§ 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. Copies and translations of foreign laws and regulations will be requested only if they are not in the files of the Plant Variety Protection Office. Applicants may learn whether such a request will be made by writing to the address given in paragraph (c) of this section.
(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;
(3) The accession number given by the depository; and
(4) A statement that the deposit is capable of reproduction.

(e) Replacement or supplement of deposit. If the depository possessing a deposit determines either that the sample viability is low or that the sample quantity is low, and if this finding is made during the pendency of an application or during the term of protection of the certificate, the Office shall notify the depositor of the need for making a replacement or supplemental deposit. Such deposits will be governed by the same considerations governing the need for making an original deposit under the provisions set forth in §97.7(d). Notification to the Office concerning deposit of the replacement or supplemental sample shall contain a statement from a person in a position to corroborate the fact, stating that the replacement or supplemental deposit is of a biological material which is identical to that originally deposited.

(f) Term of deposit. A voucher specimen deposit made in support of an application for plant variety protection shall be made for a term of at least twenty (20) years. In any case, samples must be stored under agreements that would make them available to the Office during the enforceable life of the certificate for which the deposit was made.

(g) Viability of deposit. A deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository periodically. The test must conclude only that the deposited material is capable of reproduction. No evidence necessarily is required regarding the ability of the deposited material to perform any function described in the application. If a viability test indicates that the deposit is not viable upon receipt or that the quantity of material is insufficient, the examiner shall proceed as if no deposit was made. The examiner will accept the conclusion set forth in a viability statement issued by a depository recognized under paragraph 97.7(c).

(b) Furnishing of samples. A deposit must be made under conditions that assure that:
(1) Public access to the deposit will not be available during pendency of the application or during the term of protection, and
(2) All restrictions on the availability to the public of the deposited material will be irrevocably removed upon the abandonment, cancellation, expiration, or withdrawal of the certificate.

(i) Examination procedures. The examiner shall determine, prior to issuance of the certificate, in each application if a voucher sample deposit actually made is acceptable for plant variety protection purposes.

[70 FR 54611, Sept. 16, 2005]

§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.