



United States Department of Agriculture

# Agricultural Marketing Service

Creating Opportunities for American Farmers and Businesses



**Plant Variety Protection Office**

# Agricultural Marketing Service

Plant Variety Protection Office



## Plant Variety Protection for Seed, Tuber, and Asexually Reproduced Varieties

Mara Sanders

5 August 2020

## Topics Covered

### US Plant Protection Rights

- Plant Variety Protection vs. Patents
- Plant Variety Protection Office

### Preparing to Apply

- Conducting Variety Trials
- Acceptance of DUS reports

### Application Process

- Application Criteria
- Application Sections

### Examination

- Examination Overview
- Distinctness Searches

### Certificate Issuance

- Quality Control
- Certificate Issuance Procedure

### Post-Issuance

- Enforcement of Rights

## PVPO Updates

### **COVID19:**

- PVPO: Currently open and operating business as usual
- NLGRP: Open and accepting seed variety germplasm

### **Asexually Reproduced Varieties:**

- New addition from the 2018 Farm Bill
- Germplasm Delay until 06 January 2023
- Please contact PVPO if you don't see a species on ePVP or the PDF forms (we are making them as requested)

### **Essentially Derived Varieties:**

- Currently PVPO will not make determination on EDVs, if a variety meets requirements for protection it may be granted
- Determination of an EDV depends on the owner litigation
- UPOV working on EDV guidance and explanatory notes

## US Plant Intellectual Property Rights (IPR)

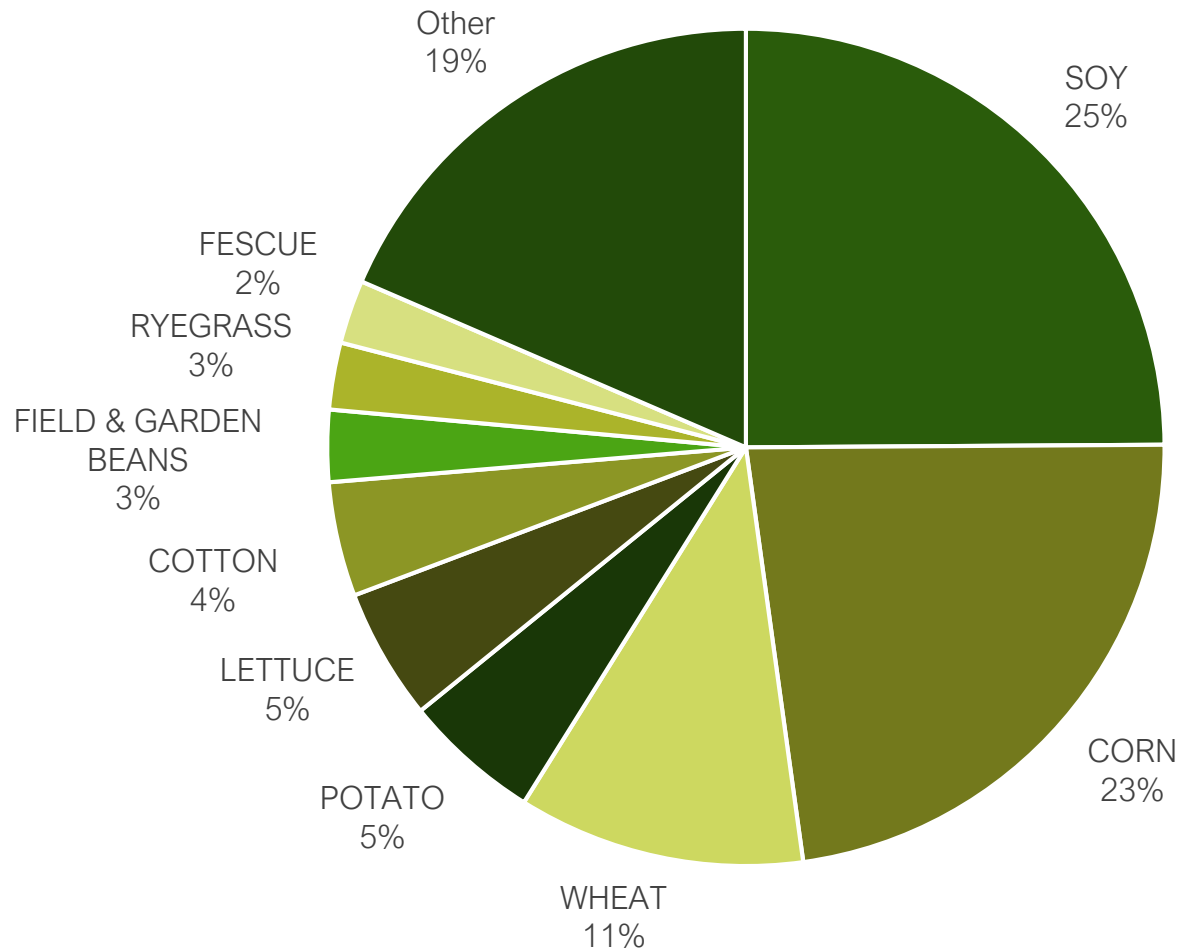
### US Dept. of Agriculture Plant Variety Protection Office

- PVP Certificate
    - Seed, Tuber, and Asexually reproduced plants
- 
- Applications accepted for varieties sold less than one year in the US and four years Internationally
  - Essentially Derived Varieties (EDV) allowed by law
  - No annual maintenance fee

### US Dept. of Commerce Patent and Trademark Office

- Plant Patents
    - Asexually reproduced plants
  - Utility Patents
    - Genes, traits, methods, plant parts and plants
- 
- Must be filed within one year of the date of sale, both in the US and Internationally
  - EDVs are not covered by Patent law
  - Annual maintenance fee for Utility Patent

# PVPs Granted Top 10 Crops in Past 10 years



## PVPO Statistics

PVPO receives **427** applications per year,  
and issues an average of **325** certificates annually!

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The average time from application to issuance is **18** months.

**110** Days was our fastest turnaround time!

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PVPO has applications for **170** species

with more being added all the time!

## International Union for the Protection of New Varieties of Plants (UPOV)

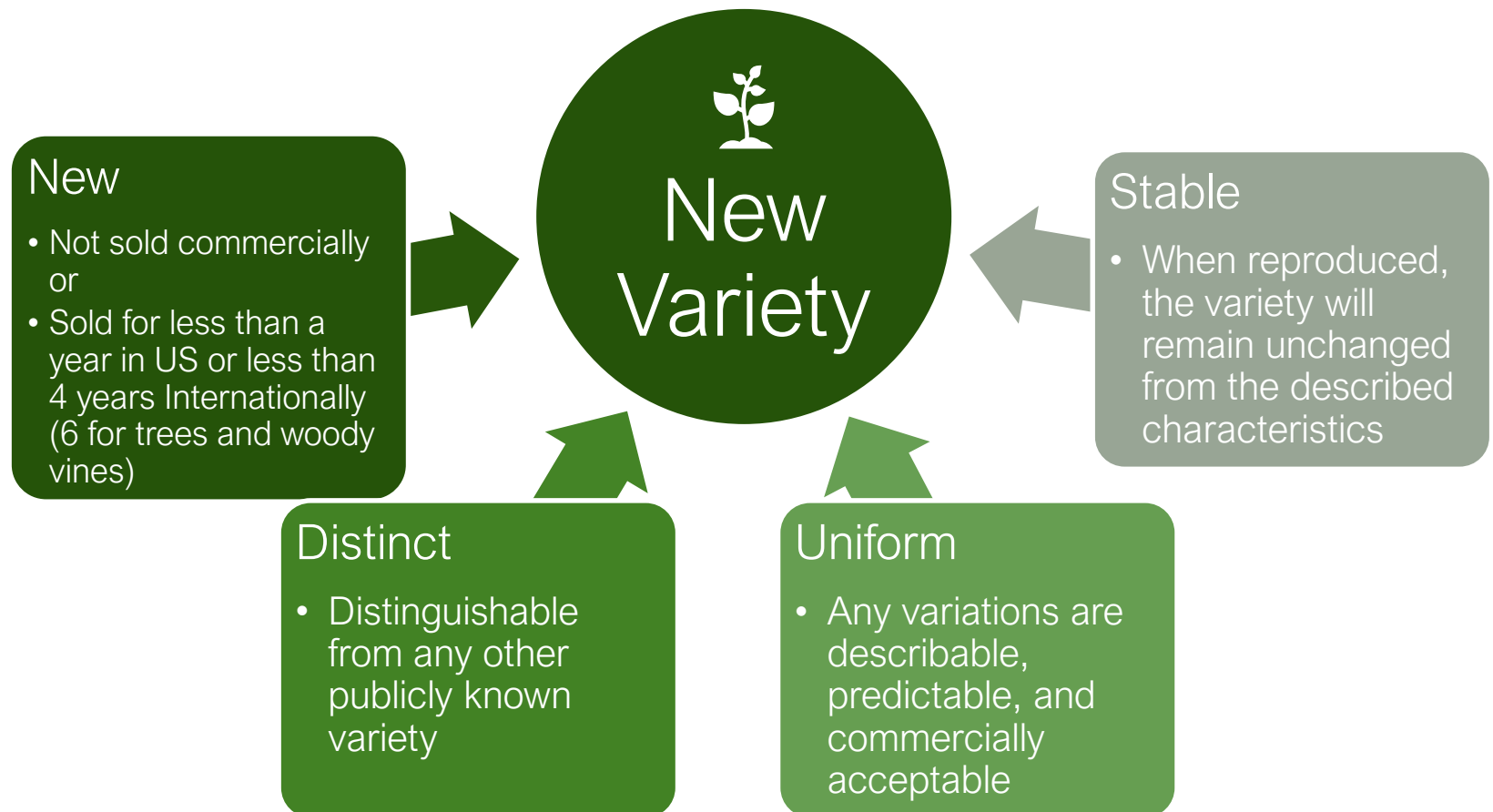
- PVPO follows UPOV guidance for Distinctness, Uniformity, and Stability (DUS) trials, forms, and cooperation between authorities.
  - PVPO accepts DUS reports from other UPOV authorities for certain species (contact PVPO for more information)
  - Applying with PVPO allows applicants to claim priority in other UPOV authorities, meaning the first application date will be used with the second authority (if claimed within one year of the original application date)
  - PVPO grants protection for 20 years (25 for trees and woody vines) from the issuance date, any priority or provisional protection does not effect the length of protection.





# Preparing to Apply

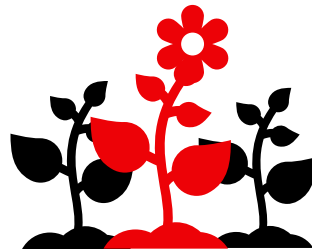
## Eligibility Requirements for Protection



## Getting Ready to Apply for Protection

The applicant (Variety Owner or Agent of Owner) should have:

- Bred a Distinct, Uniform, and Stable (DUS) variety that is New to the market
- Completed variety DUS trials between the applicant variety and the 1-3 most similar varieties
- Chosen a unique name for the variety within the crop type





# Application Process

## Who Can Apply

- Anyone who is the breeder of a unique variety of asexually reproduced, sexually reproduced, or tuber-propagated plant (or a representative of the breeder)
- The owner may be a(n):



Individual

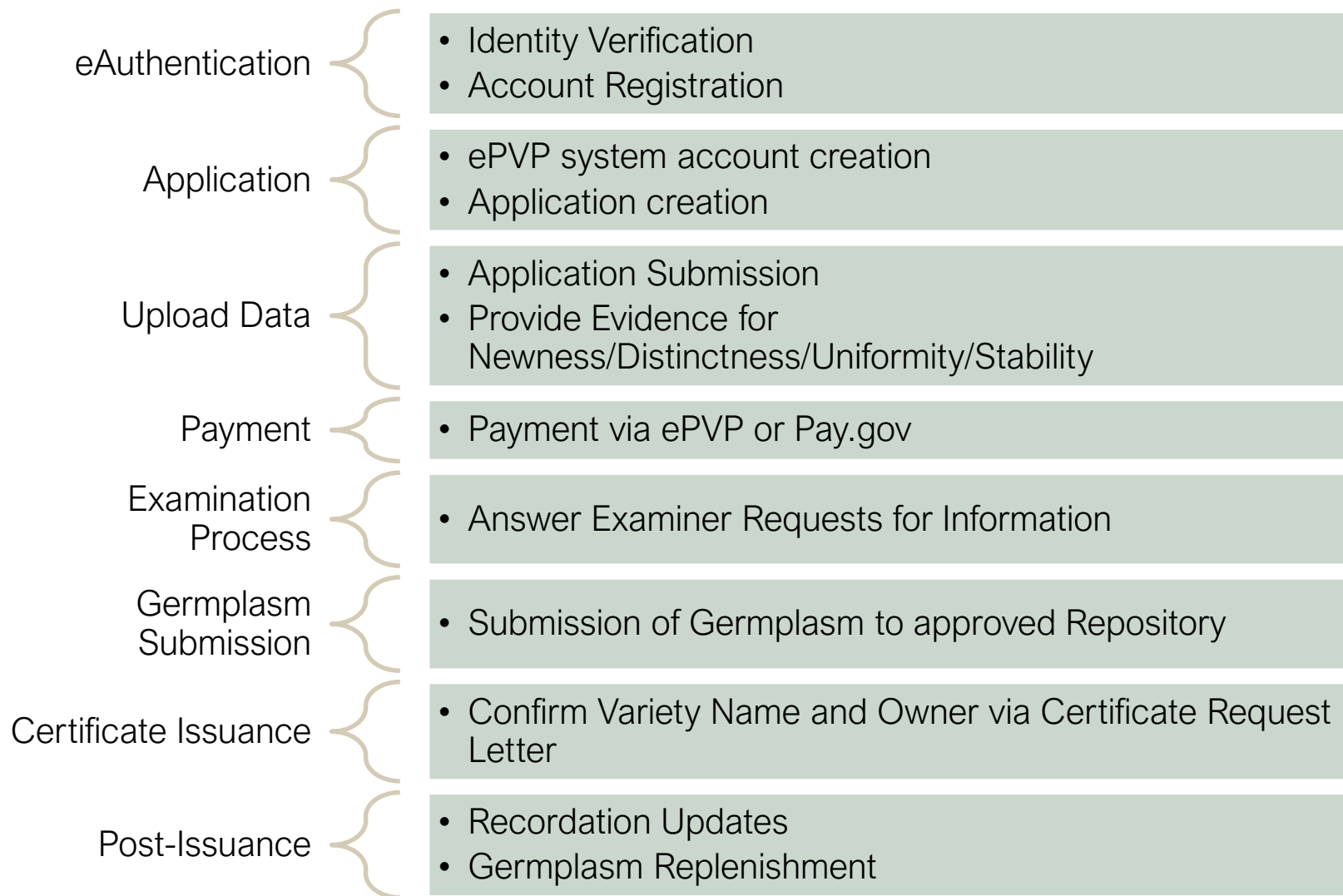


Public Institution

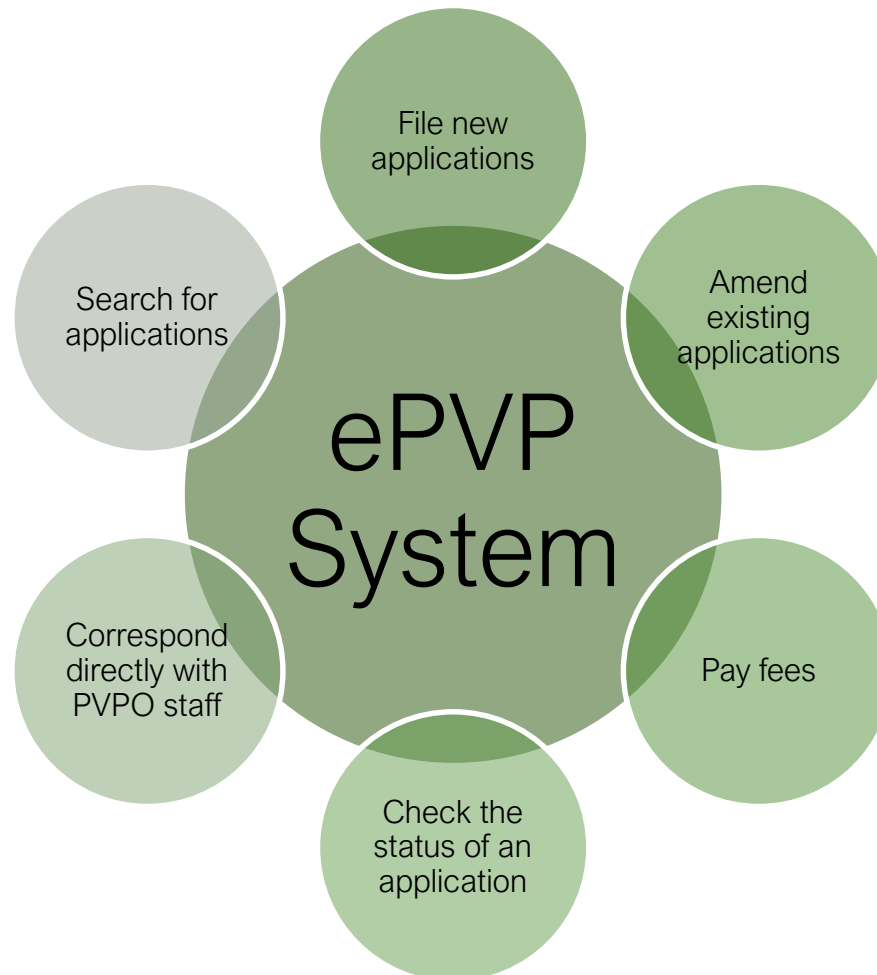


Corporation

## How to Apply



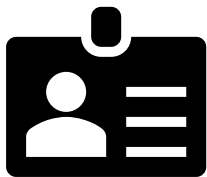
## Electronic Application System (ePVP)



The ePVP System is the best way to apply and can be accessed anywhere in the world

## Step 1 - eAuthentication

- All users must be e-Authenticated first
- Domestic users: Request level 2 access and follow the instructions to establish the eAuthentication account
- International users: Request level 1 access only; and upon creating the eAuthentication account, email name and contact information to [pvpomail@usda.gov](mailto:pvpomail@usda.gov) to finalize the eAuthentication account authorization
- System will provide you with a username and password to continue
- Logon to <http://www.eauth.egov.usda.gov/> to complete eAuthentication account



Create an Account  
(Username/Password)



Confirm Email



Verify Identity



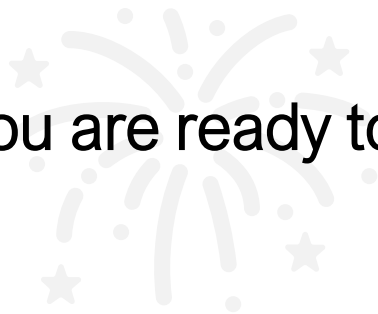
Login in to complete  
eAuthentication




## Step 2 - Establishing ePVP Account

- Click on ePVP link <https://pvpo.ams.usda.gov/>
- Enter the same username and password
- Create your ePVP account as prompted

Congratulations you are ready to enter an application!



# Creating ePVP Account



**United States Department of Agriculture**  
Agricultural Marketing Service

Electronic Plant Variety Protection (ePVP) System

[About eAuthentication](#) | [Help](#) | [Contact Us](#) | [Log Off](#)

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**ePVP System - User Profile**

**User Information**

**Required Field\***

<b>First Name*</b>	<b>Middle Initial</b>	<b>Last Name*</b>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Address*</b>	<b>City</b>	<b>Country</b>
<input type="text"/>	<input type="text"/>	<input type="text" value="--Select--"/>
<b>Zip/Postal Code</b>	<b>State</b>	
<input type="text"/>	<input type="text" value="v"/>	

**Contact Information**

<b>Mobile No*</b>	<b>Work Phone*</b>	<b>Email*</b>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Fax</b>		
<input type="text"/>		

**Role Selection**

Please select an ePVP system role from the dropdown options below:


**ePVP System Role\***

I agree to the [USDA Privacy Policy](#).

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[FOIA](#) | [Accessibility Statement](#) | [Privacy Policy](#) | [Non-Discrimination Statement](#) | [Information Quality](#) | [USA.gov](#) | [White House](#)

# Creating ePVP Account



United States Department of Agriculture  
Agricultural Marketing Service

Electronic Plant Variety Protection (ePVP) System

Home Main Profile Help Contact Us Log Off

## Add Role

Please select an EPVP system role from the dropdown options below:

EPVP System Role  
--Select--

If associated with an Organization please select the associated Organization from the below dropdown.

### Add Organization

Organization Name\* (For individuals, this will be individual's name)\*

Contact Person\*  Email Address\*  Phone Number\*  Fax

Street Address Line1\*  City

ZipCode\*  Country\* --Select--

State\* --Select--

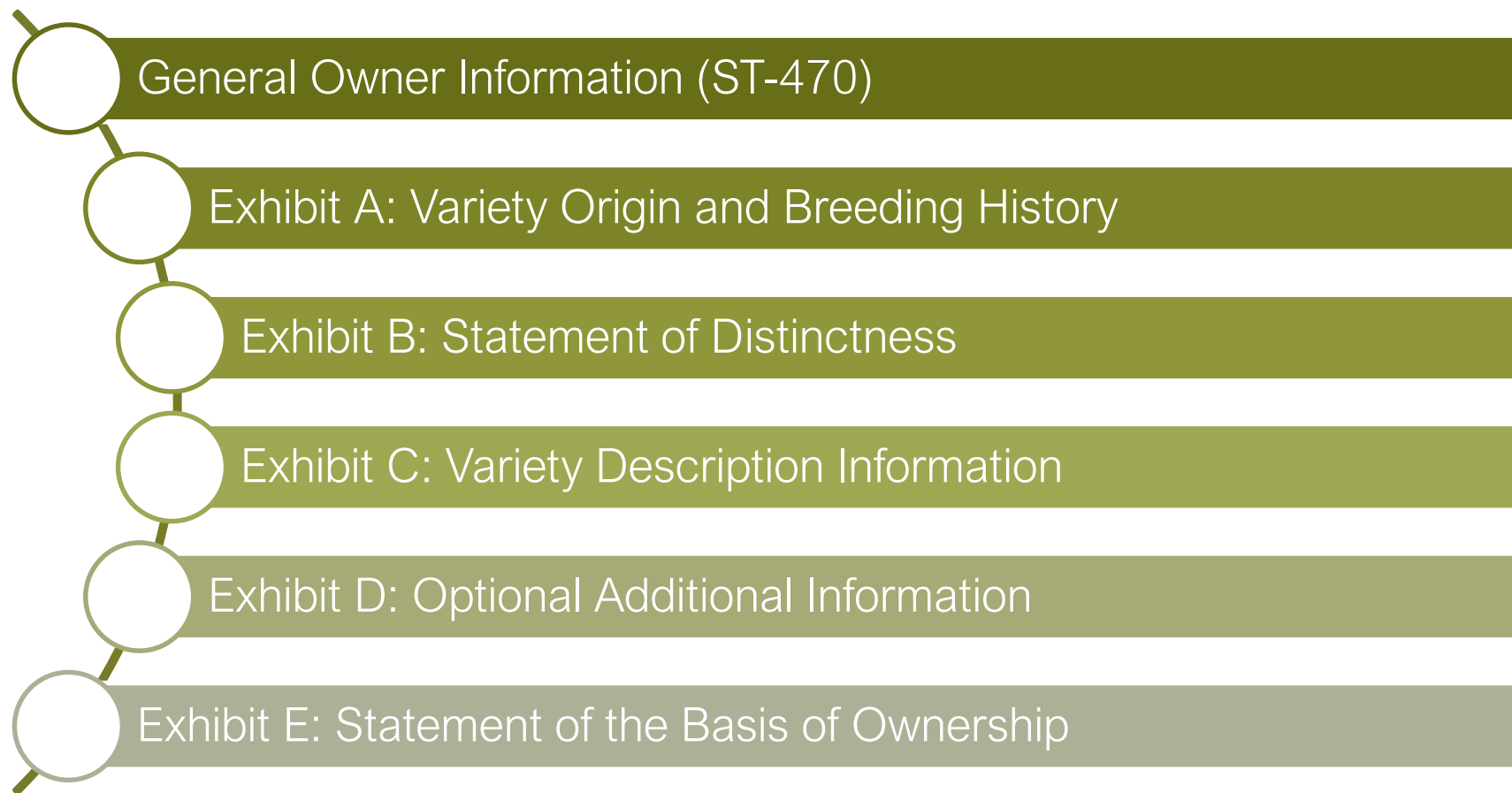
Expertise Crop  
--Select--  
Alfalfa  
Artichoke  
Bluegrass

Origin Code (Domestic/Foreign/Experiment Station)\*

Save

## Application Components

Applicants must complete all sections of application (ST-470)



## General Owner Information (ST-470)

This part establishes the name of the owner, name of the representative(s) of the owner, the variety name, and the date of first sale if one exists

Date of first sale is important, because varieties are ineligible for protection if they have been sold one year or more before the filing date for varieties released domestically, or four years or more for varieties released internationally

### ePVP Application

Experimental Name :   
Variety Name :   
Crop Kind :

**Important Note:** Selection of the crop kind in this section of the application will load the corresponding Exhibit C questions. If your crop kind is not listed, please contact PVPO at [PVPOmail@usda.gov](mailto:PVPOmail@usda.gov)

## Exhibit A: Variety Origin and Breeding History

- Describe the development and selection of the variety, including hybridization, mutation, or genetic manipulation events
- List the genealogy of the variety
  - Stock plants ownership
  - Any IP protections on the applicant variety or stock plants
  - Breeding stages and methods used
- Exhibit A includes statements to confirm the uniformity and stability of the applicant variety

## Exhibit A: Variety Origin and Breeding History Seed Example

Pepper hybrid 'SUMMER' was developed using pedigree selection and is the result of a cross between the Winter Company proprietary inbred lines 'SPRING' (seed parent) and 'FALL' (pollen parent). 'SPRING' is protected by Plant Variety Protection rights in the United States according to Certificate No.##### under the designation 'SPRING', and by Patent Rights in the United States according to Patent No.#####. 'FALL' is protected by Plant Variety Protection rights in the United States according to Certificate No.##### under the designation 'FALL'. Selection criteria included stem strength, time to fruit maturity, fruit size and color, and freedom from disease.

'SUMMER' is a hybrid bell pepper variety suited to open field cultivation. It is characterized by a concentrated early harvest. The medium sized plant produces uniform, large fruit maturing from dark green to red. The fruit has 3-4 lobes. The plant sets fruit in a moderately concentrated manner. The hybrid is resistant to: Tobacco Mosaic Virus (TMV) Pathotype 0.

## Exhibit A: Variety Origin and Breeding History Asexual Example

'Smokey the Bear' is a petunia variety originated from a controlled cross using 'Forest' (PVP201600500) as the female parent and 'Fire' (PVP201600501) as the male parent.

The cross took place at the Plant Variety Protection Office, located at 1400 Independence Ave, Office 4512-S, Washington, DC 20250 during May of 2017. From this cross, five seedlings were selected at the end of September 2017 based on their semi-erect plant growth habit and deep purple petals.

Upon final selection in September of 2018, 'Smokey the Bear' was propagated by cuttings and evaluated in pot, greenhouse and field trials from April to November of 2018.



## Exhibit B: Statement of Distinctness

A Statement of Distinctness includes the following:

- The name of the most similar variety or varieties (3 or fewer). The ideal most similar variety is one that has been previously protected
- Characteristics that clearly distinguish the new variety from the most similar variety or varieties, specifying qualities and/or quantities that differentiate the varieties
- For quantitative differentiation, statistical data should be provided that validate the differences

## Exhibit C: Variety Description Information

- The Exhibit C is comparable to the UPOV Table of Characteristics
- Each crop has its own specific Exhibit C form based on its relevant observable characteristics
- If the crop kind is not listed contact PVPO
- Incomplete Exhibit C prolongs the examination process

The screenshot shows a web-based form titled "Pepper" with a navigation bar at the top containing tabs for "ST-470 Main", "Exhibit A", "Exhibit B", "Exhibit C" (selected), "Exhibit D", and "Exhibit E".

**Pepper**

**A. Species**

1. Location and Dates of Test

--Select--

**B. Maturity in Region of Best Adaptability**

1. Days From Transplanting Until Mature Green Stage

2. Days From Transplanting Until Mature Red or Yellow Stage

3. Days From Direct Seeding Until Mature Green Stage

4. Days From Direct Seeding Until Mature Red or Yellow Stage

**C. Plant**

1. Plant Habit

--Select--

2. Plant Attitude

--Select--

3. Plant Width (cm)

4. Length of Stem from Cotyledons to First Flower (cm)

5. Length of Third Internode From Soil Surface (mm)

6. Basal Branches

--Select--

7. Branch Flexibility

--Select--

8. Stem Strength

--Select--

## Exhibit D: Optional Additional Information

This form is for additional data tables, charts, photographs, and other information related to the new variety

For example: a photograph showing the new variety beside the most similar variety in the field or greenhouse, can be attached

The screenshot shows a web application interface for 'Exhibit D - Additional Descriptive Information'. At the top, there is a navigation bar with tabs for 'ST-470 Main', 'Exhibit A', 'Exhibit B', 'Exhibit C', 'Exhibit D' (which is selected and highlighted in blue), and 'Exhibit E'. Below the navigation bar, the main content area is titled 'Exhibit D - Additional Descriptive Information'. It contains a numbered list item: '1. Please enter the additional descriptive question / text in the box below :'. This is followed by a text input field. Below that, it says 'Please enter additional descriptive answer / information in detail in the box below :', followed by a larger text area with a vertical scrollbar. To the right of this text area is an 'Add' button. At the bottom left, there is an 'Attach Document' section with a file input field and a 'Browse...' button.

Save Application

Submit Application

## Exhibit E: Statement of the Basis of Ownership

This confirms the owner's name and the country where the owner is located

If the current owner is not the original owner or breeder, the transfer should be explained in part 4

ST-470 Main Exhibit A Exhibit B Exhibit C Exhibit D **Exhibit E**

**Exhibit E - Statement of the Basis of Ownership**

1. Does the applicant own all rights to the variety?  
 Yes  No
2. Is the applicant a U.S. national or a U.S. based entity?  
 Yes  No
3. Is the applicant the original owner?  
 Yes  No
4. Additional explanation on ownership (Trace ownership from original breeder to current owner):

**PLEASE NOTE:**

Plant variety protection can only be afforded to the owners (not licensees) who meet the following criteria:

1. If the rights to the variety are owned by the original breeder, that person must be a U.S. national, national of a UPOV member country, or national of a country which affords similar protection to nationals of the U.S. for the same genus and species.
2. If the rights to the variety are owned by the company which employed the original breeder(s), the company must be U.S. based, owned by nationals of a UPOV member country, or owned by nationals of a country which affords similar protection to nationals of the U.S. for the same genus and species.
3. If the applicant is an owner who is not the original owner, both the original owner and the applicant must meet one of the above criteria.

The original breeder/owner may be the individual or company who directed the final breeding. See Section 41(a)(2) of the Plant Variety Protection Act for definitions.

Save Application  
Submit Application

## Receipt of Application

- The Filing Date is established after the application is reviewed and payment is processed
  - This is the priority and provisional protection date
- Filing letter, by e-mail, provides filing date and germplasm deposit information
- Germplasm deposit information will vary based on crop kind; instruction on submission will be included in the filing letter



## Germplasm Requirements



- **Seed:** 3,000 viable untreated seeds of the variety; additionally, for first-generation hybrids, 3,000 seeds of each parent needed to reproduce the variety. When the sample is received by the National Laboratory for Genetic Resources Preservation (NLGRP), their staff count the seeds in the sample and test it for germination rate.
- **Asexual:** Germplasm delay from January 6, 2020, to January 6, 2023, while we address the feasibility of making and maintaining those deposits. During this period germplasm can be maintained by the applicant or by a repository of their choosing and must be provided within three months of a request by PVPO. Failure to provide a specimen as requested shall result in the certificate being regarded as abandoned.

**Germplasm becomes public when certificate expires**

# Payment

- Total Cost for applying: \$5,150
- Payments can be made using ePVP or Pay.gov:
  - Bank Account
  - Amazon Account
  - PayPal Account
  - Debit or Credit Card
- Payments can also be made by phone or mailed to PVPO

**System Message**

- The system has populated the Payment Date with the next available payment date.

**Online Payment** [Return to your originating application](#)  
**Step 1: Enter Payment Information** 1 | 2  
Pay Via Bank Account (ACH) [About ACH Debit](#)

Required fields are indicated with a red asterisk \*

Account Holder Name:  \*

Payment Amount: \$809.00

Account Type:  \*

Routing Number:  \*

Account Number:  \*

Confirm Account Number:  \*

Check Number:

Routing Number      Account Number      Check Number

⑆0 26946763⑆      9243767390⑆      1234

Payment Date: 08/23/2019

Line Item 1:  
Line Item 2:  
Line Item 3:  
Line Item 4:  
Line Item 5:  
Line Item 6:

Select the "Continue with ACH Payment" button to continue to the next step in the ACH Debit Payment Process.

**Note:** Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.

The background of the slide is a photograph of a chili pepper plant. The plant has dark green, glossy leaves and several clusters of peppers. Some peppers are bright red and have a bumpy, wrinkled texture, while others are yellowish-green and appear smoother. The peppers are in various stages of ripeness. A semi-transparent white horizontal band is overlaid across the middle of the image, containing the text.

# Examination Process

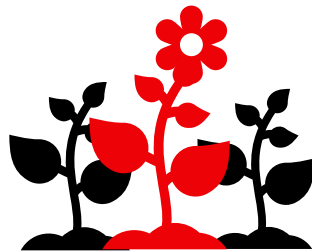


## Examination Procedure

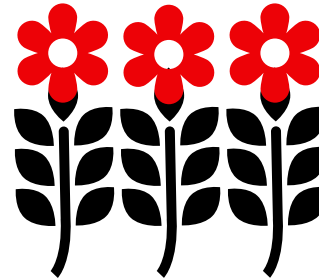
Examiners review the evidence submitted by applicants to confirm that the variety is:



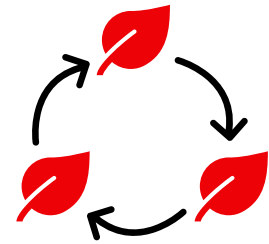
New



Distinct



Uniform



Stable

## Distinctness Examination

During this process, examiners:

- Verify that complete characteristic data is provided
- Confirm that the most similar variety is adequately described
- Develop appropriate distinctness search parameters to compare the subject variety against all other varieties in the ePVP database
- Determine other search tools needed depending on crop
- Generate examination report

## Searching the ePVP Database

- The database contains all protected varieties and known varieties that are adequately described
- The search is unique for each crop kind and includes qualitative traits and quantitative ranges
- The developed search parameters are loaded into the application record in the database
- When the search is run, the parameters exclude competing varieties
- The subject variety is shown as either unique or not

# Distinctness Database Search Example



Number of Varieties	Plant Characteristic	Varieties
10	Total Plants in Database (Same Crop Kind)	
8	Plant Type (Compact)	
5	Number of Flower Petals (Three - Six Petals)	
2	Leaf Color (Dark Green)	
1	Flower Color (Red)	

## Additional Search Tools



### Used for

- New crops
- Crops with few incoming applications at PVPO
- Crops with limited database records

# Examination Report

- Eligibility Information →
- Denomination Clearance →
- Breeding History →
- Statement of Distinctness →
- Descriptive Information →
- Basis of Ownership →
- Examination Search Results →

## Search Verification for the Common Wheat 'UI Magic' PV# 201600300

**Application:** All Items completed satisfactory. The Filing Date of this application is July 5, 2016. 'UI Magic' was not released, disposed, transferred, or sold more than one year prior to filing in the United States or more than four years prior to filing outside the United States.

**Name:** Variety name cleared by the USDA, AMS, Livestock & Seed, Federal Seed Lab.

**Exhibit A:** Indicates 'UI Magic' is derived from the cross: 07-688-10 / Bitterroot. 07-688-10 is an experimental line from University of Idaho used as a Donor of the two Imidazolinone herbicide resistance genes. The selection criteria used to develop 'UI Magic' were earliness, height, disease and herbicide resistance, vigor, yield, and regional adaptation. The applicant states 'UI Magic' has been observed uniform and stable for three generations with the following variants: up to 5 per 1000 of awnless plants, up to 3 per 1000 later flowering or greener plants, and up to 2 per 1000 taller plants - up to 8 inches above the canopy height and up to 0.75 percent red seed.

**Exhibit B:** 'UI Magic' is most similar to 'Skiles'; however, 'UI Magic' differs from 'Skiles' in Imidazolinone herbicide tolerance (tolerant vs. susceptible, respectively). 'UI Magic' has the *Als-1* and *Als-2* resistance genes, while 'Skiles' does not.

**Exhibit C:** Satisfactorily completed.

**Exhibit E:** Information satisfactory.

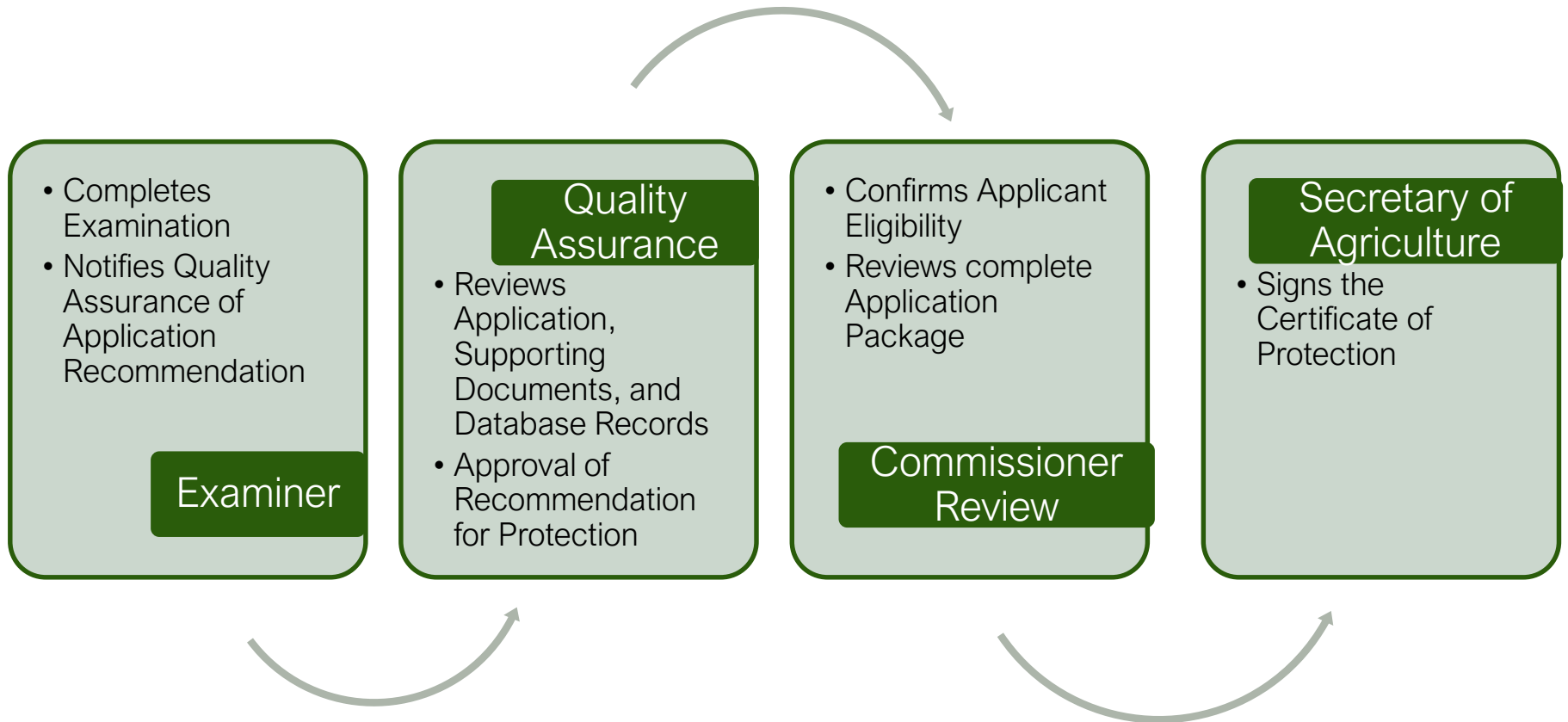
**Search:** A database record 'UI Magic' was created in the wheat database PVWHEA (#582). The wheat database was then searched for varieties similar to 'UI Magic'. One variety, the application variety, was recovered by the search criteria. See attachments for a printout of the search.

All potentially competing varieties were distinguished from 'UI Magic'.



Certificate Issuance

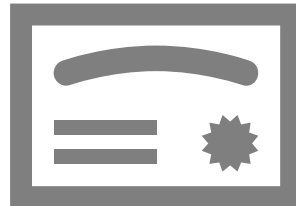
## Application Quality Control





## Certificate Issuance

- Batch of certificates assembled for signature by the Secretary of Agriculture
- Signed certificates mailed to applicants
- Final Reports (application, filing letter, examination report, notice of issuance and certificate of protection) published on the PVPO website





# Post-Issuance Process

## Enforcement of PVP Rights

- Owners of a protected variety may bring civil action against persons infringing on his or her rights
- Owners may ask a court to issue an injunction to prevent others from further violations
- Resources available on PVP infringement and enforcement include: Seed Innovation and Protection Alliance (SIPA) and Farmers' Yield Initiative
- PVPO will provide application and evidence support



## Benefits of a PVP Certificate



Provisional protection upon application receipt



Exclusive legal rights to market and to exclude others from selling your protected variety



Priority when filing with another UPOV authority



No annual maintenance fees



After expiration of protection, variety becomes publicly available for continued innovation

## PVP Advisory Board

- 14-member advisory board selected by the USDA Secretary of Agriculture
- Members represent: farmers, seed industry, trade and professional associations, and public and private research institutions
- Provides advice on issues related to PVP

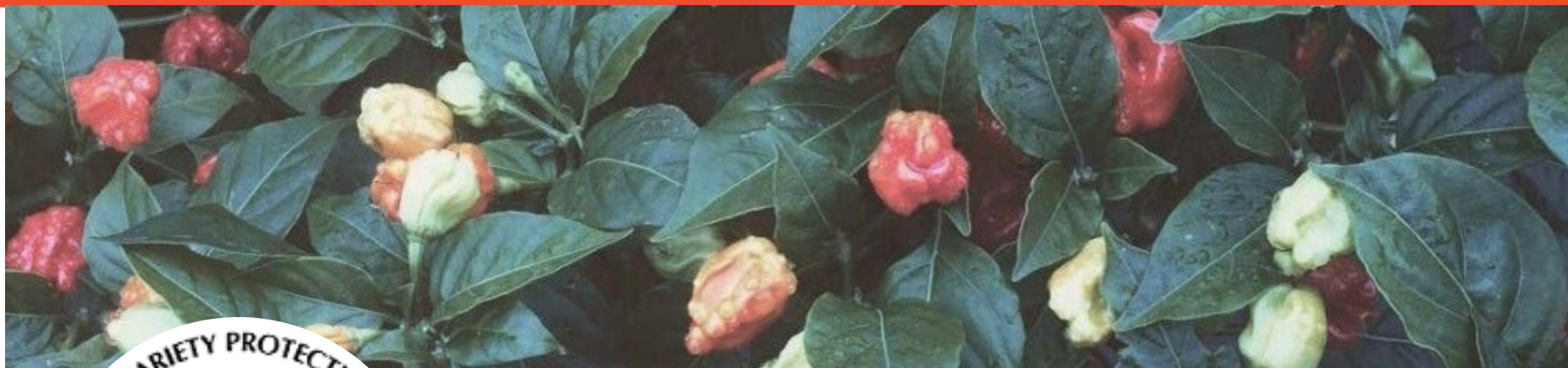
### How Can I Join the Board?

Call for nominations announced on the website and via Gov Delivery notice

For more information contact: [PVPOmail@usda.gov](mailto:PVPOmail@usda.gov)

# Agricultural Marketing Service

Creating Opportunities for American Farmers and Businesses



## **USDA Plant Variety Protection Office**

1400 Independence Avenue, S.W.  
Room 4512-South Building, Mail Stop 0274  
Washington, D.C. 20250-0002

Main Office Telephone: (202) 260-8983  
Email: [PVPOmail@usda.gov](mailto:PVPOmail@usda.gov)



## Protecting Plants and Plant Varieties –Recent Developments

- ▶ What does Essentially Derived Mean? Case Law and UPOV guidance
- ▶ Protection of Plant Varieties at the EPO -Recent Decisions
- ▶ Additional Options for Protecting Asexually Reproduced Plants



by Heidi S. Nebel  
McKee, Voorhees and Sease

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## Background UPOV PBR

- ▶ The International Union for the Protection of New Varieties of Plants (UPOV) based in Geneva, Switzerland.
- ▶ UPOV was established in 1961 by the International Convention for the Protection of New Varieties of Plants.
- ▶ The Convention was adopted in Paris in 1961 and revised in 1972, 1978 and 1991.
- ▶ To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.
- ▶ Each member state must adopt legislation consistent with the requirements of the convention and submit that legislation to the UPOV Secretariat for review and approval.
- ▶ 7 U.S.C. §§ 2321-2582, gives breeders exclusive control over new, distinct, stable varieties for 20-25 yrs.

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# UPOV PBR

1978 verse 1991 Acts

- 1978 Allowed for “discoverer” of plant to obtain protection  
Protection 15 years  
Does not cover harvested material (asexually reproduced plants)
- 1991 Gave option to restrict farmer’s exemption  
Provided breeders exemption  
Expanded coverage to “harvested materials”  
Expanded protection to EDV  
Expanded definition of variety to include hybrids  
Expanded protection to 20 years

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# UPOV PBR

Country Code	Country	UPOV Convention
AR	Argentina	1978
AT	Austria	1991
AU	Australia	1991
BR	Brazil	1991
CA	Canada	1991
CL	Chile	1978
CN	China	1978
CO	Columbia	1978
DE	Germany	1991
ES	Spain	1991
FR	France	1991
GB	United Kingdom	1991
IE	Ireland	1991
IT	Italy	1991
JP	Japan	1991
MX	Mexico	1978
NZ	New Zealand	1991
PL	Poland	1991
QZ	European Union	1991
RU	Russian Federation	1991
SE	Sweden	1991
TR	Turkey	1991
UA	Ukraine	1991
US	United States of America	1991

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## 7 U.S.C. § 2401

### Adopted from UPOV guidance on Essentially Derived

(A) in general. The term “essentially derived variety” means a variety that –

- (i) is **predominantly derived** from another variety or from a variety that is predominantly derived from the initial variety, while retaining the expression of the **essential characteristics** that result from the genotype or combination of genotypes of the initial variety; and
- (ii) **is clearly distinguishable** from the initial variety; and
- (iii) except for differences that result from the act of derivation, **conforms to the initial variety** in the expression of the **essential characteristics** that result from the genotype or combination of genotypes of the initial variety.

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## Scope of Protection

- ▶ Protection applies equally to **“any variety that is essentially derived from a protected variety, unless the protected variety is an essentially derived variety.”**
- ▶ Goal: end the practice of slightly altering a successful variety, benefiting from the desirable characteristics of that successful variety, and then escaping infringement

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## Scope of Protection



Initial Variety



EDV1



EDV2

- ▶ IV -> EDV1 -> EDV2 -> EDV3.....
- ▶ EDV1-2 may be infringing on IV.
- ▶ EDV2 not infringing on EDV1
- ▶ Breeder may PVP EDV1 and EDV2

## Defining “Predominant Derivation” and “Essential Characteristics”

- ▶ Generally:
  - Predominant = genetic origin
  - essential characteristics = degree of genetic similarity.
- Both require inquiry into genotypic and phenotypic characteristics.

## What Are Essential Characteristics?

- Perspective of the **producer, seller, supplier, buyer, recipient, or user**
- Essential characteristics **differ among crops** and species and are not restricted to those that relate to high performance or value and could be, for example, disease resistance for susceptible varieties
- the “DUS” requirements may be informative
- Example: wheat guidelines indicate 27 observable morphological characteristics such as length of ear, density of ear, presence or absence of scurs or awns on the ear.



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## Required Degree of Conformity of Essential Characteristics?

- Degree of conformity required between IV and putative EDV is not defined
- UPOV:
  - “the intention is that a variety should only be essentially derived from another variety when it retains virtually the whole genotype of the other variety”
  - The derived variety may only “be different from [the initial] variety by a very limited number of characteristics

### US CASE LAW

- No reported cases in the US on EDV, predominant derivation, or essential characteristics

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## Case Law - Netherlands

- ▶ *Van Zanten Plants B.V. v. Hofland B.V.* - clear case of a putative EDV that is in fact an EDV.
  - IV is a freesia, *Ricastor*
  - Evidence showed no genetic difference between *Ricastor* and the putative EDV *Mercurius*.
    - DNA test showed no genetic difference and
    - AFLP profiles showed complete similarity between the varieties
  - Phenotype differences considered minor
  - 38 out of 39 important morphological characteristics identical.
  - Hofland did not supply a counter analysis, nor have an explanation for the high degree of genetic similarity



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## Case Law - Netherlands

- ▶ Seminal case *Danziger Flower Farm v. Astee Flowers BV* -
- ▶ Astee's *Blancanieves* did not infringe but was considered a new variety.
  - Each party presented its own AFLP evidence with differing similarities; court disfavored this statistical method
  - Court considered 17 morphological differences examined by the Community Plant Variety Office during registration
  - Finding: morphological differences greater than "one or a few" inheritable characteristics required for essential derivation.



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## Case Law – Germany

- ▶ *Probstoder Saatzucht GmbH & Co. KG v. Pflanzzucht Oberlimpurg* – parties settled
  - Court appointed an expert to use microsatellite markers
  - showed a genetic similarity of 99%, enough to conclude an EDV
  - Defendant appealed, challenging based on the court’s failure to consider phenotype data.
  - Parties settled.



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## Case Law –Italy

- ▶ *Almo s.p.a. v Sardo Piemontese Sementi soc. Coop. Sociata Agricola* – putative EDV is an EDV
  - court appointed expert analysis: 21 out of 25 genetic markers inherited from IV
  - Court identified the relevant essential characteristics of rice: grain type, vegetative cycle duration, productive capacity, yield and resistance to herbicides.
  - Two varieties shared all the essential characteristics.



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## Case Law – Takeaways from Europe

- ▶ Phenotypic data can be the basis for a decision
- ▶ There must be only very few phenotypic differences between the varieties for one to be an EDV of the other
- ▶ What are considered important phenotypic characteristics overlap with what the CVPO uses to assess distinctness

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## Case Law – Israel

- ▶ *Danziger Flower Farm v. Astee Flowers BV* – Same case as in the Netherlands, but with a different outcome
  - Israeli law: burden of proof lies with the **defendant** to establish that the variety in question is not an EDV if the plaintiff establishes evidence of genetic conformity.
  - rejected the argument that only morphological characteristics be considered
  - accepted the AFLP evidence of the plaintiff
  - EDV threshold not limited to one trait or a small number of morphological traits
  - Here: *Blancanieves* is an EDV



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## Case Law – Israel

- ▶ The EDV threshold, as well as who bear the burden of proof, can be decisive
- ▶ Evidence produced by Danziger was sufficient to shift burden of proof to Astee, leading to a different outcome from the Netherlands.
- ▶ Threshold for burden-shifting in Israel appears to be uniquely low.
  - CVPO: “while the Basic Regulation does not explicitly say so, it must be understood
  - that it is the holder of the initial variety who must demonstrate that another variety
  - is derived from his variety in case of dispute.”

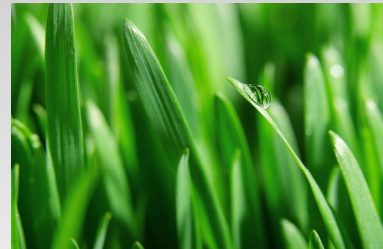


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## Australia

- ▶ Statute “essential characteristics”
  - “heritable traits ... that contribute to the principle features, performance and value of the variety”
  - EDV “does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety”
- ▶ *Sir Walter v B12*                      *B12* found to not be an EDV
  - Two characteristics that differ
  - Color and length between the stalk and the leaves (‘internode’)
  - shortened internode of *B12*
    - increases wear tolerance, a feature desirable for commercial use



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## Australia

- ▶ *Kings Pride* was accused of being an EDV of *Sir Walter*.
  - DNA evidence that *Kings Pride* was derived from *Shademaster*, the parent of *Sir Walter*.
  - *Kings Pride* not an EDV of *Sir Walter*,
  - **predominantly derived** from *Sir Walter's* parent.
  - *Kings Pride* has comparatively stronger plant vigor, longer internode length, longer stolon length than *Sir Walter*.
- Stolon length considered important for density and thatch and thus they differ in an important way.



- ▶ Take away: the statutory difference in Australia drives the differences in case law

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## The International Seed Federation System

- ▶ The International Seed Federation (ISF) has established Guidelines for the Arbitration of EDV Disputes
- ▶ EDV Methodologies and Action Thresholds.
- ▶ Based on industry agreement,
- ▶ 6 crops (corn/maize, cotton, lettuce, oilseed rape, potato<sup>2</sup>, and perennial ryegrass).



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## UPOV GUIDANCE

- ▶ October 22, 2009, “Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention was adopted by the UPOV Council.
- ▶ April 6, 2017, Document UPOV/EXN/EDV/2, entitled “Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention”, was issued by UPOV.
  - “to assist members of the Union and relevant stakeholders in their considerations in matters concerning essentially derived varieties
- ▶ At their meeting in October 2019 - UPOV Administrative and Legal Committee agreed to open those EDV Explanatory Notes from 2017
- ▶ CIOPORA (International Community of Breeders of Asexually Reproduced Horticultural Plant Varieties) and ASTA submitting comments

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## Patentability of Plant Varieties EPO

- ▶ EPO prohibits Patenting of “Essentially Biological Processes” Article 53
- ▶ 2010. Then the Enlarged Board of Appeal issued a landmark ruling in cases “Broccoli I” and “Tomato I”, confirming the scope of Article 53 as excluding plants and animals obtained through traditional breeding.
- ▶ 2015. The Board reconsidered the 2010 decision, declaring that plants or plant material derived through conventional breeding processes are indeed patentable subject matter.
- ▶ 2017. EU sets out a new Biopatent Directive to explicitly rule out the patenting of matter produced by an essentially biological process. The EPO reacted through the implementation of Rule 28(2), which states that European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.

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## Patentability of Plant Varieties EPO

- ▶ 2018. Technical Board of Appeal declared the EPO's practice under Rule 28(2), invalid for plant and animal patents. It was found to have no impact in the 2015 decision in "Broccoli I" and "Tomato I", as the guidelines had not yet been applied.
- ▶ Following this, the Board reversed the rejection of Syngenta's patenting of chilli pepper plants holding that its application to register [EP 27 53 168](#) should not have been rejected by the EPO on the basis of Rule 28(2).

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## Patentability of Plant Varieties EPO

- ▶ This led to referral of the question to the Enlarged Board of Appeal in light of the Syngenta decision and the Ruling of May 19 2020. The decision, G 3/19
- ▶ also rejects the earlier broccoli and tomato rulings.
- ▶ Contrast to *JEM Ag Supply v Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, (2001), In this decision the Supreme Court indicated that plant varieties are indeed plant eligible subject matter.
  - The last broadening case under 35 U.S.C. Section 101 that preceded many narrowing interpretations for naturally occurring DNA sequences and the like.

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# Pioneer v. J.E.M. Ag Supply, 534 U.S. 124 (2001)

confirmed the availability of utility patent protection for plants.

Case No. 00-1000  
 SCALIA, J. ANNOUNCING  
 SUPREME COURT OF THE UNITED STATES  
 No. 00-1000  
 J. E. M. AG SUPPLY, INC. v. PIONEER HUBBARD  
 INTERNATIONAL, INC.  
 ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF  
 APPEALS FOR THE FEDERAL CIRCUIT  
 (December 10, 2001)

**JUSTICE SCALIA, announcing.**  
 This case presents an interesting and difficult point of statutory construction, seemingly pitting against each other two perfectly valid means of interpretation: (1) that statutes must be construed in their entirety, so that the meaning of one provision sheds light upon the meaning of another; and (2) that words by implication are not favored. I think these sensible canons are reconcilable only if the first of them is limited by the second. That is to say, the power of a provision of law to give meaning to a provisionally created ambiguity comes to an end once the ambiguity has been authoritatively resolved. At that point, use of the later statement produces not clarification (governed by the first canon) but amendment (governed by the second).



Morrison et al. Date of Patent: Jun. 25, 1996

194. HYBRID CORN PLANT AND SEED (1996)  
 195. Morrison, Donald L., Morrison, Gordon C., and Morrison, William W. Seattle, Wash., Wash.  
 196. Janssen Pharmaceutia NV International, Inc., Leuven, Belgium  
 197. Appl. No. 08/249  
 198. Filed: Aug. 26, 1994  
 199. U.S. Cl. Class.: 607.001, 607.002, 607.003, 607.004, 607.005, 607.006, 607.007, 607.008, 607.009, 607.010, 607.011, 607.012, 607.013, 607.014, 607.015, 607.016, 607.017, 607.018, 607.019, 607.020, 607.021, 607.022, 607.023, 607.024, 607.025, 607.026, 607.027, 607.028, 607.029, 607.030, 607.031, 607.032, 607.033, 607.034, 607.035, 607.036, 607.037, 607.038, 607.039, 607.040, 607.041, 607.042, 607.043, 607.044, 607.045, 607.046, 607.047, 607.048, 607.049, 607.050, 607.051, 607.052, 607.053, 607.054, 607.055, 607.056, 607.057, 607.058, 607.059, 607.060, 607.061, 607.062, 607.063, 607.064, 607.065, 607.066, 607.067, 607.068, 607.069, 607.070, 607.071, 607.072, 607.073, 607.074, 607.075, 607.076, 607.077, 607.078, 607.079, 607.080, 607.081, 607.082, 607.083, 607.084, 607.085, 607.086, 607.087, 607.088, 607.089, 607.090, 607.091, 607.092, 607.093, 607.094, 607.095, 607.096, 607.097, 607.098, 607.099, 607.100, 607.101, 607.102, 607.103, 607.104, 607.105, 607.106, 607.107, 607.108, 607.109, 607.110, 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## Other Options For Protecting Asexually Produced Plant Varieties Or Traits

- ▶ Plant Variety Protection
- ▶ Utility patents (varieties, plant parts, genes, traits, methods)
- ▶ Plant patent - (except edible tubers)
- ▶ Contracts/MTAs
- ▶ Trademarks

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## Protecting Varieties

### *Asexually reproduced plants*

- ▶ PVP of variety
- ▶ PBR of variety
- ▶ Plant patent
- ▶ Utility patent

### *Sexually reproduced plants*

- ▶ PBR of variety
- ▶ PVP of variety
- ▶ Utility patent to variety

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## Plant Patent 35 U.S.C. §161

- ▶ Distinct and new varieties of asexually reproduced plants (other than tuber propagated plants or plants found in an uncultivated state).
- ▶ Photographs for enablement
- ▶ Protection lasts for 20 years
- ▶ Same protections as utility
- ▶ No maintenance fees
- ▶ One claim “a strawberry variety as shown and described herein”

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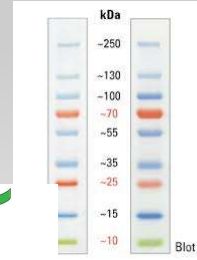
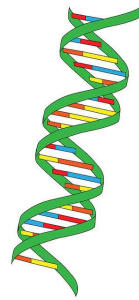
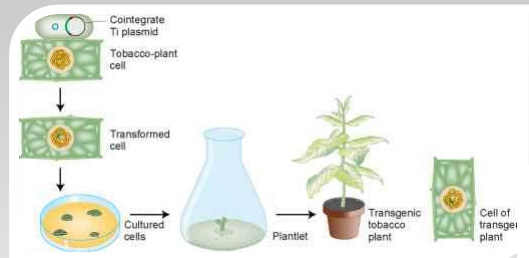
The USPTO has issued hundreds of utility patents on plant lines and varieties  
*Ex parte Hibberd, 227 U.S.P.Q. 443 (Bd. Pat. App. 1985).*



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## Other areas of protection include Transgenic plants, genes, proteins, and molecular markers



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## Utility patent Claims for varieties

- |  |  |
|--|--|
| plants and seeds   | 1. Hybrid maize seed designated XXXXX, representative seed having been deposited under ATCC accession number _____.  |
| F1 progeny   | 2. A maize plant, and its parts, produced by the seed of claim 1.  |
| Plant parts  | 3. Pollen of the plant of claim 2.   |
| Transgenic conversions and production methods                        | 4. An ovule of the plant of claim 2.   |
| Methods of plant breeding –new variety development (2+ generations)* | 5. A tissue culture of regenerable cells of a hybrid maize plant XXXXX, wherein the tissue regenerates plants capable of expressing all the morphological and physiological characteristics of XXXXX, representative seed having been deposited under ATCC accession number _____. |
| Methods of use*  | 6. A tissue culture according to claim 5, the cells or protoplasts being of a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.   |
| Harvested product  | 7. A maize plant, and its parts, regenerated from the tissue culture of claim 5 and capable of expressing all the morphological and physiological characteristics of 34G81, representative seed having been deposited under ATCC accession number _____.                           |

\*Can prevent import into US with 35 USC§271(g)

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## 2018 Farm Bill CANNABIS

- ▶ Utility patents for Cannabis
  - Deposit issue ATCC?
- ▶ Plant patents for Cannabis
- ▶ PVP sexually produced accepted in April 2019 with deposit waiver
- ▶ PVP asexually accepting with deposit waiver

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## Traits

- ▶ Wide variety options for utility patent claims
  - Plants with trait developed by inventor
  - Methods of breeding or editing
  - Genetics
  - Producing a new product
  - How to characterize
  - Markers and selection
- ▶ *Examples:*

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## Example of “Trait” Patent Claim

- ▶ U.S. Patent No. 9,173,355; “Carrots having increased lycopene content”
  - 1. A carrot plant, the roots of which comprise an average lycopene content from about 110 ppm to about 250 ppm and an average brix content from about 11” brix to about 20” brix, wherein the lycopene content of the plant is at least about 110% of the average lycopene content of roots of the carrot variety Nutri-red when the plant and Nutri-red are grown under the same conditions, and wherein said carrot plant comprises the genetic source for expressing the lycopene content in a carrot variety selected from the group consisting of red carrot hybrid 0710 0325....

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## “Breaking the Linkage”

- ▶ U.S. Patent No. 9,024,140; “Methods and compositions for producing plants with elevated Brix”
  - 1. A tomato plant comprising a hir4 allele of *Lycopersicon hirsutum* conferring elevated Brix relative to a *Lycopersicon esculentum* plant lacking said hir4 allele, wherein the plant lacks an allele genetically linked to the hir4 allele of *Lycopersicon hirsutum* conferring increased plant vegetative growth relative to a *Lycopersicon esculentum* plant lacking said allele genetically linked to the hir4 allele, wherein said hir4 allele and allele genetically linked to the hir4 allele are located in a genomic region corresponding to markers TG155 and TG500, wherein the hir4 allele is located proximal to TG155 in said region relative to the allele conferring increased vegetative growth.

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## Recombined Introgression Claim

- ▶ U.S. Patent No. 9,072,271 “Agronomically elite lettuce with quantitative *Bremia lactuca* resistance”
  - 7. A lettuce seed comprising a chromosomal segment that comprises a RBQ5 allele of *Lactuca saligna* conferring quantitative resistance to *Bremia lactucae* and lacking a *Lactuca saligna* allele genetically linked thereto that confers adventitious shoots, wherein a representative sample of seed comprising the chromosomal segment was deposited under ATCC Accession Number PTA-9046.

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## Claiming Use of a Newly Identified QTL

- ▶ U.S. Patent No. 7,759,545 “Methods and compositions for production of maize lines with increased transformability”
  - 1. A method for producing a transformable corn line comprising introgressing at least one chromosomal locus mapping to bin 6.02 to 6.04 or bin 10.04 to 10.06, wherein said locus is introgressed from a more transformable corn line into a less transformable corn line.

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## Claiming Use of a Newly Identified Source/Trait

- ▶ U.S. Patent No. 8,859,859 “Downy mildew resistant cucumber plants”
  - 1. A method of producing a cucumber plant having a resistance to Downy Mildew comprising the steps of: (a) crossing a cucumber plant of accession PI197088 with a second cucumber plant having at least one desired trait; and (b) selecting at least a first progeny cucumber plant resulting from the crossing that comprises resistance to Downy Mildew and the desired trait.

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*Thank you*



**Heidi S. Nebel**  
McKee, Voorhees and Sease

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