

540.79 ESCOP Policy Statement for Developing and Releasing Improved Plants

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Foreword

This statement offers guidance to scientists and administrators of State Agricultural Experiment Stations (SAESs) concerning the development, release, and multiplication of germplasm of seed-propagated plants as either germplasm or crop varieties. Policies and practices addressed are those for which there is general agreement or for which uniformity or continued cooperation among the SAESs is critical.

In recent years, the policies and practices of SAESs have changed significantly in response to: continuing expansion of the private plant breeding industry; the changing needs of producers, growers, seedsmen and postharvest industries; the emergence of new research opportunities and industries in molecular genetics and biotechnology; continuing concern over adequacy of funding; public and private sector needs for new and replacement scientists; changes in state and U.S. Department of Agriculture (USDA) research policies, and new interpretations of patent laws. Less visible, but equally significant, have been the changing and diverging perceptions of universities and their state legislatures relative to public purpose doctrine and the use of public funds, intellectual property rights, academic freedom and conflict of interest.

Publicly supported germplasm development research by SAES began about a century ago. Since then, most SAESs have been directed into such work by congress and state legislatures in order to meet the specific needs of agriculture of those states. New knowledge, new technologies, new and improved germplasm resources, and new varieties are major products. Cooperation among the SAESs, USDA organizations -Agricultural Research Service (ARS), Natural Resources Conservation Service (NRCS), Forest Service (FS) and private industry is positive and strengthens opportunities for germplasm improvement. Hallmarks of cooperation include free exchange of information and of germplasm materials and varieties, shared development and maintenance of germplasm resource banks, shared responsibility for regional multilocal testing of each other's materials and varieties, release of only truly superior materials and varieties individually or cooperatively as appropriate, to the relative investments in developing them and fostering infrastructures to ensure entry, movement and maintenance of public varieties in intra- and interstate commerce. Legislative mandates for SAESs today operate in markedly changed circumstances.

The SAESs contribute to the education and training of future plant breeders, geneticists, biotechnologists and other plant scientists through linkages with instructional programs of parent universities. Plant science instructional programs gain most of their capacity for continual updating and modernization by engaging SAES research scientists in instructional activities. These scientists reflect the diversity and changes in specialization characteristic of the frontiers of plant science research. Student opportunities to gain firsthand work experience in research are similarly enriched by SAES research programs. About three-fourths of the assistantships available to graduate students in agriculture are in SAES programs. But as research programs shift emphasis, so also must instructional programs change. Paradoxically, growth in private plant breeding and variety development programs reduces the need for some public breeding programs but increases the need for trained plant breeders on which private industry depends for that growth.

Since the 1930s, privately supported germplasm development has expanded greatly. Private firms then and now rely heavily on publicly funded research to supply new advances in genetics, breeding, science and technology, and improved germplasm resource materials. Today, many private firms contribute to germplasm needs of agriculture, particularly in varietal development, notably in the multimillion acre crops. This competition among firms enhances variety improvement essential to keeping U.S. producers competitive at home and abroad. Rapid variety improvements are sustained, in part, by continuing releases of public germplasm with special qualities such as resistance to a new local race of pathogens or improved protein. Public varieties also contribute, though public varietal development in many crops has given way to private varietal development.

In many states, a lack of suitable private varieties or special production or marketing conditions have enhanced public support for germplasm development and variety releases in some relatively large acreage crops. In most states, small acreage or specialty crops are economically important to the state but offer little incentive to private firms to develop either germplasm resources or varieties. The SAESs respond as resources permit.

Currently, SAESs face several troublesome and unresolved issues. Maintaining free exchange of germplasm among researchers and its relatively free use in developing new germplasm resources and varieties is a major issue. Another issue is the extent and impact of the use of utility patents to protect intellectual property rights in the public and private sector research. Yet another issue is the impact of varying university policies relative to public purpose doctrine and uses of public funds, intellectual property rights, academic freedom and conflicts of interest.

Finally, prospects of intensified long-term competition for domestic and foreign markets are causing states to seek a competitive edge through locally controlled supply, research and marketing programs. Similar competition occurs internationally as plant breeding moves to multinational firms. Such competition can impede free flow of information and germplasm.

SAES personnel will continue to cooperate jointly with ARS and other agencies of USDA and private industry, to preserve, evaluate and enhance germplasm and to advance graduate training in plant breeding. Products of joint research between SAESs and ARS will be handled as mutually agreed by the cooperators following their respective policy guidelines.

Responsibilities and Guidelines Concerning Development, Release and Multiplication of Publicly Developed Germplasm and Varieties of Seed-Propagated Crops

These guidelines are intended to identify those practices and policies relating to development, release and multiplication of germplasm and varieties in SAES programs which may best serve public interests. They cover both agronomic and horticultural crops. Cooperation among scientists and among SAESs, federal agencies and private firms takes many forms. One of the most important is sharing of germplasm and information about germplasm. In this document, germplasm includes seed and vegetatively propagated genetic material, cell and tissue culture lines, DNA fragments and pollen.

I. Sources for New Germplasm Improvement

A. Collection, Introduction and Preliminary Evaluations of New Plant Germplasm

The USDA, through its ARS and the NRCS Plant Materials Center Program, in cooperation with the SAESs, collects, evaluates, preserves and distributes plant germplasm materials from foreign and domestic sources. Each introduction or accession is identified serially by an inventory number (PI no.) along with passport data. Through various cooperative arrangements, characteristics of accessions are evaluated and catalogued. These characteristics include reactions to insects, disease and climatic conditions, quality attributes, potential promising end-products, and other desirable traits. This information is made available to public agencies and the private sector through the USDA Germplasm Resources Information Network (GRIN) database.

State and federal agencies other than ARS also conduct domestic and foreign plant explorations. Such activities should be coordinated with those of the ARS to prevent duplicate introductions, evaluations and distributions of the same germplasm. Access to resulting plant collections by public and private plant breeders is encouraged; it is required of all ARS supported collections.

B. Use of Introductions

Persons receiving new materials through the National Plant Germplasm System are requested to report to donors their observations and performance test results of materials. These reports are

compiled, annotated and disseminated through the four regional research (RRF) projects on plant introductions¹. Lists of stocks maintained in the Germplasm System are available from GRIN. Individuals or organizations proposing to increase and distribute seed or plant materials of such introductions in their original genetic form are asked to make this intention known to the donor agency. Plans for joint SAES/ARS release, thereby, can be considered. Confusion that might arise from duplication of identifying names or numbers given to the same introduction by public or private interests thus can be avoided (see Section V).

C. Recognition of Originating Source of Introduced Materials

Recipients of introduced materials should publicly acknowledge their source when such materials are increased or distributed in their original form. Recipients also should acknowledge their source when they create and release a demonstrably unique or novel line or variety by modifying the genetic makeup of the introduced materials.

¹*Reference.* The National Program for Conservation of Crop, Athens, Germplasm. A Progress Report on the Introduction, Screening and Preservation of Plant Material, June 1971. University of Georgia Georgia. done for modifications by conventional (selection, inbreeding, etc.) and unconventional means (rDNA, fusion, etc.). In addition, the agency providing the original material should be informed of the specific characters in the new variety or line that were derived from the introduced materials. Public acknowledgments should cite original plant inventory number (PI) or other identification.

II. Studies of Heredity and Methods of Improvement, Enhancement via Biotechnologies and the Conduct of Basic/ Fundamental Research

A. Obligation of State Agricultural Experiment Stations

An objective of the SAESs is to research the characters and properties of plant materials, modes of reproduction, the inheritance of characters, and the modification and control of heredity.

B. Availability and Use of Basic Genetic Materials

Fundamental research on the inheritance, physiology and interaction of plants, pathogens and pests is a vital link in the development of improved varieties. The SAESs pursue this fundamental research to support the development of improved germplasm and varieties.

C. Prompt Availability of Results

The SAESs make the results of research studies available to all researchers, public or private, through prompt publication of research findings.

D. Acknowledgment of Use of Publicly or Privately Developed Basic Genetic Materials

Public acknowledgment of the use of publicly or privately developed basic genetic materials in the development of a new variety is the responsibility of the developer. Acknowledgment is strongly encouraged because it gives due recognition to the contribution of public or private programs.

III. Development of Superior Varieties and Novel Germplasm

A. A Function of the State Agricultural Experiment Stations

SAESs have responsibility to develop improved germplasm and varieties to reduce production hazards, improve quality and increase biological efficiency.

B. Interrelations with Private Plant Breeding Program

Free interchange of materials, specialized facilities, scientific competence in many disciplines, and the opportunity to test, observe, and to study reactions under a wide range of environmental conditions enhance the probability of a successful germplasm system. SAESs encourage germplasm exchange with private industry.

IV. Testing and Evaluating Experimental Varieties

A. Adequate Comparisons with Standard Varieties

Experimental varieties and lines should be tested for yield, quality, survival, disease and insect reaction, and other important characteristics in comparison with standard varieties. Experimental designs and statistical techniques that assure valid measures of performance should be used.

B. Interstate and Regional Tests

Some varieties are widely adapted and not limited. Interstate testing and, when appropriate, international testing should be encouraged. Regional testing facilitates more general use of widely adapted varieties. It also reduces time needed to provide reliable information on varietal adaptations. Material can be included in regional/international tests only with the permission of the developer or owner.

C. Testing for Special Requirements

New crop varieties to be used for food must be tested for nutritive composition, concentration of toxic constituents, or stability in processing when they reasonably might be expected to vary significantly from varieties in commercial production. The term "vary significantly" has been defined as varying 10 percent in toxicological content and 20 percent in nutritive content. The Food and Drug Administration requires submission of data for proposed new food varieties that have had significant alteration of such composition.

Submitted data will permit determination as to whether the variety merits listing as "Generally Regarded as Safe" (GRAS). (Federal Register, Document 71-8976, page 12094, June 18, 1971.)

New varieties of crops to be used for specialized industrial or other purposes should be tested for these uses. Potential users should have the opportunity to evaluate a variety before it is released.

D. Protecting Lines and Varieties Against Premature or Unauthorized Distribution

All reasonable precautions should be taken to protect the privileged or restricted status of propagating materials, experimental lines or experimental varieties during testing and seed increase to prevent pirating and premature or unauthorized distribution prior to release. The possibility that an application for some form of variety protection may be filed intensifies the need for such precaution.

V. Guidelines for SAES Release of Germplasm

SAESs develop and release improved germplasm for the benefit of agriculture within their states. Traditional releases have been as basic genetic materials, parental lines and varieties.

A. Availability and Use of Basic Genetic Materials

Germplasm from SAES programs should be made available under reasonable terms and provisions to foster research and cooperation by public and private scientists. International sharing of germplasm should stress reciprocity or other benefits to the donor.

Basic genetic materials should generally be made available to all plant breeders who request them. The term basic genetic material refers to plant material possessing one or more potentially desirable characters which, in the opinion of the plant breeders, may be of value in plant breeding and when, in their opinion, such general release is in the best interests of United States agriculture and the state research program.

Periodically, the originating station should make notification of germplasm releases, specifying limitations on use and on the amount of material available for distribution.

Every effort should be made to insure that basic genetic materials are not monopolized by any interests. Furthermore, inbreds, experimental lines and basic genetic materials normally should not be released in foreign countries prior to their release in the United States.

B. Releasing Finished Genetic Materials

SAESs will release finished varieties and inbreds as accomplishments of research and educational programs. These releases should be accessible to the public.

A variety or inbred should not be released unless it is superior to existing varieties in one or more characteristics important for the crop, or it is superior in overall performance in areas where adapted and is satisfactory in other major requirements or is novel in some other way. A single major production hazard which a new variety can overcome, e.g., a highly destructive disease, may become the overriding consideration in releasing a variety. Varieties with a very limited range in adaptation should not be released unless performance in that limited range is superior, or the variety possesses values not otherwise available, including diversification of the germplasm base for a species.

C. Policy Committee or Board of Review for Variety Release

Decisions on the release of new varieties and the type of release should be made for each state by the SAES director. The SAES should appoint a policy committee or board of review charged with reviewing the proposal for the release of a new variety. Appropriate information concerning characteristics, performance, area of adaptation, specific use values, seed stocks, and proposed methods of varietal maintenance and increase and distribution should be presented to this committee.

D. Interstate or Interagency Release Procedures

When a variety or inbred has been tested on an interstate basis, opportunity to consider simultaneous release of the seed must be given each state in the interstate program.

If, for some reason, prior interstate testing was not conducted, the state which releases a new variety should offer seed of the new variety to all interested states for testing and increase; thus nearby states may obtain information to answer questions from potential users about the new variety. Regional advisory committees may set guidelines for sharing of Foundation Seed stocks among states.

When the development of a new variety is a cooperative effort by a state or states and a federal agency (USDA/ARS, USDA/SCS or USDA/FS), joint releases could potentially be made by the agencies involved. Appropriate use should be made of the services of the Association of Official Seed Certifying Agencies, the U.S. Plant Variety Protection Office and the U.S. Patent and Trademark Office in determining novelty of and in cataloging new varieties.

E. Protection and Restricted Release

A SAES may elect to protect (Plant Variety Protection (PVP) or patent) or otherwise restrict certain uses of germplasm. The major consideration for patenting and restricted release should be benefits to U.S. agriculture. Royalties or fees that accrue from protected germplasm should be distributed to enhance and support research according to local institutional policies. When an SAES collects royalties from seed of a variety sold in another state and the variety was developed by cooperative research between the two SAESs, these royalties should be shared.

Utility patents likely will be used commonly to protect plant germplasm. To hasten plant improvement, a SAES should seek variances in protection offered by utility patents. Such variances also would counteract the adverse effects of one SAES asking another SAES for fees for patented materials which that SAES had participated in developing. At risk are cooperative efforts such as free exchange of germplasm and information and the voluntary and free multilocational regional testing of each other's germplasm and varieties.

Unlike PVP protection, utility patents do not automatically allow use of patented material in research or plant improvement programs without approval of or compensation to the patent holder. A "research clause", or exemption from seeking approval for research use, is recommended. Also recommended is a waiver of certain dominance rights of a patent over future patents on materials derived from the initial patent. Holders of patents on marketed materials derived from an earlier patent should be required to compensate the holder of that earlier patent only during the first 5 years (time may vary according to local institutional policy) of the life of that patent rather than

the 17 stipulated in the law. In both cases, users of patented materials should acknowledge the source of germplasm.

F. Preserving Genetic Identity

Identical genetic material should not be distributed or sold under different names, varieties or brands. The genetic identity (i.e., the parentage) of all materials should be available to the user. Advanced methodologies or techniques that enable identification include analyses of seed proteins and isozymes and nuclear restriction fragment length polymorphisms.

VI. Naming and Registering Varieties

A. Designation

A new variety should be given a permanent designation before it is released. The designation should be acceptable to the states/agencies participating in the release, but the originating station or agency has the final responsibility for providing this designation and naming new varieties. Brevity in designation is desirable. When this designation is a name, one short word is preferable; two short words are, however, acceptable. Meaningful number designations or combinations of words, letters and numbers, consistent with accepted procedures, are also acceptable.

The International Code of Nomenclature for Cultivated Plants provides guidelines for naming varieties and should be consulted.

B. Use of Names

Identical germplasm can not be distributed or sold under different names. The same name should not be used more than once in a given crop. Similar names should also be avoided. Provisions of the Federal Seed Act (53 Stat. 1275) apply.

Once established, a legitimate varietal name should not be changed. Varietal names which are misleading or which are identical or similar to brand names or trademarks associated with agricultural products should be avoided, as there may be an implied association of the variety and trade names or trademarks. Proposed names should be cleared to determine previous use of the proposed variety name and for possible infringement of trademarks by contacting the Livestock and Seed Division, Agricultural Marketing Service.

C. Registering Varieties

Information on new varieties of crops for which national variety review boards have been established should be submitted to the review board following consideration by the state variety committee but before final release.

New varieties of crops should be registered. Following release of the variety, information for the registration or listing should be submitted promptly to the Crop Science Society of America (CSSA) or the American Society for Horticultural Science (ASHS). Procedures for registering varieties are available from CSSA, and procedures for listing varieties are available from ASHS. Materials registered with the CSSA become a part of the National Plant Germplasm System and small amounts of seed are freely available to bona fide researchers. This is a voluntary program.

VII. Definition of Classes Certified Seed and of Certification Standards

The Association of Official Seed Certifying Agencies, in the current issue of its "Certification Handbook", defines the various classes of certified seed and certification standards and procedures. These definitions, now and as amended in the future, are a part of this policy.

VII. Increase and Maintenance of Breeder Seed

A. Responsibility for Maintaining Breeder Seed

The originating SAES or agency should prepare a statement of plans and procedures for maintaining Breeder and Foundation Seed, including any limitations on the number of generations through which the variety may be sold by variety name.

When a variety is sufficiently promising to justify consideration for release, Breeder Seed should be increased to the volume needed to produce and maintain required Foundation Seed. So long as a variety is retained in the seed program of the originating state, that state should maintain a reasonable reserve of Breeder Seed, which will be used to replenish and restore Foundation Seed of the variety to the desired level of genetic purity. When the variety is distributed in several states, or when the originating state or agency ceases to maintain Breeder Seed of a variety, a mutually satisfactory plan should be formulated by the interested states or agencies regarding the maintenance of Breeder Seed. Interested states should be notified well in advance by the originating state or agency when it plans to discontinue maintenance of Breeder Seed of a variety.

When states jointly release a variety, they should formulate a procedure for making a supply of Foundation Seed available to each state.

B. Supplying Sample of Seed to National Seed Storage Laboratory

A sample of Breeder Seed of all newly released varieties should be supplied by the originating state or agency to the National Seed Storage Laboratory (NSSL), Fort Collins, Colorado. Recording forms are provided by that laboratory. Seed deposit in the NSSL is required for CSSA registration.

IX. Increase, Maintenance and Distribution of Foundation Seed

A. Multiplying Foundation Seed

An adequate and recurring supply of Foundation Seed is essential for multiplying a variety. Foundation Seed of publicly produced varieties should be increased by authorized parties who have the experience, facilities and skill to assure adequate supplies of seed with acceptable levels of genetic purity.

B. Distributing Foundation Seed

To avoid problems, Foundation Seed of a new variety should be simultaneously released in all interested states. If Foundation Seed is distributed into another state where the variety is being distributed under allocation as a new release, the Foundation Seed should be offered through, or with the concurrence of, the official seed stocks or certifying agency in that state.

C. Basic Principles in Foundation Seed Programs

Foundation Seed should be released in a manner that provides greatest benefit to users and the public. Within this context, Foundation Seed programs should recognize the following basic principles:

1. Qualified seed growers and seedsmen should have an opportunity to obtain appropriate planting stocks of unrestricted varieties at an equitable cost; however, selective allocations may be necessary to achieve quality increases to meet the needs of potential users.
2. Release of Breeder and/or Foundation Seed of a variety to one or a few growers or seedsmen is appropriate when more widespread distribution will not insure an adequate seed supply on a continuing basis. When limited release is anticipated, federal and state agencies and private grower or seedsmen should be notified and given an opportunity to bid for that release.
3. Planting stocks of varieties developed cooperatively with the agencies of USDA ordinarily will be made available through or with the concurrence of the seed stocks or certifying agency of the cooperating state(s) at an equitable cost to qualified seed growers and seedsmen. In special circumstances, e.g., No. 2 above, consideration may be given to, granting limited term exclusive rights. For this purpose, consideration should be given to applying for certificates of variety protection under the Plant Variety Protection Act or some other form of protection.

X. Preparation and Release of Information

A. Coordinating Publicity among States and Agencies

Seed producers, distributors and users should be informed as fully as possible, consistent with variety testing policies and procedures within each state, of the values and the adaptation of new varieties in comparison with other available varieties.

Pertinent information as to the basic facts of origin, variety characteristics, and data justifying the increase and release of a new variety shall be prepared by the fostering state(s) and agency(ies) and provided to other interested states or agencies. The information used in deciding upon release of a new variety should also be used to inform seed producers, distributors and the public of its value.

Participating states or agencies should use this material, supported or modified by their own information, in state or national publicity. Publicity intended for national or region periodicals should include information on the regional adaptation of the variety. A uniform date for the release of initial publicity should be agreed upon by the fostering states and/or federal agencies.

Appropriate information concerning actions with respect to PVP, including certification requirements, should be included in publicity releases.

The above procedure is intended to provide information that is complete, fair and unbiased, and enable seed producers, distributors and users to make sound judgments in selecting varieties.

B. Matching Seed Production and Demand for Varieties

Seed production and demand must be considered together to assure that a variety will make its maximum contribution to agriculture. Thus, promotional publicity in advance of the release of a new variety, or before seed is available, or incomplete publicity following its release are not desirable. An educational program setting forth the superior characteristics, region of adaptation, and any special limitations which have been identified should be coordinated with seed supply.

Appendix: Nomenclature

In this statement, the term variety (synonymous with the term cultivar) is used in accordance with the International Code of Nomenclature of Cultivated Plants, 1969. The correctness of use of the terms Cultivar and Variety in the English language is frequently not clearly understood. The International Code of Nomenclature of Cultivated Plants has adopted the term Cultivar as an international term which is proper for use in any language. In the English language, the term Variety may be used as an exact equivalent or as a synonym of Cultivar. Care should be taken not to confuse the term with the English translation of Varieties, also Variety, which is a botanical classification. To insure differentiation between Variety when used for a cultivated variety and Variety when used as a botanical classification, the abbreviation of the former is cv., and of the latter is var.

In the English language editions of the Code prior to 1969, the term Variety was included in parentheses following the term Cultivar to indicate the complete equivalence of the terms Cultivar and Variety when referring to cultivated varieties. This redundancy was eliminated in the 1969 edition by the International Commission for the Nomenclature of Cultivated Plants and the following explanations were included:

"The term cultivar is equivalent to the term 'variety' in English, varieties in French, variedad in Spanish,... whenever these words are used to denote a cultivated variety."

Article 10, Note 4:

"The terms cultivar and variety (in the sense of cultivated variety) are exact equivalents. In translations or adaptations of the Code for special purposes either cultivar or variety (or its equivalent in other languages) may be used in the text."

Clearly, in no way does the 1969 edition change the policy regarding use of the English term Variety. In fact, if the Code were to be reproduced for popular use in the English language, the International Commission would sanction use of only the term Variety. There certainly is no regimentation in the Code for universal use of the term Cultivar when referring to cultivated varieties.

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Good judgment should prevail in the use of the equivalent terms. In scientific papers which have international consumption, the international term Cultivar may be most clearly understood. In papers or documents intended for use by the English-speaking lay public or non-scientific community, the term Variety may often be the more desirable synonym.

The term "variety" means a subdivision of a kind which is distinct, uniform, and stable: "distinct" in that the variety can be differentiated by one or more identifiable morphological, physiological, or other characteristics from all other varieties of public knowledge; "uniform" in that variations in essential and distinctive characteristics are describable; and "stable" in that the variety will remain unchanged to a reasonable degree of reliability in its essential and distinctive characteristics and its uniformity when reproduced or reconstituted as required by the different categories of varieties. This definition of a variety is understood to include the following categories: clonal varieties, line varieties (inbreds), multilines varieties, open-pollinated varieties of cross-fertilizing crops, synthetic varieties, (first generation and advanced generation), hybrid varieties (F1), and (F2) varieties.

This statement has been developed with full cognizance of the contents and implications of the Variety Protection Act, Public Law 91-577. Mutually helpful working relationships among the SAES, the USDA, and private plant breeders and seed companies should be encouraged to enhance the effectiveness of both public and private plant breeding efforts.

The term "biotechnology" refers to the emerging techniques that include rDNA, protoplast fusion, genetic cross-protection and similar techniques.

[Editor's Note: The 1994 International Code of Nomenclature for Cultivated Plants revised the definitions of "cultivar" and "variety" and no longer considers these terms equivalent. The Plant Materials Program does not use the terms "cultivar" and "variety" interchangeably. See Section 540.34(B)(1).]