, and the EPA registration number of the restricted use pesticide that was applied;

2. The total amount of the restricted use pesticide applied;

3. The location of the application, the size of area treated, and the crop, commodity, stored product, or site to which a restricted use pesticide was applied. The location of the application may be recorded using any of the following designations:

¹Records can be handwritten on individual notes or forms, consist of invoices, be computerized, and or be maintained in record-keeping books.
(i) County, range, township, and section;
(ii) An identification system utilizing maps and/or written descriptions which accurately identify location;
(iii) An identification system established by a United States Department of Agriculture agency which utilizes maps and numbering system to identify field locations; or
(iv) The legal property description.

(4) The month, day, and year on which the restricted use pesticide application occurred; and

(5) The name and certification number (if applicable) of the certified applicator who applied or who supervised the application of the restricted use pesticide.

(b) Certified applicators shall maintain records of the application of restricted use pesticides made on the same day in a total area of less than one-tenth (\(\frac{1}{10}\)) of an acre. Except for applications of restricted use pesticides in greenhouses and nurseries, to which the requirements of paragraph (a) of this section apply, these records shall include the following information for the application:

(1) The brand or product name, and the EPA registration number of the restricted use pesticide that was applied;
(2) The total amount of the restricted use pesticide applied;
(3) The location of the application, designated as “spot application,” followed by a concise description of location and treatment; and
(4) The month, day, and year on which the restricted use pesticide application occurred.

(c) The information required in this section shall be recorded within 14 days following the pesticide application. However, whether or not the written record has been completed, the certified applicator shall provide the information to be recorded in accordance with §110.5(a).

(d) The records required in this section shall be retained for a period of 2 years from the date of the restricted use pesticide application and be maintained in a manner that is accessible by authorized representatives.

(e) A commercial applicator shall, within 30 days of a restricted use pesticide application, provide a copy of records required under this part in order to determine whether a certified applicator is complying with this part.

§ 110.4 Demonstration of compliance.

The Secretary is authorized to inspect and copy any record required to be maintained by this part in order to determine whether a certified applicator is complying with this part.

§ 110.5 Availability of records to facilitate medical treatment.

(a) When the attending licensed health care professional, or an individual acting under the direction of the attending licensed health care professional, determines that any record of the application of any restricted use pesticide required to be maintained under §110.3 is necessary to provide medical treatment or first aid to an individual who may have been exposed to the restricted use pesticide for which the record is or will be maintained, the
§ 110.6 Federal cooperation with States.

(a) For the purpose of carrying out this part, the Administrator may enter into agreements with States.

(b) The Administrator may, after entering a State-Federal cooperative agreement with a State, utilize employees and facilities of the State to carry out any provisions of this part in that State. This State-Federal cooperative agreement shall specify:

(1) The agency of the State that is designated as the State lead agency;

(2) The responsibilities of State agencies for the enforcement of this part and the imposition of penalties under this part;

(3) The qualifications required of the State employees administering and enforcing this part;

(4) That the State-Federal cooperative agreement may be terminated at any time by the mutual agreement of the parties to the agreement;

(5) That the State-Federal cooperative agreement may be terminated by either party by giving written notice to the other party at least 90 days before a specified date of termination; and

(6) The provisions for liaison between the State and the Administrator concerning the administration and enforcement of this part as may be agreed by the Administrator and the State.

(c) If at any time the Administrator shall determine that the State lead agency or other State agencies charged with carrying out the terms of the State-Federal cooperative agreement are unable or unwilling to carry out the terms of the agreement, or, if for any reason the Administrator or State shall determine that the agreement is no longer in effect, the Administrator shall administer and enforce this part in the State.

(d) If a State shall notify the Administrator of its readiness to enter into a State-Federal cooperative agreement prior to passage of State legislation and regulations governing record-keeping by certified applicators of restricted use pesticides, the Administrator may enter into a State-Federal cooperative agreement with the State on an annual basis.

(e) For a State to be eligible for Federal technical or financial assistance under a State-Federal cooperative agreement, the State requirements for recordkeeping by all certified applicators of restricted use pesticides must be comparable to the recordkeeping requirements under this part.

§ 110.7 Penalties.

Any certified applicator who violates 7 U.S.C. 136l–1(a), (b), or (c) or this part shall be subject to a civil penalty of not more than the amount specified in section §3.91(b)(1)(i)(A) of this title in the case of the first offense, and in the case of subsequent offenses, be subject to a civil penalty of not less than the

284
amount specified in §3.91(b)(i)(B) of this title for each violation, except that the civil penalty shall be less than the amount specified in §3.91(b)(i)(B) of this title if the Administrator determines that the certified applicator made a good faith effort to comply with 7 U.S.C. 136i–1(a), (b), and (c) and this part.

[70 FR 29579, May 24, 2005]

§ 110.8 Rules of practice.

(a) Notice of violation. If there is reason to believe that a person has violated or is violating any provision of this part, the complainant may file with the Presiding Officer a notice of violation signed by the complainant. The notice of violation shall state:

(1) The date of issuance of the notice of violation;

(2) The nature of the proceeding;

(3) The identification of the complainant and respondent;

(4) The legal authority under which the proceeding is instituted;

(5) The allegations of fact and provisions of law which constitute the basis for the proceeding;

(6) The amount of the proposed civil penalty; and

(7) The name, mailing address, and telephone number of the Presiding Officer.

(b) Answer. Within 30 days after the service of the notice of violation, the respondent shall file with the Presiding Officer an answer signed by the respondent or by the attorney of record in the proceeding. The answer shall:

(1) Admit, deny, or explain each of the allegations in the notice of violation and set forth any defense asserted by the respondent; or

(2) State that the respondent admits all the facts alleged in the notice of violation; or

(3) State that the respondent admits the jurisdictional allegations in the notice of violation and neither admits nor denies the remaining allegations and consents to the issuance of an order without further procedure.

(c) Default. Failure to file an answer within 30 days after service of the notice of violation shall be deemed, for purposes of the proceeding, an admission of the allegations in the notice of violation, and failure to deny or otherwise respond to an allegation in the notice of violation shall be deemed, for purposes of the proceeding, an admission of the allegation, unless the complainant and respondent have agreed to a consent decision pursuant to paragraph (e) of this section.

(d) Amendment of notice of violation or answer. At any time prior to the filing of a motion for a hearing, the notice of violation or answer may be amended with the consent of the complainant and respondent or as authorized by the Presiding Officer upon a showing of good cause.

(e) Consent decision. At any time before the Presiding Officer files the decision, the complainant and respondent may agree to the entry of a consent decision. The agreement shall be in the form of a decision signed by the complainant and respondent with appropriate space for signature by the Presiding Officer, and shall contain an admission of at least the jurisdictional facts, consent to the issuance of the agreed decision without further procedure, and such other admissions or statements as may be agreed to by the complainant and respondent. The Presiding Officer shall enter such decision without further procedure, unless an error is apparent on the face of the document. The consent decision shall have the same force and effect as a decision issued after a full hearing, shall become final upon issuance, and shall become effective in accordance with the terms of the decision.

(f) Procedure upon failure to file an answer or admission of facts. The failure to file an answer with the Presiding Officer, or the admission by the answer of all the material allegations of fact contained in the notice of violation, shall constitute a waiver of hearing. Upon such admission or failure to submit an answer, complainant shall file with the Presiding Officer a proposed decision, along with a motion for the adoption of the proposed decision both of which shall be served upon the respondent by the Presiding Officer. Within 20 days after service of the motion and proposed decision, the respondent may file with the Presiding Officer objections to the motion and proposed decision. If the Presiding Officer finds that meritorious objections have been filed,
complainant's motion shall be denied with supporting reasons. If meritorious objections are not filed, the Presiding Officer shall issue a decision without further procedure or hearing. Copies of the decision or denial of complainant's motion shall be served by the Presiding Officer upon the respondent and the complainant and may be appealed pursuant to paragraph (l) of this section. Where the decision as proposed by complainant is entered, such decision shall become final and effective without further proceedings 35 days after the date of service of the decision upon the respondent, unless there is an appeal to the Administrator by the complainant or respondent, pursuant to paragraph (l) of this section.

(g) Conferences. (1) Upon motion of the complainant or respondent, the Presiding Officer may direct the complainant and respondent or their counsel to attend a conference at any reasonable time, prior to or during the course of the hearing, when the Presiding Officer finds that the proceeding would be expedited by a conference. Reasonable notice of the time and place of the conference shall be given. The Presiding Officer may order the complainant or respondent to furnish at or subsequent to the conference any or all of the following:
   (i) An outline of the case or defense;
   (ii) The legal theories upon which the party will rely;
   (iii) A list of documents which the party anticipates introducing at the hearing; and
   (iv) A list of anticipated witnesses who will testify on behalf of the party. At the discretion of the party furnishing such list of witnesses, the names of the witnesses need not be furnished if they are otherwise identified in some meaningful way such as a short statement of the type of evidence they will offer.

(2) The Presiding Officer shall not order a party to furnish the information or documents listed in paragraph (g)(1) (i) through (iv) of this section if the party can show that providing the particular information or document is inappropriate or unwarranted under the circumstances of the particular case. (3) At the conference, the following matters may be considered:
   (i) The simplification of issues;
   (ii) The necessity of amendments to the notice of violation or answer;
   (iii) The possibility of obtaining stipulations of facts and of the authenticity, accuracy, and admissibility of documents, which will avoid unnecessary proof;
   (iv) The limitation of the number of expert or other witnesses;
   (v) Negotiation, compromise, or settlement of issues;
   (vi) The exchange of copies of proposed exhibits;
   (vii) The identification of documents or matters of which official notice may be requested;
   (viii) A schedule to be followed by the parties for completion of the actions decided at the conference; and
   (ix) Such other matters as may expedite and aid in the disposition of the proceeding.

(4) A conference will not be stenographically reported unless so directed by the Presiding Officer.

(5) In the event the Presiding Officer concludes that personal attendance by the Presiding Officer and the parties or counsel at a conference is unwarranted or impractical, but determines that a conference would expedite the proceeding, the Presiding Officer may conduct the conference by telephone or correspondence.

(6) Actions taken as a result of a conference shall be reduced to a written appropriate order, unless the Presiding Officer concludes that a stenographic report shall suffice, or, the Presiding Officer elects to make a statement on the record at the hearing summarizing the actions taken.

(h) Procedure for hearing—(1) Request for hearing. The complainant or respondent may request a hearing on the facts by including such a request in the notice of violation or answer, or by a separate request, in writing, filed with the Presiding Officer within the time in which an answer may be filed. Failure to request a hearing within the time allowed for the filing of the answer shall constitute a waiver of a hearing. In the event the respondent denies any material fact and fails to file a timely request for a hearing, the
matter may be set down for hearing on motion of the complainant filed with the Presiding Officer or upon the Presiding Officer’s own motion.

(2) Time and place. If any material issue of fact is joined by the pleading, the Presiding Officer, upon motion of any of the parties stating that the matter is at issue and is ready for hearing, shall set a time and place for hearing as soon as feasible with due regard for the public interest and the convenience and necessity of the parties. The Presiding Officer shall issue a notice stating the time and place of hearing. If any change in the time or place of the hearing is made, the Presiding Officer shall issue a notice of this change, which notice shall be served upon the complainant and respondent, unless it is made during the course of an oral hearing and made a part of the transcript, or actual notice is given to the parties.

(3) Appearances. The parties may appear in person or by attorney of record in the proceeding. Any individual who appears as an attorney must conform to the standard of ethical conduct required of practitioners before the courts of the United States.

(4) Debarment of attorney. Whenever a Presiding Officer finds that an individual acting as attorney for any party to the proceeding is guilty of unethical or contumacious conduct, in or in connection with a proceeding, the Presiding Officer may order that the individual be precluded from further acting as attorney in the proceeding. An appeal to the Administrator may be taken from any such order, but no proceeding shall be delayed or suspended pending disposition of the appeal: Provided, That the Presiding Officer shall suspend the proceeding for a reasonable time for the purpose of enabling the party to obtain another attorney.

(5) Failure to appear. A respondent who, after being duly notified, fails to appear at the hearing without good cause, shall be deemed to have waived the right to an oral hearing in the proceeding and to have admitted any facts which may be presented at the hearing. The failure by the respondent to appear at the hearing shall also constitute an admission of all the material allegations of fact contained in the notice of violation. The complainant shall have an election whether to follow the procedure set forth in paragraph (f) of this section or whether to present evidence, in whole or in part, in the form of affidavits, exhibits, or by oral testimony before the Presiding Officer. Failure to appear at a hearing shall not be deemed to be a waiver of the right to be served with a copy of the Presiding Officer’s decision and to appeal to the Administrator pursuant to paragraph (l) of this section.

(6) Order of proceeding. Except as may be determined otherwise by the Presiding Officer, the complainant shall proceed first at the hearing.

(7) Evidence. (i) The testimony of witnesses at a hearing shall be on oath or affirmation and subject to cross-examination.

(ii) Upon a finding of good cause, the Presiding Officer may order that any witness be examined separately and apart from all other witnesses except those who are parties to the proceeding.

(iii) Evidence which is immaterial, irrelevant, or unduly repetitious, or which is not of the sort upon which reasonable persons are accustomed to rely, shall be excluded insofar as practicable.

(8) Objections. (i) If a party objects to the admission of any evidence or to the limitation of the scope of any examination or cross-examination or to any other ruling of the Presiding Officer, the party shall state briefly the grounds of such objection, whereupon an automatic exception will follow if the objection is overruled by the Presiding Officer.

(ii) Only objections made before the Presiding Officer may subsequently be relied upon in the proceeding.

(9) Exhibits. Unless the Presiding Officer finds that the furnishing of copies is impracticable, four copies of each exhibit shall be filed with the Presiding Officer: Provided, That, where there are more than two parties in the proceeding, an additional copy shall be filed for each additional party. A true copy of an exhibit may be substituted for the original.
(10) Official records or documents. An official government record or document or entry in such a record or document, if admissible for any purpose, shall be admissible in evidence without the production of the individual who made or prepared the same, and shall be prima facie evidence of the relevant facts stated in the record or document. Such record or document shall be evidenced by an official publication of the record or document or by a copy certified by an individual having legal authority to make such certification.

(11) Official notice. Official notice shall be taken of such matters as are judicially noticed by the courts of the United States and of any other matter of technical, scientific, or commercial fact of established character: Provided, That the parties shall be given adequate notice of matters so noticed, and shall be given adequate opportunity to show that such facts are erroneously noticed.

(12) Offer of proof. Whenever evidence is excluded by the Presiding Officer, the party offering such evidence may make an offer of proof, which shall be included in the transcript. The offer of proof shall consist of a brief statement describing the evidence excluded. If the evidence consists of a brief oral statement, the statement shall be included in the transcript in its entirety. If the evidence consists of an exhibit, it shall be marked for identification and inserted in the hearing record. In either event, the evidence shall be considered a part of the transcript and hearing record if the Administrator, upon appeal, decides the Presiding Officer’s ruling excluding the evidence was erroneous and prejudicial. If the Administrator, upon appeal, decides the Presiding Officer’s ruling excluding the evidence was erroneous and prejudicial and that it would be appropriate to have such evidence considered a part of the hearing record, the Administrator may direct that the hearing be reopened to permit the taking of such evidence or for any purpose in connection with the excluded evidence.

(13) Transcript. Hearings shall be recorded and transcribed verbatim.

(i) Post-hearing procedure—(1) Corrections to transcript. (i) Within the period of time fixed by the Presiding Officer, any party may file a motion proposing corrections to the transcript.

(ii) Unless a party files a motion proposing corrections to the transcript in the time fixed by the Presiding Officer, the transcript shall be presumed, except for obvious typographical errors, to be a true, correct, and complete transcript of the testimony given at the hearing and to contain an accurate description or reference to all exhibits received in evidence and made part of the hearing record and shall be deemed to be certified without further action by the Presiding Officer.

(iii) As soon as practicable after the close of the hearing and after consideration of any timely objection filed as to the transcript, the Presiding Officer shall issue an order making any corrections to the transcript which the Presiding Officer finds are warranted, which corrections shall be entered on to the original transcript by the Presiding Officer without obscuring the original text.

(2) Proposed finding of fact, conclusions, order, and briefs. Prior to the Presiding Officer’s decision, each party shall be afforded a reasonable opportunity to submit for consideration proposed findings of fact, conclusions, order, and brief in support of the proposed findings of fact, conclusions and order. A copy of each such document filed by a party shall be served upon each of the other parties.

(3) Presiding Officer’s decision. (i) The Presiding Officer shall issue a decision within 30 days after the hearing, or, if any party submits proposed findings of fact, conclusions, order, and a brief in support thereof in accordance with paragraph (i)(2) of this section, 30 days after the last such submission. The Presiding Officer’s decision shall include the Presiding Officer’s findings of the fact, conclusions of law, and the reasons or basis for the findings of fact and conclusions of law.

(ii) The Presiding Officer’s decision shall become effective without further proceedings 35 days after the date of service of the decision upon the respondent, unless there is an appeal to the Administrator by a party to the proceeding pursuant to paragraph (l) of this section.
(j) **Motions and requests**—(1) **General.** All motions and requests shall be filed with the Presiding Officer, and served upon all the parties, except:

(i) requests for extensions of time pursuant to paragraph (m)(3) of this section; and

(ii) motions and requests made on the record during the oral hearing. The Presiding Officer shall rule upon all motions and requests filed or made prior to the filing of an appeal of the Presiding Officer’s decision pursuant to paragraph (l) of this section except motions directly relating to the appeal. Thereafter, the Administrator will rule on any motions and requests, as well as the motions directly relating to the appeal.

(2) **Motions entertained.** (i) Any motion will be entertained other than a motion to dismiss on the pleading. (A motion by the complainant seeking the voluntary dismissal of the notice of violation may be entertained by the Presiding Officer or the Administrator.)

(ii) All motions and requests concerning the notice of violation must be made within the time allowed for filing an answer, except motions by the complainant seeking voluntary dismissal of the notice of violation.

(3) **Contents.** All written motions and requests shall state the particular order, ruling, or action desired and the grounds for the order, ruling, or action desired.

(4) **Response to motions and requests.** Within 10 days after service of any written motion or request, or within a shorter or longer period as may be fixed by the Presiding Officer or the Administrator, an opposing party may file a response to the motion or request. The other party shall have no right to reply to the response; however, the Presiding Officer or the Administrator, in their discretion, may order that a reply be filed.

(k) **Presiding Officer**—(1) **Assignment.** No Presiding Officer shall be assigned to serve in any proceeding who:

(i) Has any pecuniary interest in any matter or business involved in the proceeding;

(ii) Is related within the third degree by blood or marriage to any party to the proceeding; or

(iii) Has any conflict of interest which might impair the Presiding Officer’s objectivity in the proceeding.

(2) **Disqualification of Presiding Officer.**

(i) Any party to the proceeding may, by motion made to the Presiding Officer, request that the Presiding Officer withdraw from the proceeding because of an alleged disqualifying reason. Such motion shall set forth with particularity the grounds of alleged disqualification. The Presiding Officer may then either rule upon or certify the motion to the Administrator, but not both.

(ii) A Presiding Officer shall withdraw from any proceeding for any reason deemed by the Presiding Officer to be disqualifying.

(3) **Powers.** The Presiding Officer, in any assigned proceeding, shall have power to:

(i) Rule upon motions and requests;

(ii) Set the time and place of a conference and the hearing, adjourn the hearing from time to time, and change the time and place of hearing;

(iii) Administer oaths and affirmations;

(iv) Summon and examine witnesses and receive evidence at the hearing;

(v) Admit or exclude evidence;

(vi) Hear oral argument on facts or law;

(vii) Do all acts and take all measures necessary for maintenance or order, including the exclusion of contumacious counsel or other persons; and

(viii) Take all other actions authorized under this section.

(l) **Appeal to the Administrator**—(1) **Filing of petition.** Within 30 days after receiving notice of the Presiding Officer’s decision, a party who disagrees with the Presiding Officer’s decision, or any part of the Presiding Officer’s decision, or any ruling by the Presiding Officer or a party who alleges a deprivation of rights, may appeal the Presiding Officer’s decision or rulings to the Administrator by filing an appeal petition with the Administrator. As provided in paragraph (h)(8) of this section, objections regarding evidence or a limitation regarding examination or cross examination or other ruling made before the Presiding Officer may be relied upon in an appeal. The appeal petition shall state...
the name and address of the person filing the appeal petition. Each issue set forth in the appeal petition, and the arguments on each issue, shall be separately numbered; shall be plainly and concisely stated; and shall contain detailed citations of the record, statutes, regulations, or authorities being relied upon in support of the argument. A brief may be filed in support of the appeal simultaneously with the appeal petition.

(2) Response to appeal petition. Within 20 days after the service of a copy of an appeal petition and any brief in support of the appeal petition, filed by a party to the proceeding, any other party may file with the Administrator a response in support of or in opposition to the appeal petition and, in such response any relevant issue, not presented in the appeal petition, may be raised.

(3) Transmittal of record. Whenever an appeal to the Presiding Officer’s decision is filed and a response to the appeal has been filed or time for filing a response has expired, the Presiding Officer shall transmit to the Administrator the record of the proceeding. The record shall include: the pleading; motions and requests filed and rulings on such motions and requests; the transcript of the testimony taken at the hearing, together with the exhibits filed in connection with the hearing; any documents or papers filed in connection with a conference; such proposed findings of fact, conclusions, and orders, and briefs in support thereof, as may have been filed in connection with the proceeding; the Presiding Officer’s decision; and such exceptions, statements of objections and briefs in support thereof as may have been filed in the proceeding.

(4) Decision of the Administrator on appeal. As soon as practicable after the receipt of the record from the Presiding Officer, the Administrator, upon the basis of and after due consideration of the record and any matter of which official notice is taken, shall rule on the appeal. If the Administrator decides that no change or modification of the Presiding Officer’s decision is warranted, the Administrator may adopt the Presiding Officer’s decision as the final order in the proceeding, preserving any right of the party bringing the appeal to seek judicial review of such decision in the proper forum.

(m) Filing; service; extensions of time; and computation of time—(1) Filing; number of copies. Except as otherwise provided in this section, all documents or papers required or authorized by this section to be filed with the Presiding Officer or Administrator shall be filed in quadruplicate: Provided, That where there are more than two parties in the proceeding, an additional copy shall be filed for each additional party.

(2) Service; proof of service. Copies of all documents or papers required or authorized by this section to be filed with the Presiding Officer or Administrator shall be served upon the parties by the Presiding Officer or any director of the corporation or association to be served, or to the attorney of record representing such person, at the last known residence or principal office of such person: Provided, That if the registered or certified document or paper is returned undelivered because the addressee refused or failed to accept delivery, the document or paper shall be served by remailing it by regular mail. Proof of service under this paragraph shall be made by the certificate of the person who actually made the service: Provided, That if the service be made by mail, under paragraph (m)(2)(iii) of this section, proof of service shall be made by the return
post-office receipt, in the case of registered or certified mail, or by the certificate of the person who mailed the matter by regular mail. Any certificate or post-office receipt returned to the Presiding Officer or Administrator shall be filed by the Presiding Officer or Administrator, and made a part of the record of the proceeding.

(3) Extensions of time. The time for the filing of any document or paper required or authorized under this section to be filed may be extended by the Presiding Officer or the Administrator as provided in paragraph (j) of this section, if in the judgment of the Presiding Officer or the Administrator, as the case may be, there is good reason for the extension. In all instances in which time permits, notice of the request for extension of the time shall be given to the other party with opportunity to submit views concerning the request.

(4) Effective date of filing. Any document or paper required or authorized under this section to be filed shall be deemed to be filed at the time when it reaches the person with whom the document or paper must be filed.

(5) Computation of time. Saturdays, Sundays, and holidays shall be included in computing the time allowed for the filing of any document or paper: Provided, That, when such time expires on a Saturday, Sunday, or holiday, such period shall be extended to include the next following business day.

(n) Ex parte communications. (1) At no stage of the proceeding between its institution and the issuance of the final decision shall the Presiding Officer or Administrator discuss ex parte the merits of the proceeding with any person who is connected with the proceeding in an advocative or in an investigative capacity, or with any representative of such person: Provided, That the Presiding Officer or Administrator may discuss the merits of the case with such a person if all parties to the proceeding, or their attorneys have been given notice and an opportunity to participate. A memorandum of such discussion shall be included in the record.

(2) No interested person shall make or knowingly cause to be made to the Presiding Officer or Administrator an ex parte communication relevant to the merits of the proceeding.

(3) If the Presiding Officer of the Administrator receives an ex parte communication in violation of this paragraph (n), the individual who receives the communication shall place in the public record of the proceeding:

(i) Any such written communication;
(ii) Memoranda stating the substance of such oral communication; and
(iii) Any written response, and memoranda stating the substance of any oral response to the ex parte communication.

(4) For purposes of this section ex parte communication means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or the proceeding.

§ 110.9 Miscellaneous.

In accordance with Section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507), the recordkeeping provisions in this rule have been approved by the Office of Management and Budget (OMB) and there are no new requirements. The assigned OMB control number is 0581-AA39.

PARTS 111–159 [RESERVED]