

UF/IFAS Cultivar Release Guidelines – January 2014

Introduction

The University of Florida Institute of Food and Agricultural Sciences (UF/IFAS) supports an active and widely recognized cultivar development program. Breeding programs address many of the major crops grown in the state and routinely release cultivars destined to be grown in Florida, surrounding states, or throughout the world. The purpose of this document is to outline and describe the broad strategies and policies for cultivar release, from UF/IFAS. The strategies contained here have been discussed and vetted through the University of Florida Plant Breeders Work Group, the IFAS Dean for Research, and the Florida Foundation Seed Producers, Inc. There are four major themes represented beginning with the pre-release issues of Materials Transfer Agreements (MTA) and Research Agreements (RA), and followed by considerations relating to decisions made on exclusive/non-exclusive release, intellectual property protection, and the movement and commercialization of germplasm outside of Florida. These descriptions represent the current institutional guiding principles for the processes related to cultivar development, testing, release, and commercialization. The document is, however, intended to be a “living document,” and as times and situations change, the approaches outlined here may be modified to adequately address the changing circumstances.

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Materials Transfer Agreements

The University of Florida’s Institute of Food and Agricultural Sciences (UF/IFAS) Florida Agricultural Experiment Station (FAES) has the responsibility of developing, introducing, and releasing new cultivars of field, forage, vegetable, fruit, ornamental, and forest plants to support agricultural, horticultural, and natural resource development. Often times, during the development of novel plant cultivars, the primary breeder or developer may benefit from having elite germplasm or selections evaluated by third-party industry producers or university scientists in a non-commercial field setting. The policy and procedure statements outlined in this document are intended to provide guidelines for the transfer of proprietary UF/IFAS/FAES plant germplasm to organizations or entities outside of UF/IFAS.

What is a Materials Transfer Agreement?

A Materials Transfer Agreement (MTA) is an agreement between two or more parties that governs the transfer of tangible research materials. Among other things, an MTA outlines the rights of the provider and recipient, the ownership of the research materials that are being transferred, the specific purpose of the transfer, and any restrictions which must be adhered to by the recipient. For the purposes of this document, the term “MTA” shall refer specifically to a Materials Transfer Agreement which governs the transfer of proprietary UF/IFAS/FAES plant germplasm.

Purpose of MTAs

In general, the creation of an MTA is triggered when a FAES scientist desires or agrees to transfer (see IFAS IMM: http://imm.ifas.ufl.edu/6_120/6120-6.htm) plant germplasm to an external state or federal agency, land-grant university, industry producer, or other agricultural-related entity. Although the creation of an MTA may be triggered when a university scientist not affiliated with UF or an industry producer expresses interest in trialing unreleased plant germplasm, the final decision regarding the transfer of proprietary plant germplasm shall be made by the Director of FAES, in conjunction with the primary breeder/developer and his/her academic department chair and center director (if applicable). FAES is not obligated to provide any proprietary plant germplasm to any third-party.

Often, MTAs are used to govern the evaluation of proprietary plant germplasm by third-party cooperators. Evaluation MTAs are beneficial in providing IFAS faculty and staff with additional data regarding the performance of a particular cultivar or experimental germplasm under differing climates, disease pressures, cultural or agricultural practices, etc. Under an Evaluation MTA, the cooperator is

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expressly prohibited from using the plant germplasm for breeding purposes, commercializing, or transferring the plant germplasm to any third party. The cooperator must provide FAES with all data, results, and records obtained from its evaluation of the proprietary FAES plant materials upon request.

MTAs may also be used for breeding purposes. Breeding MTAs are most commonly used to incorporate disease resistance or other valuable traits from UF germplasm into a cultivar which is more suitable for agricultural production (due to increased yields, more suitable fruit or foliage characteristics, etc.). Breeding MTAs can help to promote/strengthen the relationship between IFAS faculty and their land-grant colleagues and industry producers, and they can also help to hasten the introduction of improved genetics to agricultural producers in the State of Florida and worldwide.

MTAs protect proprietary plant germplasm from unauthorized distribution, use, or sale. MTAs are vital to the continued success of UF/IFAS plant breeding programs because they allow the primary breeder or developer to obtain additional data on the performance of a particular cultivar, while at the same time providing a legal foundation that allows UF/IFAS-developed germplasm to be protected by intellectual property certificates and licensed once a cultivar has been approved for release by the UF/IFAS Cultivar Release Committee. MTAs must be used when any proprietary UF/IFAS plant germplasm is transferred beyond UF. UF/IFAS faculty and staff members shall be prohibited from transferring any proprietary plant germplasm without first ensuring that a fully executed MTA has been signed that expressly covers the individual germplasm to be transferred.

Types of MTAs

Each request for an MTA by a UF/IFAS breeder/developer will fall into one of the following two categories. Once a cultivar has been approved for release by the UF/IFAS Cultivar Release Committee, decisions relative to MTAs should be made at the discretion of Florida Foundation Seed Producers, Inc. (FFSP), a direct support organization (DSO) of the University of Florida, in consultation with the primary/breeder and representatives from UF/IFAS, as appropriate.

1) Academic Materials Transfer Agreement

Academic Materials Transfer Agreements shall be used for each transfer of proprietary plant germplasm to public institutions, state and federal agencies, and not-for-profit corporations.

2) Industry Producer Materials Transfer Agreement

An Industry Producer Materials Transfer Agreement shall be used for each transfer of proprietary plant germplasm to commercial, for-profit entities, including individuals, nurseries, growers, producers, packers, marketers, etc. Each Industry Producer MTA shall explicitly state that the materials are being provided for non-commercial, evaluation purposes only and that the recipient is prohibited from selling the materials and transferring the materials to any third-party without the express written approval of FAES.

Representations and warranties

All recipients of proprietary, unreleased UF/IFAS plant germplasm shall be notified that there is no guarantee that the plant material will be eventually approved for release by the UF/IFAS Cultivar Release Committee.

Fees associated with materials transfer agreements

At the request of the primary breeder/developer and with the approval of the Director of FAES, FAES may collect a transmittal fee from the recipient in order to reimburse excessive, direct costs associated with the transfer of proprietary UF/IFAS/FAES plant germplasm. Transmittal fees are not a

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sale of the plant germplasm, and shall only reimburse the direct cost incurred by the breeding program, including land use costs, materials costs (pots, tags, fertilizer, soil, etc.), labor costs (propagation, maintenance, etc.), and shipping and handling costs. For each transmittal fee requested by each primary breeder/developer, the primary breeder or developer must submit a detailed budget of anticipated costs. Outside of transmittal fees, FAES will not charge any fees for the transfer of unreleased, proprietary plant germplasm. These fees should not be confused with other fees that may be charged by FFSP, including but not limited to fees charged for the distribution of released plant materials, license fees, or running royalties.

Research Agreements

Introduction

A Research Agreement (RA) is a contractual document between UF/IFAS plant breeding programs and external entities. An RA is used to monetarily support research within the breeding program and can be used when the external entity has no interest in intellectual property protection (IPP) or exclusively licensing a cultivar. An RA can also be used to support the development of a cultivar when the external entity is interested in IPP or the first right of refusal to exclusively license the future cultivar. In the latter case an Invitation to Negotiate (ITN) must be considered before an RA is developed.

The Invitation to Negotiate (ITN) provides equal opportunity for interested parties to obtain exclusive rights to intellectual property developed by UF/IFAS plant breeders. The ITN process insures an open and public process for granting exclusive rights. The ITN helps ensure fair access by insuring that all interested parties have the same opportunity to license IP produced by the program. The ITN process is described below on page 7 and is described in the FFSP website <http://www.ffsp.net/> and in the IFAS IMM http://imm.ifas.ufl.edu/6_120/6120-6.htm

How are exclusive and non-exclusive cultivar release/licensing defined?

When a cultivar is licensed to a single company for sale in a particular territory at the exclusion of other potential licensees in that territory, it is considered to be an exclusive release/license. If a cultivar is offered for license in a given territory to all potential licensees, it is considered a general or non-exclusive release regardless of whether licensed by one or many licensees. A single cultivar may be licensed exclusively, non-exclusively, or both. For instance, a cultivar may be licensed non-exclusively within the USA, but exclusively in a different country/territory.

Process of determining whether an ITN is needed for a Research Agreement

When a research agreement that will offer exclusivity is under consideration, the involved breeder will contact the Associate Dean for Research to deploy the Research Agreement committee, which will determine if an ITN is required to announce and award the research agreement. The members of the committee will be:

- Associate Dean for Research
- The breeder involved in the research agreement
- The Department Chair and (if applicable) REC Director of the involved breeder

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- FFSP Executive Director
- Chair of the Plant Breeders Working Group Executive Committee (in the event that the involved breeder is the Chair, the Past Chair will serve on this committee)

To initiate the committee, the breeder will contact the Associate Dean via email and copy all other members. The Associate Dean will organize the meeting and the breeder will distribute information to the committee members prior to the meeting. The group will make a recommendation to the Director of FAES who, in turn, will make the final decision on the ITN requirement.

Research Agreements requiring an ITN for an exclusive license

The goal of an ITN is to provide a public process for awarding an exclusive license. It should ensure competitive fairness for Florida growers and prevent any individual or company, whether in-state or out-of-state, from having an advantage to obtain an exclusive license. When an exclusive license is desired and potential exists for the license holder to compete for the same market as Florida producers, then the ITN procedure will be followed.

Research Agreements not requiring an ITN

Any time an exclusive license is not desired by UF or potential license holders, an RA will be developed without an ITN. This could be used for released cultivars or other developed technologies such as markers for phenotyping or genotyping.

For crops that are bred by UF but not produced in Florida, UF/IFAS can negotiate/license at its own discretion with individuals or companies that are known to provide adequate marketing, production and protection of cultivars.

When UF plant breeders are approached by external entities or partners who want to collaborate on the breeding and development of their own germplasm or use UF germplasm (with special characteristics needed by the collaborator) in their breeding process, an ITN is not necessary. In this case, the material is already owned outside the university or any research conducted by UF plant breeders would be collaborative and the resulting IP would fall under the ownership of the external entity or jointly between the collaborator and UF. Any outside entity or collaborator has equal opportunity to develop research agreements with UF plant breeders to improve their current products. A research agreement with one entity or collaborator would not necessarily prevent concurrent research agreements with other entities or collaborators.

Exclusive vs. Non-Exclusive Release and the ITN

What factors govern exclusive or non-exclusive cultivar release?

The question of whether to release an IFAS cultivar exclusively or non-exclusively hinges on several factors, including the marketing territory, attributes of the cultivar, and prior agreements, with the overall goal being to optimize use of the cultivar. If the marketing territory is within the USA, where there are pre-existing relationships with licensees, intellectual property laws are well established, and the market is relatively mature, non-exclusive licensing may be the best option. A non-exclusive licensing approach seems to be best suited for a situation in which incremental improvements to new cultivars are the norm and broad use of the cultivar is best accomplished by several licensees. However, if a cultivar has unique attributes that make it useful to only part of the industry, to one particular company, or requires investment in market development, exclusive licensing may be advantageous. Exclusive licensing may also be required by the sponsor of a research agreement that specifies the characteristics of the future cultivars and allows the sponsor the first option to negotiate for an exclusive license.

Matters relating to the question of exclusivity, as they pertain to international relationships, are discussed in the section on licensing UF cultivars outside of Florida on page 8. If IFAS is to protect its germplasm, programs and stakeholders, engagement in foreign countries is imperative. The major question is “How do we best engage in other countries?” There is no single answer to that question, but there are some guiding principles to assist with an appropriate answer. When research agreements are involved, exclusive licensing is generally the choice.

How are exclusive rights awarded?

The Invitation to Negotiate (ITN) policy was implemented by UF/IFAS in January 2006. This policy was created to implement a fair and objective process to evaluate all commercial proposals for exclusive license agreements of plant cultivars and germplasm that are developed at UF/IFAS. As described in the section on Research Agreements, a committee will meet to determine if an ITN is needed with an RA that offers the sponsor the first option to negotiate for an exclusive license agreement with FFSP if new cultivars and/or germplasm are developed and released under the project in the research agreement.

Principles of the ITN for cultivar release

The ITN process is founded on four guiding principles. Decisions regarding which of several potential responders to the ITN should be first engaged in discussion of possible licensing conditions and terms are assessed on the basis of what is:

1. Good for the State of Florida and its people including the growers of the commodity
2. Good for the University of Florida and IFAS
3. Good for the breeding program and the breeders
4. In the case of food crops, good for world food security

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The ITN process encourages an open engagement of all interested parties to propose and/or comment on the potential exclusive opportunity. Proposals and comments submitted through the ITN process are evaluated consistently and fairly by a review committee made up of the following:

1. The lead breeder (PI)
2. An independent breeder
3. The Licensing Associate of FFSP
4. The Executive Director of FFSP
5. The statewide research leader for the crop/species (where applicable)

ITN Respondents are evaluated using a consistent methodology, allowing the ITN Review Committee to weigh core elements and objectively evaluate multiple proposals. The ITN specifications objectively guide critical responses and ask respondents to describe:

1. Prior experience (both within the industry and with UF/IFAS and FFSP) and current business model
2. A plan of action concerning the new business opportunity
3. Details regarding production plans and capabilities
4. Details regarding marketing plans and capabilities; and
5. Financial considerations (license fees, royalties, annual minimum performance expectations, etc.)

The ITN Review Committee reviews all proposals and comments submitted to FFSP and makes a recommendation to the Director of the FAES. With the approval of the Director of the FAES, FFSP is authorized to start exclusive license negotiations.

Intellectual Property Protection

When is Intellectual Property (IP) protection not needed?

In the majority of cases, IFAS cultivars should be protected by the appropriate legal mechanism, i.e. Plant Variety Protection (PVP), Plant Patent (PP), and/or Utility Patent (UP). However IP protection is not warranted in some cases. Intellectual property protection options are outlined in IFAS IMM 6120-6 (http://imm.ifas.ufl.edu/6_120/6120-6.htm) and include non-protection. IP protection may not be warranted in cases where there is very limited production of a crop or when the market longevity of cultivars is short. The costs of IP protection in such cases may not be recuperated through licensing fees or royalty returns. Examples include annual ryegrass, certain perennial forage grasses, and certain foliage species. Annual ryegrass is a species that is cross-pollinated and the majority of production occurs in a centralized region where preventing pollen flow is not possible. Some perennial forage grass species are freely shared among livestock producers making the tracking of IP and royalty collection extremely difficult. Many ornamental foliage species occupy small niche markets with limited production potential and have short market longevity. The breeder shall inform the Cultivar Release Advisory Committee (CRAC) if they think that IP protection is not needed and the CRAC will make a

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recommendation to the Cultivar Release Committee (CRC) regarding IP protection of the proposed cultivar.

How do exclusive licenses, non-exclusive licenses, and intellectual property protection impact the ability to release new cultivars for humanitarian or global food security purposes?

New cultivars and germplasm have the ability to significantly advance the betterment of the planet and humanity, and global food security is an important component of the UF/IFAS mission. As a standard practice, IFAS cultivars are often protected using the appropriate legal mechanisms, both domestically and internationally. Merely seeking intellectual property protection, however, does not preclude UF/IFAS and FFSP from designating certain territories and/or circumstances that may warrant the need to forgo the collection of royalties for the use of cultivars and germplasm. UF/IFAS and FFSP are reliant on licensees (seed companies, nurseries, charitable foundations, etc.) to serve as conduits to bring commercial quantities of new cultivars and germplasm to market, regardless of financial return to the UF/IFAS breeding programs. Appropriate IP protection and licensing of cultivars for humanitarian purposes protects UF/IFAS, the licensee and ultimately the end user of UF/IFAS cultivars by insuring adequate supply of genetically and physically pure planting stocks. It also creates an incentive and a mechanism to insure that planting stocks are widely distributed in the target area. Therefore, both exclusive licenses and non-exclusive licenses can be effectively used for humanitarian purposes.

Licensing UF Cultivars in Florida vs. Outside of Florida (US and International)

What are the benefits of commercialization, licensing, and testing of UF cultivars outside of Florida (domestically or internationally)?

When properly managed there often are several benefits of commercialization, licensing and testing outside of Florida (within other states of the US or internationally). Where competitive situations exist, licensing of UF-developed cultivars provides a powerful tool to prevent illegal production. If intellectual property protection and licensees are not sought in international territories, cultivars eventually become part of the public domain and can be openly commercialized with no reinvestment into the UF breeding programs and no control of the marketing of these cultivars in international territories. In short, it is widely recognized that in most cases, plant materials are propagated and distributed through relatively easy means, whether legally or illegally, and a proactive approach to licensing germplasm is advantageous.

Royalty income, generated through licensing, substantially feeds back into the breeding program that developed the cultivar(s), thus further supporting the efforts to research and develop new cultivars for Florida stakeholders. Very successful cultivars that generate even greater royalty revenues support the broader UF/IFAS breeding program, through investments into educational programs.

When commercializing UF-developed cultivars in international territories, a careful analysis must be made in each case to determine the type of licensing that will be most advantageous for the people of

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Florida and the IFAS breeding programs. In cases where international territories are not competitive with Florida growers, there is considerable flexibility in models of commercialization. In cases where Florida stakeholders express that international production territories pose a direct threat to Florida growers, this concern will be carefully evaluated and licensing structures that strategically restrict availability and enhance control of the intellectual property will be strongly considered. For instance, a licensing model for a territory may restrict a cultivar to a limited number of reputable and proven partners who have an interest and capacity in managing propagation and/or production.

Testing UF developed cultivars or advanced selections under evaluation in the UF breeding programs outside of Florida provides breeders with performance data on germplasm in other environments, as well as information that can inform future commercialization in the territory. The evaluation of advanced selections must be done under the protection of MTAs and with reputable partners. Such experimental trials can demonstrate the commercial potential of UF cultivars in the growing region, provide information to support the commercialization efforts, and test the reliability and adequacy of the cooperator as a potential licensee partner.

In certain cases, having production of a specific and identifiable product outside Florida can extend the season of product availability, beyond the normal time of production and harvest within Florida. This is especially true with fresh fruits and vegetables, where supermarkets and their buyers look for sufficient supply to occupy shelf space with a given commodity, ideally on a year-round basis. A lack of adequate supply can dissuade supermarket chains from carrying a product, thereby eliminating a potentially lucrative opportunity for Florida growers and preventing Florida consumers from having access to improved varieties and food products.

Engaging with partners in developing areas of the world to grow and market improved cultivars developed at UF/IFAS provides an opportunity to contribute to global health and food security. Many of the UF/IFAS breeding programs develop new cultivars of specialty crops that do not have counterparts in private or commercial breeding operations. Additionally, due to the unique Florida environment in which UF/IFAS breeders perform selection and testing, UF-developed cultivars are often suited for the subtropical areas of the world that typically do not have the research and development infrastructure to operate similar breeding programs.

What are the potential dangers, challenges and drawbacks of commercialization outside of Florida?

In some cases commercialization outside of Florida could create or accentuate competition in the marketplace with Florida stakeholders, either inside the US or in foreign markets to which Florida-produced product may be exported. Unfortunately, there is no system available that can guarantee and preserve a competition-free marketplace for Florida growers, as cultivars are just one piece of agricultural business operations in an expanding, complex international marketplace. As mentioned in the previous section, blanket restrictions on commercialization are ineffective, as they are not likely to prevent illegal propagation and widespread use of UF-developed cultivars. In addition, cultivars from other sources (e.g., from other breeding programs and public germplasm/cultivar repositories) may substitute for UF-developed cultivars, making such restrictions ineffective in mitigating competition. To minimize competitive economic impacts on Florida stakeholders, we carefully evaluate potential impacts of international engagement on Florida stakeholders. When benefits outweigh risks, we seek out reputable, professional licensing partners where possible, to work under licensing structures that limit

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production, coordinate marketing strategies with Florida licensees and companies, and incentivize enforcement of the intellectual property rights in the given region.

Other challenges relate to the difficulty of finding reliable and capable international partners. An advantage of a pre-licensing trial with partners under an MTA is that it provides an opportunity to assess their integrity and capability to function if a decision is made to commercialize. A good partner is one who is forthright in providing timely reports on selection performance, numbers of propagations, etc. Confirming the validity of partner reports can be a costly venture, particularly for research programs with limited resources. A partner that is able and willing to provide travel expenses for UF and/or FFSP personnel to visit the locations to make first hand observations in validation of reports, is considered to be one demonstration of serious interest in professional commercialization and adherence to MTA or license agreement conditions. Strong, reputable partners are an important key to monitoring adherence to license agreements outside of Florida.

How do we address the needs of Florida agricultural industries, while also seeking to capitalize on national/international opportunities?

The issue of commercialization of UF-developed cultivars outside of Florida is one that generates important concerns within our Florida stakeholder community and requires close stakeholder engagement and sensitivity to these concerns. It is essential that UF/IFAS and FFSP interact on a regular and continued basis with stakeholders, and that stakeholders are asked to evaluate the potential implications of new cultivars being released and commercialized outside of Florida and internationally, and to make those concerns known prior to licensing. When new cultivars are developed that have potential to be produced internationally, FFSP members will be notified after the quarterly IFAS CRC meeting that release approval is granted and their input sought about release strategies.

Because of diverse conditions and cultivar-specific consideration, a specific formula, on how, when and where to license internationally, is not feasible. However, throughout the release and ITN process, specific information is gathered to make informed decisions. When proposing a new cultivar for release, the plant breeder is required to present a clear chain of custody of the proposed cultivar, including testing performed outside of Florida. The breeder is also required to present available information on the limits of adaptation and market potential in particular geographies. The CRAC and the IFAS CRC weigh this information when recommending commercialization strategies at the time of release.

Finally, UF/IFAS' and FFSP's policies on the availability of planting stock is to serve Florida growers first. After the demand of Florida growers has been satisfied, excess plant materials may be made available for regions outside of Florida, in accordance with license agreements. However, during the early stages of commercialization, some limited access to planting stock outside of Florida is often necessary for commercial partners, particularly in areas where smaller trial plantings of the material have already been established and continued testing is necessary to maintain market interest. This is particularly the case in regions where there are procedural delays in larger stock availability, such as for plant quarantine restrictions.