



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 97

[Document Number AMS-ST-19-0004]

Regulations and Procedures Under the Plant Variety Protection Act

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule revises the regulations, fees for services, and procedures established under the Plant Variety Protection Act. The revisions are necessary to conform with recent amendments to the Plant Variety Protection Act, which added authority for the Plant Variety Protection Office to issue certificates of protection for varieties of plants that are reproduced asexually. This rule adds references to the term “asexual reproduction” to the regulations established under the Plant Variety Protection Act and establishes procedures for obtaining variety protection for asexually reproduced plant varieties. This rule also modernizes the regulations by simplifying the fee schedule for PVPO services and updating the regulations relating to administrative procedures to reflect current business practices.

DATES: *Effective date:* January 6, 2020.

Delayed enforcement date: Enforcement of the requirement to deposit propagating material for asexually reproduced varieties is delayed until January 6, 2023.

FOR FURTHER INFORMATION CONTACT: Jeffery Haynes, Deputy Commissioner, Plant Variety Protection Office, AMS Science and Technology Program,

USDA; 1400 Independence Avenue SW, Room 4512-S, Stop 0274, Washington, DC 20250-0002; telephone: (202) 260-8983; email: Jeffery.Haynes@usda.gov.

SUPPLEMENTARY INFORMATION: Section 10108 of the Agriculture Improvement Act of 2018 (Public Law 115-334) (2018 Farm Bill) amended the Plant Variety Protection Act of 1970, as amended (7 U.S.C. 2321 – 2582) (Act), by adding a definition for the term “asexually reproduced” as it pertains to plant propagation and adding authority to offer intellectual property protection to breeders of new varieties of plants developed through asexual reproduction. The Agricultural Marketing Service’s (AMS) Plant Variety Protection Office (PVPO) processes applications and grants certificates of protection for plant varieties under the Act. PVPO also administers the Plant Variety Protection (PVP) regulations established under the Act at 7 CFR part 97 (regulations).

AMS published a proposed rule in the Federal Register on July 12, 2019 (84 FR 33176). The proposed rule invited comments on proposed changes to the regulations that correspond with amendments to the Act. AMS allowed a sixty-day public comment period for interested parties to submit comments. The comment period ended September 10, 2019. AMS received six comments on the proposed rule. In anticipation of the regulatory changes, AMS also sought approval from the Office of Management and Budget (OMB) for revisions to the information collection forms PVPO uses to administer the PVP program. AMS announced the forms’ revisions in the Federal Register on May 14, 2019 (84 FR 21314). AMS received two comments on the forms’ revisions during the sixty-day comment period that ended July 15, 2019. Both submissions also included comments pertaining to the proposed rule, so AMS also considered those two comments

in the development of this final rule. Based on the comments received, AMS modified the provisions in the proposed rule related to required deposits of propagating material with applications for protection under the Act. The comments and the modifications are discussed later in this document.

Background Information

The Act authorizes PVPO to provide intellectual property protection to breeders or owners of new plant varieties to facilitate the marketing of those new varieties. Currently, owners can apply for and receive certificates that protect new varieties of seed- and tuber-propagated plants for 20 years, or 25 years for seed-propagated vines and trees. A certificate of plant variety protection is granted to the owner of a variety after examination by PVPO indicates that the variety is new, distinct from other varieties, genetically uniform, and stable through successive generations. PVPO-issued certificates are recognized worldwide and facilitate filing for plant variety protection in other countries. Certificate owners have the right to exclude others from marketing and selling protected varieties, manage the use of their varieties by other breeders, and enjoy legal protection of their work.

Asexually reproduced varieties are those derived using vegetative material, other than seed, from a single parent, including cuttings, grafts, tissue cultures, and root divisions. These varieties are a significant and growing portion of the industry. Developers of asexually reproduced varieties desire access to the internationally recognized intellectual property rights that can only be obtained through PVPO-issued certificates. 2018 Farm Bill amendments to the Act make that possible.

Provisions

This final rule revises the Plant Variety Protection regulations by adding references to asexual plant reproduction, as appropriate, to the regulations that apply to the protection of seed and tubers. Revised § 97.1 extends the protection breeders can obtain from PVPO to plants propagated through asexual means. As with other plants covered by the Act, plant breeders can receive certificates that protect asexually reproduced plant varieties for 20 years, or 25 years for trees and vines. Revisions to the definition of the term *sale for other than seed purposes* in § 97.2 add “propagating material” to that term as used in the regulations.

Revised §§ 97.6 and 97.7 require that except for during a temporary enforcement delay explained below, applications for plant variety protection for asexually propagated varieties must be accompanied by the commitment to deposit propagating material to a public repository approved by the Commissioner. Such deposits must be maintained for the duration of the certificate.

Section 97.7(d) specifies that original deposits of propagating material for seed- and tuber-reproduced plants must be made within three months of the notice of certificate issuance. Tuber-reproduced plants are already eligible for plant variety protection under the Act and regulations. Addition of the reference to tuber-reproduced plants in § 97.7(d) corrects inadvertent omission of that reference in previous revisions to the regulations. Section 97.7 also provides for waiver of the time requirements for making original deposits for good cause, such as delays in obtaining a phytosanitary certificate for the importation of propagating material for deposit.

The requirement to make deposits of propagating material to accompany applications for variety protection under the Act applies to asexually reproduced varieties

on the effective date of this rule. However, revised § 97.7(d)(3) provides that enforcement of that requirement is delayed through January 6, 2023. Stakeholder feedback and comments submitted in response to the proposed rule suggest that it may sometimes be technically infeasible to deposit or store propagating material for certain asexually reproduced varieties. AMS is delaying enforcement of the deposit requirement for asexually reproduced varieties to give PVPO time to determine the number and type of deposits that may be technically infeasible at this time. The three-year delay will also allow PVPO and the industry to identify possible solutions to technical problems. Although applicants for protection of asexually reproduced varieties are not required to make original deposits during the delayed enforcement period, applicants may make the deposits if they choose.

Revised § 97.7(d)(2) provides that after the delayed enforcement period, PVP applicants may request and be granted delay waivers on a case-by-case basis. The revised introductory paragraph of § 97.7(d) as proposed is further revised to clarify that the granting of such waivers will be based on the repository's determination of whether it is feasible to deposit propagating material for certain asexually reproduced plants. For instance, the repository may report to PVPO that it is infeasible to store the propagating material of asexually reproduced grafted trees because of the space required to do so, or because the repository is unable to prepare or maintain a viable tissue culture that can be stored for the life of the protection certificate or grow out true to type upon recovery. Applicants who obtain delay waivers must agree to maintain the propagating material at a specific physical location that PVPO could inspect upon request. Applicants who obtain delay waivers must also agree to provide propagating material, when it is needed, within

three months of PVPO's request. PVPO will consider a certificate abandoned if the applicant fails to provide the requested propagating material within the three-month timeframe. New § 97.7(d)(2)(iii) specifies that delay waivers are effective until PVPO notifies the applicant that the technical infeasibility has been resolved. Once so notified, the applicant must deposit propagating material within three months. If the applicant fails to make the required deposit, PVPO will consider the certificate abandoned.

Revised § 97.19(c) replaces the reference to "name of the kind of seed," which appears on PVPO posts about pending applications, with the more generic reference to "name of the crop," to accommodate all types of plant material that can be protected, including asexual reproduction material. This final rule replaces references to seed deposits in § 97.104 with references to seed and propagating material deposits made in the application and certification processes. Previously, § 97.141 of the regulations allowed owners of plant varieties for which certificates had been issued to prohibit unauthorized multiplication of the seed of those varieties. Revised § 97.141 extends that protection to prohibit the unauthorized multiplication of propagating material of those varieties. Similarly, revised § 97.142 allows owners of protected plant varieties to prohibit unauthorized increases of all propagating material released for testing or increase. Previously, § 97.142 only specified such prohibition for seed and reproducible plant material released for testing or increase.

This final rule modernizes the regulations to reflect current industry and government practices. The regulations were most recently revised in 2005 and contained obsolete or incomplete references to processes that have changed over the years. For instance, when color is a distinguishing characteristic of a plant variety, the color can be

described according to any recognized color charts used in the industry for that purpose. Previously, § 97.9 provided one example of a named color chart – the Nickerson Color Fan, which has long been in use. This final rule expands the list of examples in § 97.9 to include two additional examples of color charts that can be referenced, the Munsell Book of Color and the Royal Horticultural Society Colour Chart, as well as any other commonly recognized color charts. A further revision to § 97.9 clarifies that color photos that accompany PVP applications may be submitted by email, as has been the practice for several years.

Many of the changes in this final rule pertain to PVPO's application process, including the timing of different steps in the process. PVPO expects the changes to simplify the requirements for applicants and to expedite the issuance of variety protection certificates, which would benefit their customers. Previously, applicants paid fees associated with certain steps of the application process as they went through the process, but revised § 97.6(c) requires all portions of the application fee – for filing an application, for application examination by PVPO, and for certificate issuance – to be paid at the time of application. This final rule makes corresponding revisions to §§ 97.103(a) and 97.104(a) and (c). Revised § 97.20(a) specifies that, subject to certain exceptions, filing and examination fees are not refundable after an application is deemed by PVPO to be abandoned. Revised § 97.23(c) requires payment of new filing and examination fees for reconsideration of an original application that has been withdrawn by the applicant. Previously, § 97.101 – Notice of Allowance specified that an applicant must pay the certificate fee within one month of the notice of allowance. Revised § 97.101 requires the applicant to verify the names of the plant variety and the owner within 30 days.

Under revised § 97.101, the applicant may opt instead to withdraw the application before the certificate is issued, in which case the certificate fee portion of the application fee would be refunded. After the 30 days, an administrative fee for delayed response will be charged to the applicant or deducted from the certificate fee refund, if the applicant chooses to withdraw the application. If the applicant fails to respond at all, the application will be considered abandoned, and no fees will be refunded. Revisions to § 97.178 removed references to searches and search fees and specify that the examination fee may be refunded if an application is either voluntarily withdrawn or abandoned before the examination has begun. Section 97.178 is further revised to provide that the certificate issuance fee will be refunded if an application is voluntarily withdrawn or abandoned after an examination, but before a certificate is issued.

This final rule reorganizes and simplifies the schedule of fees and charges for PVPO services in § 97.175. The revisions consolidate and simplify the fee schedule to reflect the revisions described above. Fee amounts for filing an application, examination, certificate issuance, application reconsideration, revival of abandoned applications, and filing appeals with the Commissioner or the Secretary have not been changed from the previous fee schedule. However, flat fees for PVPO services like reproducing records, authentication, and correction or reissuance of a certificate are no longer specified separately in the fee schedule in the regulations and will be charged at rates prescribed by the Commissioner, not to exceed \$97 per employee hour. Previously those services were estimated to average \$107 per employee hour. Office automation and other process improvements make the proposed decreases feasible. One such improvement is the ability to process fee payments through electronic payment systems. Revised § 97.177

specifies that payments can be made through the Plant Variety Protection system or through pay.gov, although payments by check or money order will still be allowed.

This final rule replaces obsolete references in the regulations to the Official Journal of the Plant Variety Protection Office with references to the PVPO website, which is the current business portal used by PVPO to provide service to its customers. Another revision adds reference to the PVPO website to the section. Such changes are made to §§ 97.5(c), 97.7(c)(5), 97.14(d), 97.19, 97.403(d), and 97.800. Such changes are also made to what were paragraphs (b) and (d) of § 97.104, but which have been redesignated paragraphs (a) and (c) through other revisions to the section. Further revised § 97.5(c) provides that applicants can request forms and information at a PVPO email address. Revised § 97.12 clarifies that PVPO can use mail or email to notify applicants of the filing number and effective filing date of applications received by PVPO. Revised § 97.23(c) specifies that refiling a voluntarily withdrawn original application must be accompanied by payment of a new filing and examination fee, while § 97.23(d) has been removed altogether, as it contained obsolete references to applications pending on April 4, 1995. An additional revision to the section previously designated § 97.104 (b), but now redesignated § 97.104(a), removes reference to the return of seed samples deposited with applications, since that is no longer the practice of PVPO, and provides that samples of seed and propagating material associated with abandoned applications and certificates will be retained or destroyed by the repository. This final rule corrects a reference in § 97.500 to the U.S. Court of Appeals for the Federal Circuit, to whom applicants may appeal if they are dissatisfied with decisions of the Secretary related to plant variety protection issues. Finally, this rule revises the

heading for § 97.600 by replacing the term “Rules of Practice” with the term “Administrative procedures” in accordance with Code of Federal Regulations naming conventions.

Comments

The six comments submitted in response to the proposed rule were generally supportive of the proposed revisions to the regulations. Some commenters said they advocated the Farm Bill amendments to the Act. Commenters recognized the value of the protection obtainable through PVPO services and welcomed the addition of protection for asexually reproduced plants particularly, noting that it would give plant breeders additional options regarding intellectual property protection, which would in turn spur innovation, benefitting growers and consumers. Finally, commenters welcomed proposed efforts to modernize the regulations through technical and administrative changes to the regulations.

As explained earlier in this document, AMS received two additional comments during the comment period that were filed in response to a related notice on proposed revisions to the information collection forms used in the PVP program. In addition to addressing the information collection, these submissions included comments and questions about the proposed rule. The portions of these comments related to the information collection are addressed in the Paperwork Reduction Act section below. The portions of these comments related to the proposed rule are addressed here.

Deposit Requirement

AMS proposed to require that, in conjunction with a PVP application, a deposit of propagating material be made to a public repository approved by the Commissioner, and

that the deposit be maintained for the duration of the certificate. As with deposits of seed and tubers, AMS proposed requiring deposits for asexually reproduced plants be made within three months after notice of certificate issuance. To address situations in which it is technically infeasible to deposit or store propagating materials for certain asexually reproduced plants, AMS proposed to allow applicants to request delay waivers that would let them provide a deposit within three months of a PVPO request when needed. All but two of the comments addressed the proposed deposit requirement.

Comment: One comment from an industry trade association supported the proposed deposit requirement, explaining that the industry benefits from the public availability of germplasm in repositories and that such deposits can be referred to during dispute settlements. The commenter also suggested that placing germplasm in public repositories would alleviate the breeder's burden for maintaining an asexually propagated variety beyond its commercial lifespan. The commenter assumed that repository fees for deposits of propagating material would be the same regardless of the type of protection the breeder is seeking, for example, a utility patent or a PVP certificate.

AMS Response: AMS agrees that germplasm deposits are useful in resolving disputes and that maintaining a deposit in a repository would relieve the breeder's burden for doing so beyond the variety's commercial lifespan. We believe requiring a deposit also ensures that upon expiration of the term of protection the propagating material will be available to interested parties. AMS understands that repository fees may differ for handling different types of propagating material. For instance, storing viable seed would probably be much less complicated than maintaining propagating material for tree or shrub specimens. We presume that a repository's fees would depend on a variety of

factors, including the services provided, storage logistics, and duration. We are not aware that the purpose for the deposit would dictate its cost. Accordingly, this final rule makes no changes to the proposed rule based on these comments.

Comment: Three comments, including one from an individual, one from a plant breeders' marketing service, and one representing two associations of plant breeders, expressed concern about the cost of the required deposit, as described in the Regulatory Flexibility Analysis of the proposed rule. Commenters suggested that a \$3,000 deposit fee would be prohibitive for many breeders and could deter them from seeking protection through the PVP system. Commenters asserted that other member countries within the International Union for the Protection of New Varieties of Plants (UPOV)¹ do not require breeders to make deposits for asexually reproduced plants, although they may for seed-propagated varieties, in order to obtain protection. One commenter suggested that rather than making deposits, applicants be required to declare where the plant will be maintained during its term of protection, similar, according to the commenter, to obligations under Canadian Plant Breeders' Rights². Commenters believed that the underlying rationale for AMS's proposed deposit requirement was to ensure public access to the propagating material after the protection expires. But commenters argued that plants are commercialized, are maintained by the breeders, and/or may be part of public collections in landscapes and botanical gardens, and thus would likely be readily available to interested parties.

¹ International Union for the Protection of New Varieties of Plants; <https://upov.int/portal/index.html.en>; accessed 9/23/2019.

² Canadian Food Inspection Agency, Plant Breeders' Rights Office; <https://www.inspection.gc.ca/plants/plant-breeders-rights/eng/1299169386050/1299169455265>; accessed 9/20/2019.

AMS Response: AMS appreciates that paying the repository's fee at the same time as paying the PVP application fee could seem prohibitive for some applicants. Because protection for asexually reproduced plants is new for PVPO, we can only speculate about how many protection applications might be submitted and how many applicants would be deterred from seeking protection under the amended Act because of the deposit cost. In the regulatory analysis for this rule, we estimated that 50 applicants would apply for protection for asexually reproduced plants each year. At this time, we don't know how many deposits would be technically infeasible and eligible for delay waivers.

Accordingly, based on comments and other information, AMS revised the rule as proposed to provide for delayed enforcement of the deposit requirement for asexually reproduced variety PVP applications until January 6, 2023. Applicants are not required to make propagating material deposits during that period but are required to make declarations that they will maintain propagating material at a specific physical location PVPO could inspect and that they will provide propagating material within three months of PVPO's request. We believe a delayed enforcement date will allow PVPO to get a feel for the number and type of deposits that are technically infeasible at this time. Further, a delayed compliance date would give PVPO time to work with the industry to identify and resolve feasibility problems. Although it is not required during the delayed enforcement period, applicants who choose to do so may submit a deposit of propagating material to the repository as provided in the regulations.

To date, AMS has identified and approved only one facility that could serve as a repository for deposits of propagating material for asexually reproduced plants. Current

deposit fees for propagating material from asexually propagated varieties at that facility are \$3,000 at the time of the deposit and cover preparation of the tissue culture and maintenance of the deposit for the term of the protection (20 years for herbaceous plants, 25 years for trees and vines) plus an additional 10 years beyond the protection's expiration. Thus, over the total life of the deposit (30 or 35 years), the average annual cost is minimal. AMS believes the cost to be appropriate and reasonable, considering the value of the propagating material preserved.

Commenters are correct in that neither other UPOV member countries nor the U.S. Plant Patent Act require propagating material deposits for asexually reproduced plants at this time. The Plant Variety Protection Act requires deposits with PVP applications for seed and tuber-propagated plants, and PVPO intends to make the application process for all plant types consistent. Therefore, the final rule requires applicants to make deposits with PVP applications for asexually reproduced plants, subject to the delayed enforcement and waiver provisions discussed above.

As explained in the response to an earlier comment, one of the reasons for requiring deposits with protection applications is to ensure that the propagating material will still be available when the protection expires. Commenters are correct that some protected varieties may still be publicly or commercially available after the protection expires, but there is no guarantee that they would. Plants in public areas may be replaced over time, and the commercial lifespan of a plant variety may be much shorter than the term of its protection. Therefore, this final rule continues to require deposits of propagating material for varieties protected under the Act in PVPO-approved repositories.

AMS finds merit in the suggestion that protected plant varieties or their propagating material be maintained by the owner, although we do not believe it should be the permanent solution to preserving protected varieties' propagating material. Requiring owners to maintain propagating material would strengthen the value of protection for varieties for which PVPO grants delay waivers for technical infeasibility purposes. Accordingly, based on comments, AMS revised the rule as proposed to provide that applicants who request delay waivers due to technical difficulties with depositing propagating materials must maintain the propagating material at a specific physical location, subject to PVPO inspection. AMS further revised the delay waiver provision in the rule as proposed to clarify that the delay waiver is effective until PVPO notifies the applicant that the technical infeasibility has been resolved. The applicant will have three months from notification to make the required deposit. PVPO will consider the PVP certificate abandoned if the applicant fails to make the required deposit.

Comment: One comment from an association of plant breeders, producers, and traders questioned the value of the obligatory deposit for asexually reproduced plants. The comment stated that the provision and storage of tissue culture material is complicated and that such material is prone to mutations. The commenter suggested it might be more convenient to store a sample of the new plant's DNA instead, which could be compared to varieties in the market in case of doubt about their origin.

AMS Response: As we discussed in an earlier comment response, AMS acknowledges that providing and maintaining tissue cultures is complicated. The suggestion about storing DNA is interesting, and in the future, it may be possible to use DNA to satisfy distinctness tests. But at this time, we cannot reproduce a plant from its

DNA alone. It's essential to preserve propagating material under PVP certification to ensure a protected plant can be reproduced when needed. Accordingly, this final rule continues to require PVP applicants to make propagating material deposits, subject to the delayed enforcement and waiver provisions described above.

Comment: One comment from an individual noted that the potato industry has been depositing tissue culture samples with the National Center for Genetic Resources Preservation (NCGRP)³ depository since 1996, when a previous amendment to the Act⁴ allowed tuber propagated plants to be protected but did not allow for fees to be charged for deposits. According to the commenter, NCGRP's cost for storing potato tissue cultures was about \$3,200 per deposit. The commenter asked whether potato breeders would have to pay \$3,000 per deposit under the proposed rule.

AMS Response: This rule makes no changes to the deposit requirements for potato varieties. Now known as the National Laboratory for Genetic Resources Preservation (NLGRP), the repository at a USDA Agricultural Research Service facility in Fort Collins, Colorado, will continue to serve as the approved repository for potato tissue cultures. AMS understands that NLGRP currently charges \$2,400 per application deposit. NLGRP stores the tissue culture for 20 years. The cost cited earlier for the deposit of material for asexually reproduced plants is based on a repository that specializes in asexually reproduced plants and that would prepare the tissue cultures and provide 30-35 years of storage.

³ Agricultural Research Service, USDA. The National Laboratory for Genetic Resources Preservation (NLGRP) (formerly NCGRP) is located at the Center for Agricultural Resources Research in Fort Collins, Colorado. <https://www.ars.usda.gov/plains-area/fort-collins-co/center-for-agricultural-resources-research/>; accessed 9/24/2019.

⁴ The *Plant Variety Protection Act Amendments of 1994*, Pub. L. 103-349, October 6, 1994.

Comment: Aside from concerns about the cost of the deposit requirement, commenters unanimously supported the proposed delay waiver, with the stipulation that propagating material be produced within three months of PVPO's request. Commenters noted that establishing and maintaining propagating material in vitro can sometimes be difficult, and that the waiver option would address technical infeasibilities. One commenter suggested expanding the proposed waiver option to include waivers for plants the breeder attests will be placed in the public domain as a matter of their commercialization.

AMS Response: As discussed earlier, AMS acknowledges there may be technical difficulties associated with deposits of propagating material for some asexually reproduced plants. It may be difficult to successfully preserve tissue cultures of some asexually reproduced varieties over the long term by cryogenic freezing or other means of cold storage. The delayed enforcement provision described earlier will allow PVPO and the industry to explore those issues before enforcing compliance with the deposit requirement.

As with the unknown longevity of commercialized plant varieties, there is no way to guarantee that varieties placed in the public domain will be available for the term of protection under the Act. Thus, waivers attesting that plant varieties would be placed in the public domain could not provide adequate assurance. As described in an earlier comment response, AMS revised the rule as proposed to provide that applicants who request delay waivers due to technical difficulties with depositing propagating materials must maintain the propagating material at a specific physical location, subject to PVPO inspection. AMS further revised the delay waiver provision in the rule as proposed to

clarify that the delay waiver is effective until PVPO notifies the applicant that the technical infeasibility has been resolved. The applicant will have three months from notification to make the required deposit. PVPO will consider the PVP certificate abandoned if the applicant fails to make the required deposit. AMS made no further changes to the rule as proposed based on these comments.

Comment: The commenter representing plant breeder associations asked AMS to clarify several points regarding the proposed propagating material deposit. Relaying questions from stakeholders, the commenter asked how the germplasm deposit system would operate with respect to germplasm access by other breeders. The commenter also asked whether other breeders would have access to varieties for comparison purposes. The commenter asked what rights, if any, the breeder would have over the deposit, and whether the breeder would be obligated to allow public access to the deposit at the end of the grant title. Finally, the commenter asked what rights the PVP office would have to the deposit.

AMS Response: The public does not have access to germplasm deposits during the life of protection. Breeders must purchase comparison varieties from the market or request plant material from the owners of a protected variety. Owners have access to their deposits once they are placed with the repository. For instance, an owner may need to request propagating material from the deposit as a backup to their own supply if it is destroyed or lost. Owners cannot prohibit public access to the deposit at the end of the protection term. Only varieties for which protection has expired, or public varieties, are freely available to the public. PVPO has access to germplasm deposits for examination

purposes and for resolving any disputes about a variety during the term of protection. AMS is making no changes to the rule as proposed based on these comments.

Distinctness Requirement

Currently, to obtain variety protection under the Act, applicants must submit, among other things, a complete description of the candidate plant's origin and breeding history. The applicant must describe the characteristics by which the new plant can be distinguished from its parents. The applicant must also supply a statement of uniformity reporting the level of variability in any characteristics of the new variety. And finally, the applicant must show that the new plant's characteristics are stable within its progeny. Collectively, this information is known in the industry as a Distinctness, Uniformity, and Stability (DUS) report. In response to AMS's proposal to extend variety protection to asexually reproduced plant varieties, two comments from trade associations and one comment from a research university's technology and licensing program posed several technical questions about the variety examination process, including use of DUS reports and other requirements.

Comment: Two commenters asked whether PVPO would adopt the UPOV Technical Guidelines⁵ related to distinctness for each crop. All three commenters advocated PVPO acceptance of UPOV DUS examination reports in lieu of some standard PVPO application requirements to reduce duplication of work and cost breeders have already expended to obtain variety protection in other countries. One commenter advocated establishing a set of minimum requirements for each crop to enable PVPO to compare varieties from different applicants. One of the commenters, assuming UPOV

⁵ Commenters refer to UPOV Technical Guidelines, but AMS assumes they mean the UPOV Test Guidelines, as shown at: https://www.upov.int/test_guidelines/en/; accessed 9/23/2019.

requirements would be used until PVPO could update one of its application forms to accommodate asexually reproduced plants, asked whether the UPOV requirements would remain in place permanently or be replaced by PVPO forms. One commenter suggested technical questionnaires for PVP applications should follow UPOV questionnaires and not be overly detailed.

AMS Response: PVPO is a member of UPOV, which is the international convention for plant variety protection. UPOV standards are agreed upon by its 88 country members. As a member, PVPO recognizes and employs many UPOV protocols where they are consistent with the statutory requirements of the Act. As explained in the Paperwork Reduction Act section of this document, AMS, in conjunction with revising the regulations to provide for protection of asexually reproduced plant varieties, revised the package of forms used in the PVP program. The Table of Characteristics for each crop in UPOV's Test Guidelines is included in the crop specific Exhibit C form of the PVP application. Consistent with the Table of Characteristics' asterisked (prioritized) characteristics⁶, PVPO considers those characteristics minimum requirements in the PVP application. Because PVPO has already updated its application forms, there is no need to temporarily rely on UPOV requirements or to provide for a transition period before applying the PVP requirements established in this rule.

PVPO will consider accepting DUS reports applicants have used to obtain variety protection in other countries on a case-by-case basis. The UPOV Test Guidelines are instructions used by each UPOV member country, including the United States, to create

⁶ Asterisked characteristics (denoted by *) are those included in the UPOV Test Guidelines which are important for the international harmonization of variety descriptions and should always be examined for DUS and included in the variety description by all members of the Union, except in certain circumstances.

their own DUS report that references the Table of Characteristics. The applicant must work with PVPO to determine whether the applicant's country's report provides the information necessary to approve a PVP application. PVPO collects only that information necessary to establish whether a new plant is distinct from other plants. PVPO's examination process, including the questionnaire, incorporates only those questions necessary to provide variety protection under the Act and reflects the UPOV questionnaire. The questionnaire may evolve over time as the industry and PVPO gain experience examining applications for variety protection for asexually propagated plants. Accordingly, AMS is making no changes to the rule as proposed based on these comments at this time.

Comment: Commenters asked whether PVPO would continue to recognize breeder-conducted testing and breeders' variety descriptions. One commenter also encouraged PVPO to continue providing and publishing detailed breeding histories included in applications because the commenter believes the histories are useful to other breeders, and along with other elements of the PVP application, make its protection one of the world's strongest.

AMS Response: AMS will continue to recognize breeder-conducted testing and breeders' variety descriptions. AMS agrees that providing detailed breeding histories is helpful to other breeders and will continue to publish breeding histories included in PVP applications once the new variety is issued a certificate of protection. Breeding histories are published on the PVPO website. Accordingly, AMS is making no changes to the rule as proposed based on these comments.

Fee Structure

PVPO fees are established in the regulations and are published on its website⁷. The current total cost for variety protection is \$5,150, including separate fees for distinct steps of the application and certification process. PVPO also charges for additional services, such as reviving abandoned applications or reproducing records. Currently, applicants pay fees associated with distinct steps of the application process in advance, as they go along. Charges for other services, including clerical work, are payable when the services are requested.

The proposed rule included a revised fee structure that would consolidate all the fees for the application and certification process into one payment due in advance at the time of application. AMS proposed no changes to the total cost of application and certification, nor to the rates for individual elements of the application process. AMS proposed changing the fee structure for certain additional services by eliminating flat fees for those services and reducing the effective hourly rate charged. Two comments addressed the proposed revisions to the fee structure.

Comment: Both comments from trade associations pointed out that variety protection offered by PVPO is more costly than that available from the U.S. Patent Office. Commenters speculated that costs would impact small businesses particularly and could deter many from using PVPO services. Both commenters suggested AMS consider implementing a tiered system that would adjust fees for small businesses and individuals.

AMS Response: PVPO acknowledges the cost of obtaining a PVP certificate is more costly than obtaining a plant patent from the U.S. Patent Office. The PVP program

⁷ <https://www.ams.usda.gov/services/plant-variety-protection/pvpo-services-and-fees>

is funded by user fees. PVPO fees are based on the actual cost of providing services, including examinations, office expenses, and agency overhead. Fees are the same for all applicants. AMS does not believe it would be appropriate or practical to introduce a tiered pricing system based on business size. AMS proposed to consolidate the application and certification fees into one up-front charge because PVPO has considerably reduced the time it takes to approve a PVP application over the years. Whereas the process used to take up to five years, PVP can now complete the work in as little as 18 months. Thus, the waiting period between each step of the process is much shorter. Requiring full payment up front is expected to further streamline the application and certification process by eliminating the need to contact applicants and wait for payments before progressing to the next step. Collecting the fee up front reduces administrative expense and allows PVPO to continue providing faster service at the same, or in some cases lower, cost. Thus, AMS is making no changes to the rule as proposed based on these comments.

Miscellaneous Comments

Three comments made suggestions or requested clarification about PVP regulations.

Comment: One comment from an individual suggested that labels on asexually propagated plants should include information about how the plant was propagated.

AMS Response: The Act and PVP regulations allow for labeling of a protected variety, but there is no statutory requirement to provide specific information. PVP labeling regulations only specify the terminology that may be used on plant labels for which the owners have applied for or obtained U.S. variety protection under the Act.

Under the regulations, labels may contain other information that is not false or misleading. *See* §§ 97.140 to 97.144. Accordingly, AMS is making no changes to the rule as proposed based on this comment.

Comment: One comment from a trade association stated that the regulations are vague regarding the grace period during which breeders can file for PVP after a plant has been commercialized outside the United States. Additionally, the commenter believes there is some ambiguity in the regulations about how the grace period for trees and vines will be applied and suggested that a six-year grace period should be applied to woody plants.

AMS Response: The PVP regulations do not specify the grace period between the dates of commercialization and application for protection under the Act. PVPO references the Act to determine whether a plant can be considered “new” and eligible for PVP protection. *See* 7 U.S.C. § 2402. A breeder who commercializes a new tree or vine outside the U.S. has up to six years to apply for variety protection under the Act. Once a new tree or vine is commercialized in the U.S., the breeder has only one year to apply for variety protection under the Act. To date, PVPO has not received applications for trees or vines, which are usually propagated asexually, and has not had to consider whether a plant is a tree or vine and subject to the Act’s timeframes for those types of plants. Nevertheless, PVPO refers to USDA’s Natural Resources Conservation Service definitions⁸ for *tree* and *vine* to determine whether a plant is a tree or vine for eligibility purposes. Thus, PVPO considers vines to be twining or climbing woody plants with relatively long stems. PVPO considers trees to be perennial, woody plants with a single

⁸ USDA, Natural Resources Conservation Service; https://plants.usda.gov/growth_habits_def.html; accessed 9/25/2019.

stem (trunk), normally greater than 4 to 5 meters (13 to 16 feet) in height. Under certain circumstances, some tree species may develop a multi-stemmed or short growth form (less than 4 meters or 13 feet in height). AMS is making no changes to the rule as proposed based on this comment.

Comment: One comment from a trade association questioned a reference in the proposed rule to a change to § 97.104(a) regarding the disposition of seed deposits of abandoned applications.

AMS Response: The commenter is correct in that the proposed change applied to the existing § 97.104(b), which was proposed elsewhere in the proposed rule to be redesignated § 97.104(a). We have clarified that in the preamble discussion, but AMS made no change to the rule as proposed based on this comment.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small business entities. The affected industry falls under the North American Industry Classification System (NAICS) as code 54171-- Research and development in the physical, engineering, and life sciences. This classification includes firms that are not plant breeders/plant research; however no detailed industry data was available for the analysis.

Table 1 shows the most recent descriptive data for the industry, obtained from the County Business Pattern 2016 survey. This data set provides information on the number of establishments, number of employees, and total annual payroll.

Table 1. Number of Establishments, Revenue and Payroll by Employee Count, NAICS Code 54171, 2016 County Business Patterns ⁹			
	Number of Establishments	Number of Paid Employees	Annual Payroll (\$1,000)
All Establishments	17,292	695,810	\$82,865,611

The Small Business Administration (SBA) determines firm size for this industry by number of employees, but on a per firm basis, with small firms defined as having fewer than 1,000 employees and 1,000 or more employees per firm classified as large. Because firms may own more than one establishment, and the County Business Patterns data are compiled on an establishment rather than a firm basis, we must use the Economic Census data to determine the number of small and large firms for the industry.

Table 2 shows the most recent data available on the breakdown between small (<1,000 employees) and large (1,000 or more employees) firms in this industry, according to the SBA's guidance.¹⁰ The data are from the 2002 Economic Census, with monetary values converted to 2016 dollars. More recent Economic Census data is not available at this level of detail for this industry.

<p>Table 2. Number of Firms and Establishments, Revenue and Payroll by Employee Count, NAICS Code 54171, 2002 Economic Census¹¹</p>
--

⁹ Geography Area Series: County Business Patterns by Employment Size Class, 2016 Business Patterns, https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=BP_2016_00A3&prodType=table

¹⁰ "Table of Small Business Size Standards Matched to North American Industry Classification System Codes", Small Business Administration, effective January 1, 2017, https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf

¹¹ Professional, Scientific, and Technical Services: Subject Series - Establishment and Firm Size: Employment Size of Firms for the United States: 2002 Economic Census of the United States, https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2002_US_54SSS25&prodType=table

Size of Firm by Number of Employees	Number of Firms	Number of Establishments	Number of Paid Employees	Revenue* (\$1,000)	Annual Payroll* (\$1,000)
Small-- Firms with fewer than 1,000 employees	10,200	11,753	273,601	\$49,702,793	\$24,780,487
Large-- Firms with 1,000 employees or more	79	1,380	283,816	\$30,095,258	\$27,776,903
All firms	10,279	13,133	557,417	\$79,798,051	\$52,557,389
*Adjusted to 2016 values.					

The 2002 Economic Census reported that fewer than one percent of firms were considered large (79 of 10,279 firms, or 0.54 percent). The 10,279 firms at that time owned a total of 13,133 establishments, with 1,380 (nearly 11 percent) of these facilities owned by the 79 large firms.

The tables show the extent of growth in the industry over time. The number of establishments has grown from 13,133 in 2002 to 17,292 in 2016 (32 percent, or 2.3 percent per year). Total employment increased from 557,417 workers to 695,810 (25 percent, or 1.8 percent per year), and total annual payroll increased from \$52,557,389 to \$82,865,611 (58 percent, or 4 percent per year). These figures indicate that the industry has seen small to moderate growth, with a more highly paid work force over time. There do not appear to have been significant changes in the structure of the industry between 2002 and 2016.

In reviewing PVPO's list of customers, AMS found evidence that the size distribution of the firms affected by this rule was consistent with data reported in the 2002 Economic Census. AMS estimates that most PVPO customers would be considered small business entities under the criteria established by SBA (13 CFR 121.201), while

fewer than 5% of the plant breeders and plant research and development firms using PVPO services would be considered large businesses with 1,000 or more employees.

The PVP Office administers the PVP Act of 1970, as amended (7 U.S.C. 2321 *et seq.*), and issues certificates of plant variety protection that provide intellectual property rights to developers of new varieties of plants. A certificate is awarded to the owner of a variety after examination indicates that it is new, distinct from other varieties, genetically uniform, and stable through successive generations. PVP is a voluntary service.

This final rule amends the regulations to add application and certification procedures for asexually reproduced plants that mirror procedures currently in use for sexually reproduced and tuber propagated varieties. This final rule is intended to give breeders of new plant varieties additional tools for protecting new and emerging crops that were not previously available. This benefit will accrue to breeders of all sizes. As well, this final rule simplifies the fee schedule for services provided by the PVPO and reduces maximum chargeable fees for some services from \$107.00 per hour to \$97.00 per hour. The new fee schedule and rates will streamline the certification process and reduce the cost of maintaining a PVP certificate of plant variety protection and will apply to applicants of all sizes. Finally, the modernization of business processes under the regulations is intended to improve service delivery to PVPO customers of all sizes.

There are currently more than 800 users of the plant variety protection service, of whom about 95 file applications in a given year. Some of these users are small business entities under the criteria established by SBA (13 CFR 121.201). With this action, the number of users is expected to increase by roughly 40 firms. AMS expects the industry to submit an additional 50 new applications on a yearly basis.

PVP applicants are subject to an application fee of \$5,150 per certificate. This final rule allows firms that withdraw their applications to be reimbursed \$3,864 prior to examination, and \$768 prior to issuing a PVP certificate. Additional services are available from the PVPO at the request of the applicant. Applicants using these services are subject to fees as listed in the rule schedule (7 CFR 97.175), with the inclusion of the reduction in fees for specified services. It is expected that new applicants will also participate in the germplasm deposit, at a cost of \$3,000 per deposit, after the delayed enforcement period, which ends January 6, 2023.

The burden on new entrants is calculated by multiplying the cost of application, \$5,150, by the number of expected new applications (50), for an additional cost of $\$5,150 \times 50 = \$257,500$. The cost to new entrants for the germplasm deposit after January 6, 2023, is $\$3,000 \times 50 = \$150,000$. In total this represents an additional cost to industry for this proposed rule of \$407,500. The estimate is an upper boundary made without including the cost savings that result from deposit waivers, the reduced hourly fee for additional services, or the reimbursement for withdrawn applications, as these cost reductions are expected to be needed infrequently.

Due to the limited cost of the final rule expanding a voluntary program, AMS has determined that this action will not have a significant economic impact on a substantial number of these small business entities.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), AMS submitted the information collection requirements for this program as a new collection to OMB for approval. AMS developed a new PVP application form for

asexually reproduced plant varieties. AMS estimated a total annual reporting burden of 553 hours associated with the new form, based on an estimated 50 respondents (the number of additional applications) making approximately 12.82 responses averaging 0.86 hours per response.

On May 14, 2019, AMS published a notice concerning the request for OMB approval of the new form and solicited comments on the new information collection and estimated burden (84 FR 21314). The notice provided a 60-day comment period to allow interested parties to submit comments on the approval request. AMS received two comments. Both included comments on certain aspects of the concurrent proposed rule as well as comments on the information collection. AMS addressed comments on the proposed rule in the Comments section of this document above, and addresses comments on the information collection here.

Comment: One comment from a university technology and licensing program recommended that PVPO employ online technical questionnaires to collect crop-specific information. According to the commenter, UPOV uses such questionnaires, which the commenter believes are more practical and less burdensome to file and would harmonize the ST-470 series of forms with similar DUS forms used in other countries.

AMS Response: PVPO incorporated the UPOV Test Guidelines into its forms related to asexually reproduced crops in order to harmonize with the UPOV system. The PVPO still requires the use of Form ST-470 and related exhibits, since the U.S. PVP system is breeder-based. Under PVP, the breeder performs the two required grow-out trials and provides the characteristics data from those trials on the crop-specific Exhibit C form, which incorporates the UPOV Table of Characteristics. Form ST-470 and its

exhibits provide PVPO with information needed by the examination staff in the absence of PVPO-controlled grow-out trials. Accordingly, AMS made no changes to the approved forms based on this comment.

Comment: One comment from an association of plant breeders, producers, and traders supported replacing Form ST-470-C (Exhibit C – Objective Description of Variety) with an approved DUS report from a UPOV member state. The commenter also supported merging Forms ST-470-A, -B, and -E (Exhibits A, B, and E) into one form for the PVPO information collection, although they did not explain why. Finally, the commenter asserted that the information collected on Form ST-470-A (Exhibit A – Origin and Breeding History) is not necessary for all plant species because plant pedigree information is irrelevant to the variety description. The commenter believes requiring such information is administratively burdensome and breaches business confidentiality.

AMS Response: PVPO will accept DUS reports from other UPOV countries on a case-by-case basis for all asexually reproduced varieties and several sexually propagated varieties. The information applicants provide on Form ST-470-A (Exhibit A - Origin and Breeding History) demonstrates to PVPO examiners that a variety has been further developed beyond just discovery of a new variety. AMS believes the information requested does not differ in principle from the questions asked on the UPOV Technical Questionnaire regarding breeding type and history. AMS believes the information collected on Form ST-470 and its exhibits allows PVPO to complete a full examination of a new variety for distinctness, uniformity, and stability. Accordingly, AMS made no changes to the new information collection in response to the comments.

OMB approved the new information collection and the new application form, which will be merged with PVPO's existing information package, OMB No. 0581-0055.

This final rule revises the PVP regulations to allow PVPO to issue certificates of protection for asexually reproduced plant varieties. This final rule also simplifies the fee schedule for applicants and will lower the fees for some services. Finally, this rule modernizes the PVPO regulations to reflect current industry and government business operations. Reports and forms used in PVPO operations are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

E-Government Act

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Orders 12866 and 13771

This final rule does not meet the definition of a significant regulatory action contained in section 3(f) of Executive Order 12866 and is not subject to review by the Office of Management and Budget (OMB). Additionally, because this proposed rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Costs'" (February 2, 2017).

Executive Order 13175

This final rule has been reviewed under Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires

Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) policies that have tribal implication, including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

AMS has assessed the impact of this rule on Indian tribes and determined that this rule will not have tribal implications that require consultation under Executive Order 13175. AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about changes to the regulations were shared during one such quarterly call, and tribal leaders were informed about the revisions to the regulations and invited to ask questions and share concerns. AMS will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the PVPO regulations.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a major rule as defined by 5 U.S.C. 804(2).

Executive Order 12988

This rule has been reviewed under Executive Order 12988 – Civil Justice Reform. This action is not intended to have retroactive effect, nor will it preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with the rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 63 of the Act, when an application for plant variety protection has been refused by the PVPO, the applicant may appeal to the Secretary. The Secretary must seek the advice of the Plant Variety Protection Board on all appeals before deciding an appeal. The Act provides that an applicant can appeal the Secretary's decision in the U.S. Court of Appeals for the Federal Circuit or institute a civil action in the U.S. District Court for the District of Columbia, provided that such action is taken within 60 days of the Secretary's decision, or such further time as the Secretary allows.

List of Subjects in 7 CFR part 97

Plants, seeds

For the reasons set forth in the preamble, USDA amends 7 CFR part 97 as follows:

PART 97 – PLANT VARIETY AND PROTECTION

1. The authority citation for part 97 continues to read as follows:

Authority: Plant Variety Protection Act, as amended, 7 U.S.C. 2321 *et seq.*

2. Revise § 97.1 to read as follows:

§ 97.1 General.

Certificates of protection are issued by the Plant Variety Protection office for new, distinct, uniform, and stable varieties of sexually reproduced, tuber propagated, or asexually reproduced 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.

3. Amend § 97.2 by removing the definition for “Official Journal” and revising the definition for “Sale for other than seed purposes”.

The revision reads as follows:

§ 97.2 Meaning of words.

* * * * *

Sale for other than seed or propagating purposes. The transfer of title to and possession of the seed or propagating material by the owner to a grower or other person, for reproduction for the owner, for testing, or for experimental use, and not for commercial sale of the seed, reproduced seed, propagating material, or reproduced propagating material for planting purposes.

4. Amend § 97.5 by revising paragraph (c) to read as follows:

§ 97.5 General requirements.

* * * * *

(c) Application and exhibit forms shall be issued by the Commissioner. (Copies of the forms may be obtained from the Plant Variety Protection Office by sending an email request to PVPOmail@usda.gov or downloading forms from the PVPO website (<https://www.ams.usda.gov/PVPO>)).

* * * * *

5. Amend § 97.6 by revising paragraphs (c) and (d)(3) and adding paragraph (d)(4) to read as follows:

§ 97.6 Application for certificate.

* * * * *

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

(d) * * *

(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, or

(4) Except as provided in § 97.7(d)(3), with the application for an asexually propagated variety, a declaration that a deposit of propagating material in a public depository approved by the Commissioner will be made and maintained for the duration of the certificate.

6. Amend § 97.7 by revising the first sentence of paragraph (b) introductory text and paragraphs (c)(5) and (d) to read as follows:

§ 97.7 Deposit of Voucher Specimen.

* * * * *

(b) *Need to make a deposit.* Except as provided in (d)(3), applications for plant variety protection require deposit of a voucher specimen of the variety. * * *

* * * * *

(c) * * *

(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 on the Plant Variety Protection Office website
(<https://www.ams.usda.gov/PVPO>).

(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. An original deposit of materials for tuber-propagated plants or asexually reproduced plants shall be made within three months from the notice of certificate issuance date. A waiver from these time requirements may be granted for good cause, such as delays in obtaining a phytosanitary certificate for the importation of voucher sample materials. A delay waiver may also be granted if the repository determines that it is technically infeasible to deposit propagating materials for certain asexually reproduced plants.

(1) 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:

- (i) The name and address of the depository;
- (ii) The date of deposit;
- (iii) The accession number given by the depository; and
- (iv) A statement that the deposit is capable of reproduction.

(2) The following conditions apply to delay waivers granted due to technical difficulties with depositing propagating material for asexually reproduced plants:

(i) The applicant is required to make a declaration that the propagating material will be maintained at a specific physical location, subject to Plant Variety Protection Office inspection when requested; and

(ii) The applicant is required to make a declaration that propagating material will be provided within three months of a request by the Plant Variety Protection Office. Failure to provide propagating material as requested shall result in the certificate being regarded as abandoned.

(iii) The delay waiver is effective until the Plant Variety Protection Office notifies the applicant that the technical infeasibility has been resolved. Upon that notification, the applicant must provide a deposit within three months. Failure to provide a deposit shall result in the certificate being regarded as abandoned.

(3) Original deposits of propagating material for asexually reproduced varieties are not required for applications submitted between January 6, 2020, and January 6, 2023; provided: *That* the applicant is required to make the declarations described in paragraphs (d)(2)(i) and (ii) of this section.

* * * * *

7. Amend § 97.9 by revising paragraphs (b) and (c) to read as follows:

§ 97.9 Drawings and photographs.

* * * * *

(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 color fan, the Munsell Book of Color, the Royal Horticultural Society Colour Chart, or other recognized color chart.

(c) Drawings shall be sent flat, or may be sent in a suitable mailing tube or by e-mail in high resolution format, in accordance with instructions furnished by the Commissioner.

* * * * *

8. Amend § 97.12 by revising paragraph (a) to read as follows:

§ 97.12 Number and filing date of an application.

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

* * * * *

9. Amend § 97.14 by revising paragraph (d) to read as follows:

§ 97.14 Joint applicants.

* * * * *

(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 the address of the missing owner is unknown, notice of the filing of the application shall be published once on the Plant Variety Protection Office website (<https://www.ams.usda.gov/PVPO>). Prior to the issuance of the certificate, a missing owner may join in an application by filing a written explanation. A certificate obtained by fewer than all of the joint owners under

this paragraph conveys the same rights and privileges to said owners as though all of the original owners had joined in an application.

10. Amend § 97.19 by revising the introductory text and paragraph (c) to read as follows:

§ 97.19 Publication of pending applications.

Information relating to pending applications shall be published periodically as determined by the Commissioner to be necessary in the public interest. With respect to each application, the Plant Variety Protection Office website (<https://www.ams.usda.gov/PVPO>) shall show:

* * * * *

(c) The name of the crop; and

* * * * *

11. Amend § 97. 20 by revising paragraph (a) to read as follows:

§ 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 filing and examination fees in such cases will not be refunded.

* * * * *

12. Amend § 97.23 by revising paragraph (c) and removing paragraph (d).

The revision reads as follows:

§ 97.23 Voluntary withdrawal and abandonment of an application.

* * * * *

(c) An original application which has been voluntarily withdrawn shall be returned to the applicant and may be reconsidered only by refiling and payment of new filing and examination fees.

13. Revise § 97. 101 to read as follows:

§ 97.101 Notice of allowance.

If, on examination, PVPO determines that the applicant is entitled to a certificate, a notice of allowance shall be sent to the applicant or his or her attorney or agent of record, if any, requesting verification of the variety name and of the name of the owner. The notice will also provide an opportunity for withdrawal of the application before certificate issuance. The applicant must respond within 30 days from the date of the notice of allowance. Thereafter, a fee for delayed response shall be charged as specified in § 97.175(f).

14. Amend § 97.103 by revising paragraph (a) to read as follows:

§ 97.103 Issuance of a certificate.

(a) After the notice of allowance has been issued 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.

* * * * *

15. Revise § 97.104 to read as follows:

§ 97.104 Application or certificate abandoned.

(a) Upon request by the Office, the owner shall replenish the seed or propagating material of the variety and shall pay the handling fee for replenishment. Samples of seed or propagating material related to abandoned applications or certificates will be retained or destroyed by the depository. Failure to replenish seed or propagating material 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 on the Plant Variety Protection Office website (<https://www.ams.usda.gov/PVPO>), 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.

(b) If the seed or propagating material is 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 seed or propagating material before declaring the certificate abandoned.

(c) A certificate may be voluntarily abandoned by the applicant or his or her attorney or agent of record or the assignee of record by notifying the Commissioner in writing. Upon receipt of such notice, the Commissioner shall publish a notice on the Plant Variety Protection Office website (<https://www.ams.usda.gov/PVPO>) 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.

16. Revise § 97.141 to read as follows:

§ 97.141 After issuance.

Upon issuance of a certificate, the owner of the variety, or his or her designee, may label the variety, propagating material of the variety, or containers of the seed of the variety or plants produced from such seed or propagating material substantially as follows: “Unauthorized Propagation Prohibited—(Unauthorized Seed or Propagating Material Multiplication Prohibited)—U.S. Protected Variety.” Where applicable, “PVPA 1994” or “PVPA 1994—Unauthorized Sales for Reproductive Purposes Prohibited” may be added to the notice.

17. Revise § 97.142 to read as follows:

§ 97.142 For testing or increase.

An owner who contemplates filing an application and releases for testing or increase seed of the variety or propagating material 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.”

18. Revise § 97.175 to read as follows:

§ 97.175 Fees and charges.

The following fees and charges apply to the services and actions specified in paragraphs (a) through (f) of this section:

(a) Application:

- (1) Initial fee for filing, examination, and certificate issuance -- \$5,150
- (2) Submission of new application data prior to issuance of certificate -- \$432
- (3) Granting extensions for responding to data requests -- \$89

(4) Refunds pursuant to § 97.178 may be issued for portions of the initial application fee as follows: examination - \$3,864, and certificate issuance - \$768.

(b) Reconsideration of application -- \$589

(c) Revival of an abandoned application -- \$518

(d) Appeals:

(1) Filing a petition for protest to Commissioner -- \$4,118

(2) Appeal to Secretary (refundable if appeal overturns protest to Commissioner) -- \$4,942

(e) Field inspections or other services requiring travel by a representative of the Plant Variety Protection Office, made at the request of the applicant, shall be reimbursable in full (including travel, per diem or subsistence, salary, and administrative costs), in accordance with standardized government travel regulations.

(f) Any other service not covered in this section, including, but not limited to, reproduction of records, authentication, correction, or reissuance of a certificate, recordation or revision of assignment, and late fees will be charged for at rates prescribed by the Commissioner, but in no event shall they exceed \$97 per employee hour. Charges will also be made for materials, space, and administrative costs.

19. Revise § 97. 177 to read as follows:

§ 97.177 Method of payment.

Payments can be submitted through the electronic Plant Variety Protection system or pay.gov. 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.

20. Revise § 97.178 to read as follows:

§ 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 fee shall be refunded if an application is voluntarily withdrawn or abandoned pursuant to § 97.23(a) before the examination has begun. The certificate issuance fee shall be refunded if an application is voluntarily withdrawn or abandoned after an examination has been completed and before a certificate has been issued. Amounts of \$1 or less shall not be refunded unless specifically demanded.

21. Amend § 97.403 by revising paragraph (d) to read as follows:

§ 97.403 Manner of service.

* * * * *

(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 on the Plant Variety Protection Office website (<https://www.ams.usda.gov/PVPO>).

22. Revise § 97.500 to read as follows:

§ 97.500 Appeal to U.S. Courts.

Any applicant dissatisfied with the decision of the Secretary on appeal may appeal to the U.S. Courts of Appeals for the Federal Circuit or institute a civil action in the U.S. District Court for the District of Columbia, 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.

23. Amend § 97.600 by revising the heading to read as follows:

§ 97.600 Administrative provisions.

* * * * *

24. Revise § 97.800 to read as follows:

§ 97.800 Publication of public variety descriptions.

Voluntary submissions of varietal descriptions of “public varieties” on forms obtainable from the Office will be accepted for publication on the Plant Variety Protection Office website (<https://www.ams.usda.gov/PVPO>). Such publication shall not constitute recognition that the variety is, in fact, distinct, uniform, and stable.

Dated: December 18, 2019.

Bruce Summers, Administrator,
Agricultural Marketing Service.

BILLING CODE 3410-02 P

[FR Doc. 2019-27636 Filed: 1/3/2020 8:45 am; Publication Date: 1/6/2020]