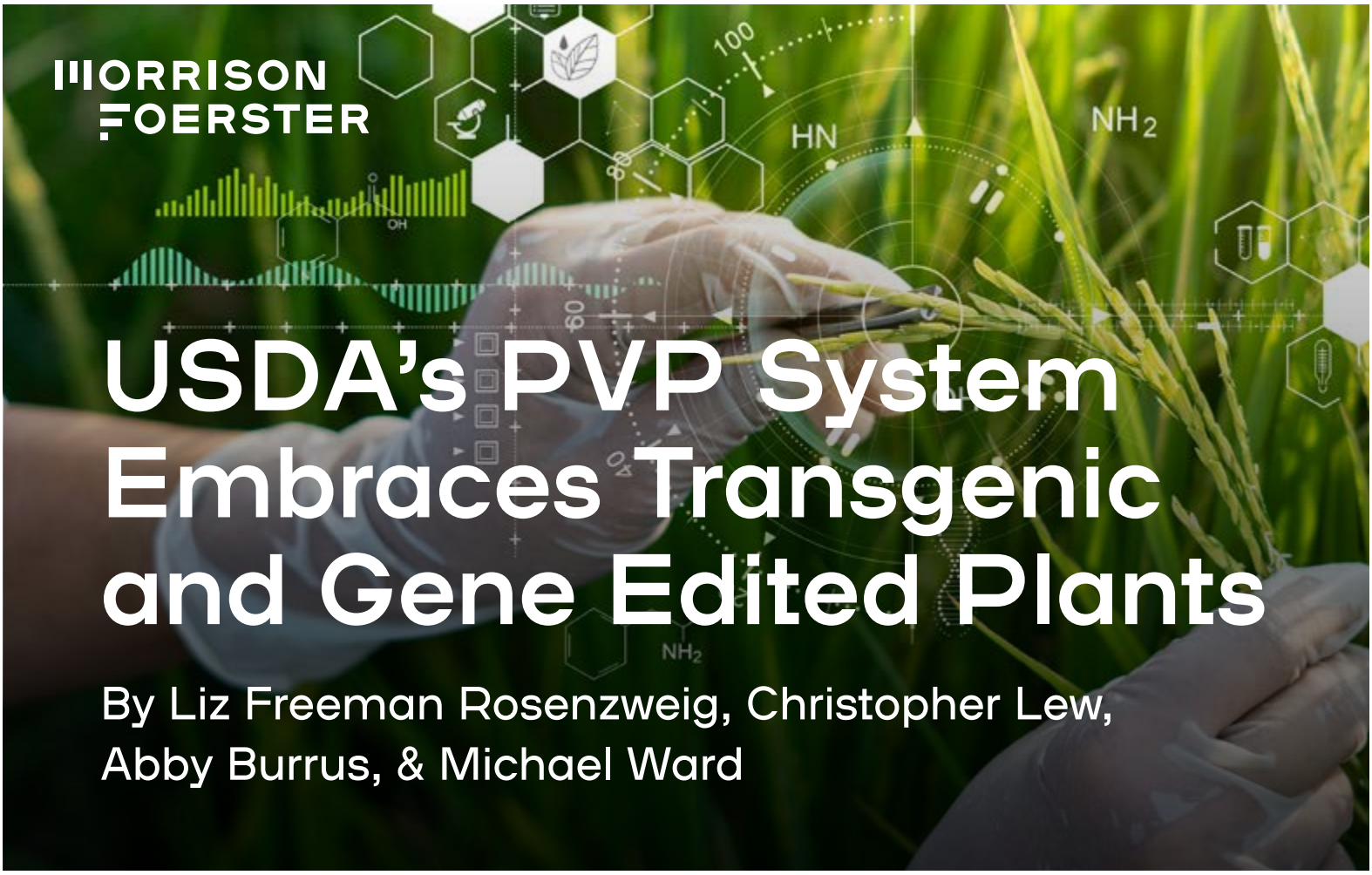


# USDA's PVP System Embraces Transgenic and Gene Edited Plants

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Plant Variety Protection (PVP) is a form of intellectual property protection administered through the United States Department of Agriculture (USDA) for new varieties of plants. PVP certificates (PVPs), which have been available in the U.S. since the enactment of the Plant Variety Protection Act of 1970 (PVPA; 7 U.S.C. §§ 2321-2582), have historically been associated with traditional breeding. However, there are actually numerous granted PVPs covering transgenic plant varieties, and the USDA is now also granting PVPs to gene edited plants. This article describes a recently granted PVP for a gene edited plant, contextualizing this example PVP in the broader landscape of PVP certificates that are directed to plant varieties created using modern biotechnology.

As of this writing, there have been at least 1,952 granted PVPs covering transgenic plant varieties since 1998, when the USDA started collecting this information (**Figure 1a**). This represents roughly 20% of all PVPs granted during this time frame. PVPs covering transgenic varieties are identifiable by an affirmative answer in field 18 in the PVP ST-470 application form (**Figure 1b**). These transgenes are often used to confer traits that do not usually occur in a crop's gene pool, such as herbicide tolerance or insecticidal protein synthesis.

**Figure 1a**

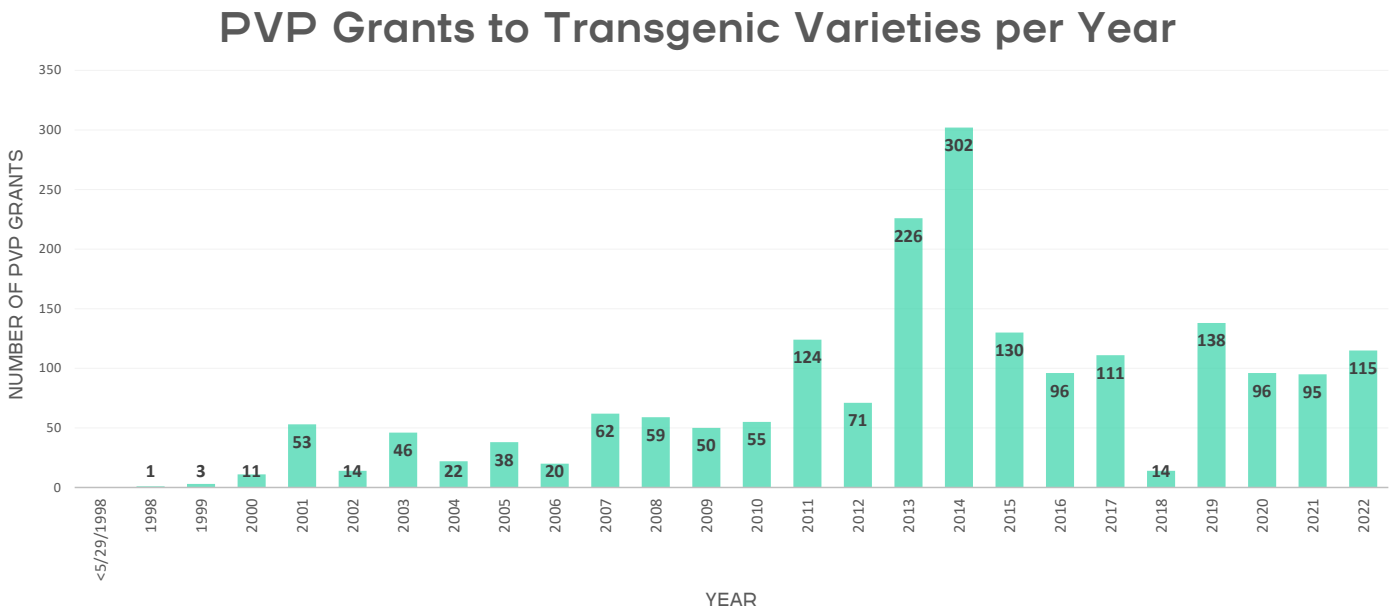


**Figure 1a**: PVP grants covering transgenic plant varieties by year. Data source: USDA, AMS, S&T, Plant Variety Protection Office, July 2022. The raw data consists of all PVP varieties where the answer to the question "Does the variety contain any transgenes?" is "Yes." The bar graph was generated by filtering this raw data for records with an issue date, then sorting by issue year.

**Figure 1b**

**18. DOES THE VARIETY CONTAIN ANY BIOTECHNOLOGY EVENTS?**

■ Yes ☐ No

A biotechnology event is defined as a single insertion of a nucleic acid construct into a specific site in a plant's chromosome that is regulated under the U.S. Coordinated Framework for the Regulation of Biotechnology.

**Figure 1b**: Field 18 of a PVP certificate, indicating the presence of inserted nucleic acids. Source: PVP application form for rape variety 'KSR4652'. Note that the USDA changed the language in this field around 2018; an earlier version referred to "transgenes" rather than "biotechnology events" (for an example of the previous language, see field 18 in the PVP application form for rape variety 'Cara'). According to the USDA, AMS, S&T, and Plant Variety Protection Office, this change was due to industry pressure for the field to be written more broadly, in order to better encompass newer methods of genetic modification (personal communication, July 2022). USDA-AMS, for its part, views the use of "transgenes" and "biotechnology events" in this context as synonymous, and it collects the information in field 18 in order to assist the National Laboratory for Genetic Resource Preservation in handling seed deposits after expiration (USDA, AMS, S&T, and Plant Variety Protection Office; personal communication, July 2022).

In addition to PVPs on transgenic varieties, which contain foreign DNA by definition, the USDA has also recently begun granting PVPs on gene edited plant varieties. Gene editing is a form of modern biotechnology used to make precise genetic changes, but which does not necessarily entail insertion of foreign DNA.

For example, the USDA recently granted a PVP certificate to GreenVenus, LLC for the 'GVR-108XL' lettuce variety, which was created using gene editing without transgene insertion. Thus, in contrast to the PVPs discussed above, field 18 in this Certificate is marked as "No." The table below summarizes the bibliographic information of the 'GVR-108XL' lettuce PVP, including links to relevant documents.

| | |
|---|---|
| **PVP Certificate** | No. 202000361 |
| **Crop** | Lettuce *(Lactuca sativa* L.*)* |
| **Variety Name** | 'GVR-108XL' |
| **Applicant & Owner** | GreenVenus, LLC |
| **Filing Date** | August 24, 2020 |
| **Issue Date** | May 13, 2022 |
| **Related Applications** | 1) US Provisional Patent 62/925,853 (filed October 25, 2019);<br>2) International patent application PCT/US2020/54082 (published April 29, 2021) |

GreenVenus, LLC's romaine lettuce variety 'GVR-108XL' has edits to five polyphenol oxidase (PPO) genes, which are enzymes responsible for damage-related browning in fruits and vegetables, and negatively affect the shelf life of products such as pre-cut salads. As described in the publicly available description and data included with the published PVP application, the genetic edits in 'GVR-108XL' lettuce lower the activity of PPOs to delay browning, without the presence of transgenes in the plant's genome. These edits were accomplished using a nuclease and guide RNAs to target multiple PPO genes. The nuclease and guide RNAs were originally introduced on a T-DNA using *Agrobacterium*-mediated transformation. This foreign DNA was integrated into the lettuce genome, thereby producing a transgenic lettuce plant that mediated its own gene editing. Once the transgenic nuclease and guide RNAs accomplished the desired edits to the PPO genes, the transgenic DNA was segregated out in subsequent generations by traditional breeding. The final 'GVR-108XL' lettuce plants thus include the PPO edits, but do not include foreign DNA (for more information, see pg. 8 and Exhibit B of the 'GVR-108XL' PVP application).

## What is the transgenic PVP certificate landscape like, and how has it evolved?

The USDA started collecting information in PVP applications on transgenic insertions in 1998. From 2000 to 2010, transgenic PVPs averaged 40 grants annually, and then a sharp increase culminated with a maximum of 302 grants in 2014 (**Figure 1a**). This trend of increasing annual grants was largely driven by grants on transgenic soybeans, which comprise the overwhelming majority of these transgenic PVP grants. Of the 302 grants in 2014, soybeans comprised 295, nearly 98% (**Figure 2**). This surge was likely driven by the publication of the soybean genome in 2010.

**Figure 2**

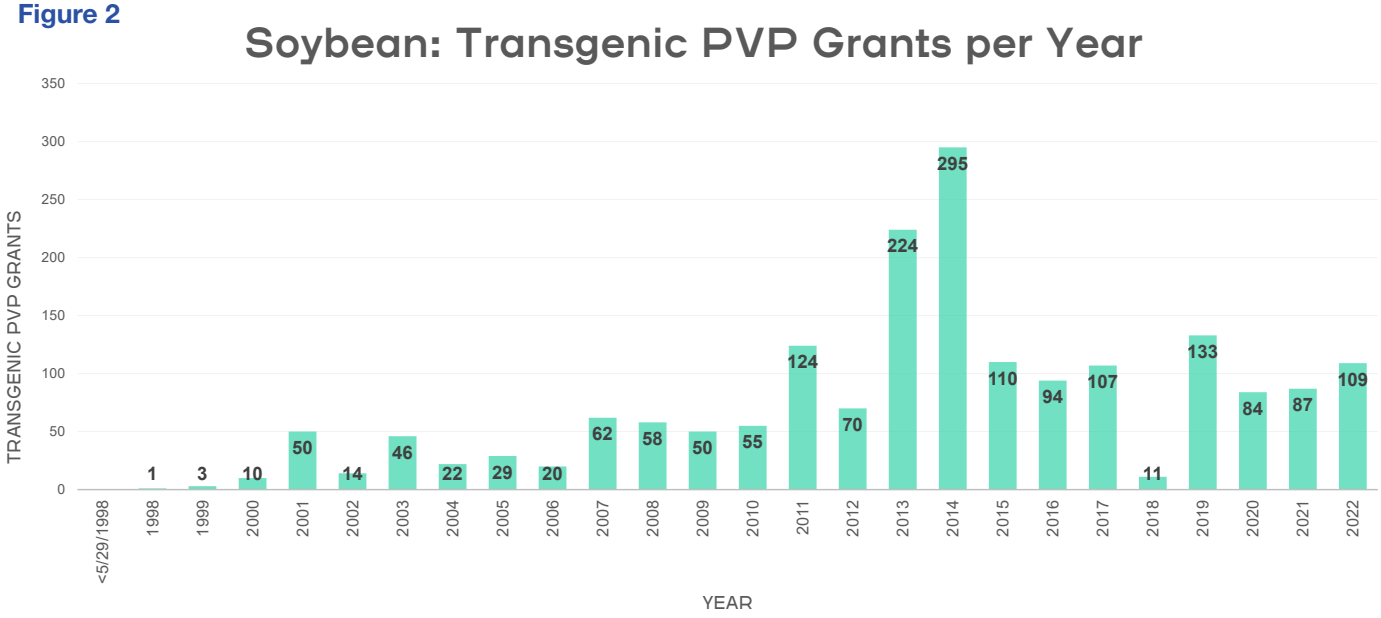


**Figure 2**: PVP grants to transgenic soy varieties. Data source: USDA, AMS, S&T, Plant Variety Protection Office, July 2022. The raw data consist of all PVP varieties where the answer to the question "Does the variety contain any transgenes?" is "Yes." The bar graph was generated by filtering this raw data for records with an issue date, further filtering for records with the crop type "soybean", and then sorting by issue year. Note that the soybean genome was published in 2010.

From 2015 to 2021, the number of transgenic PVP grants remained relatively stable, averaging 99 annually. Five crops represent all transgenic PVP grants, with over 95% of grants being soybean varieties (**Table 1**). The remainder consists of cotton (nearly 3% of all transgenic PVP grants) and maize, potato, and rape (each less than 1% of all transgenic PVP grants) (**Table 1**).

**Table 1**

| Crop | Percent of all transgenic PVP grants | Percent of the crop's PVP grants that are transgenic (1998 - present) |
|---|---|---|
| **Soybean** | 95.70% | 84.91% |
| **Cotton** | 2.97% | 12.78% |
| **Maize** | 0.92% | 0.91% |
| **Potato** | 0.20% | 0.77% |
| **Rape** | 0.20% | 11.11% |

**Table 1**: Spread of PVP grants across all transgenic crops that possess a PVP certificate. Data source: USDA, AMS, S&T, Plant Variety Protection Office, July 2022. The crop types "corn", "corn, sweet", and "field corn" found in the raw data are combined into the single "maize" category; "rape", "rapeseed", and "canola" are likewise combined into the single "rape" category. These percentages are conversions of the numbers in Figure 3 (e.g. soybean: 1,868 [transgenic soybean grants] ÷ 1,952 [all transgenic PVP grants] = 95.70% of transgenic PVP grants are soybean; 1,868 [transgenic soybean grants] ÷ 2,200 [all soybean grants] = 84.91% of soybean PVP grants are transgenic).

Notably, there is only one crop for which the majority of PVP grants are on transgenic varieties—that honor goes to soybean, for which nearly 85% of all PVP grants are transgenic (**Figure 3**). The overwhelming majority of PVPs for non-soy crops were granted in 2012 or later (**Figure 4**); transgenic soybean grants have also increased in roughly the same time period, but they were also relatively common earlier (**Figure 2**).

**Figure 3**

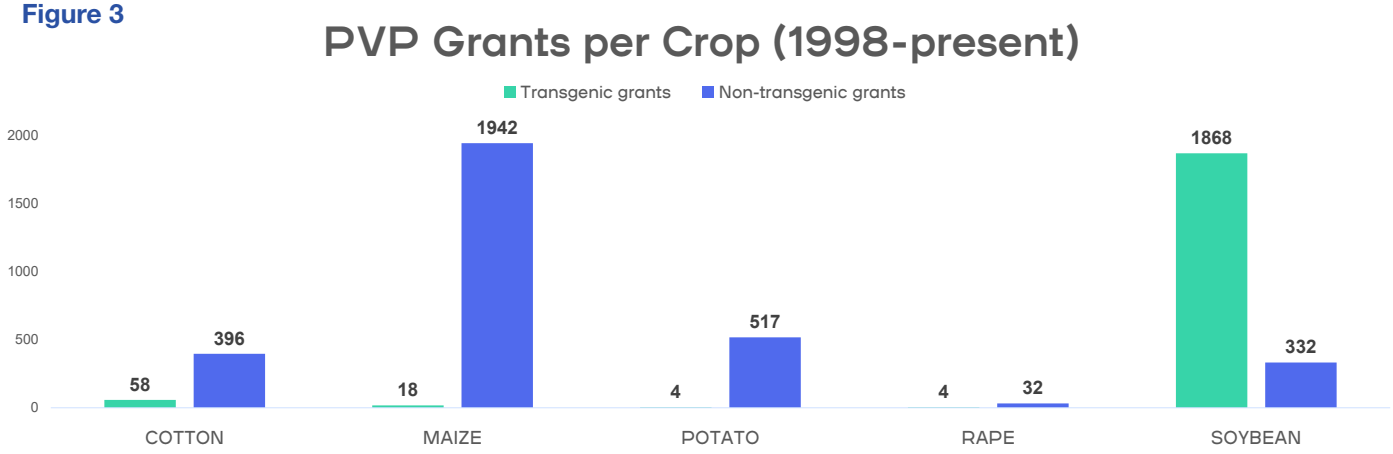


**Figure 3:** PVP grants to transgenic plant varieties by crop. Data source: USDA, AMS, S&T, Plant Variety Protection Office, July 2022. The raw data consist of all PVP varieties where the answer to the question "Does the variety contain any transgenes?" is "Yes." The bar graph was generated by filtering this raw data for records with an issue date, then sorting by crop. The crop types "corn" (n=1) and "field corn" (n=17) found in the raw data are combined into a single "maize" category. Data for non-transgenic plant types was calculated from the USDA's PVPO Application Status (June 2022 update) by filtering for applications with grant dates from 1998-2022, filtering by crop type, then subtracting the number of transgenic PVP grants for that crop to find the total number of non-transgenic PVP grants for the five crop types since 1998. The crop types "corn", "corn, sweet", and "field corn" found in the Application Status data are combined into the single "maize" category; "rape", "rapeseed", and "canola" are likewise combined into the single "rape" category.

**Figure 4**

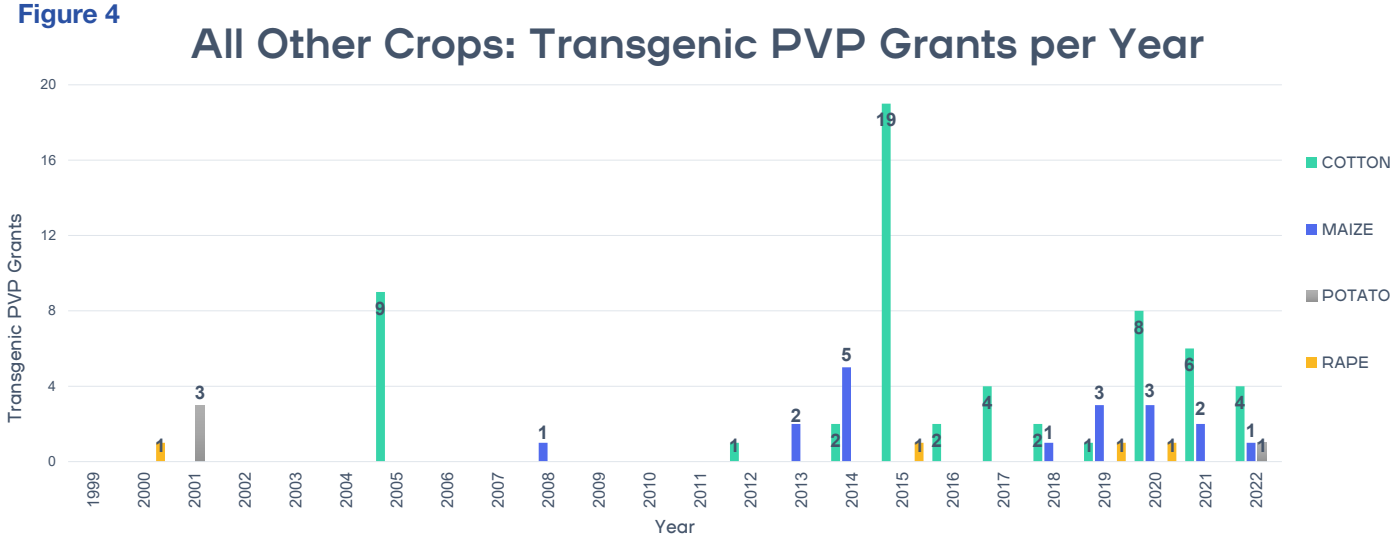


**Figure 4**: PVP grants to transgenic plant varieties by crop. Data source: USDA, AMS, S&T, Plant Variety Protection Office, July 2022. The raw data consist of all PVP varieties where the answer to the question "Does the variety contain any transgenes?" is "Yes." The bar graph was generated by filtering this raw data for records with an issue date, further filtering for records with the crop types other than "soybean", and then sorting by crop type and issue year. The crop types "corn" (n=1) and "field corn" (n=17) found in the raw data are combined into a single "maize" category.

More details on exemplary PVPs from these transgenic crops are included in Table 2, alongside the parallel information on the gene edited lettuce.

## What kinds of modifications have been made in transgenic plants that are the subject of PVPs?

PVPs have been granted on transgenic plants incorporating many different technologies, featuring several methods of editing genes as well as diverse desired traits that these genes confer. These plant varieties may exhibit improved yield, better tolerance of adverse growing conditions, or better resistance of certain infections, among other possible traits (see Table 2 for more information). Table 2 highlights the first application granted a PVP covering a transgenic plant since USDA began tracking this information (in 1998), as well as examples of PVPs on transgenic varieties in each crop for which such a PVP has been granted, including the two most recently granted transgenic PVPs as of this writing (PVPs nos. 202000060 and 202000061).

**Table 2**

| PVP No. | Crop | Variety Name | Modified Traits | Transfomation Method | Contains Transgenes | Grant Date | Applicant | Significance |
|---|---|---|---|---|---|---|---|---|
| 9800060 | Soybean | '92B51' | Glyphosate tolerance | Unknown | Yes | May 29, 1998 | Pioneer Hi-Bred | First transgenic PVP grant |
| 202000060 | Soybean | '5PMFU17' | Dicamba and glyphosate tolerance | Transgenic expression cassette insertion | Yes | June 10, 2022 | Pioneer Hi-Bred | Most recent transgenic PVP grant (1/2) |
| 202000061 | Soybean | '5PNDZ36' | Dicamba and glyphosate tolerance | Transgenic expression cassette insertion | Yes | June 10, 2022 | Pioneer Hi-Bred | Most recent transgenic PVP grant (2/2) |
| 201900405 | Cotton | 'FM2398GLTP' | Bt protein synthesis (×3), glyphosate tolerance | Unknown | Yes | July 30, 2021 | BASF | Sample transgenic PVP grant for cotton |
| 201100139 | Maize | 'NPXO5745GT21' | Glyphosate tolerance | Unknown | Yes | December 19, 2013 | Syngenta Crop Protection AG | Sample transgenic PVP grant for maize |
| 20190029832 | Potato | 'Elevate' | Disruption of PPO, asparagine synthase, phosphorylase-L, and starch-related genes | Transgenic expression cassette insertion | Yes | March 31, 2022 | Bohm-Nordkartoffel Agrar-produktion GmbH & Co. OHG | Sample transgenic PVP grant for potato |
| 201800533 | Rape | 'KSR4652' | Glyphosate tolerance | Transgenic expression cassette insertion | Yes | May 19, 2020 | Kansas State University Research Foundation | Sample transgenic PVP grant for rape |
| 202000361 | Lettuce | 'GVR-108XL' | PPO gene disruption (×5) | Genome editing nuclease and guide RNAs | No | May 13, 2022 | GreenVenus, LLC | Potentially, the first gene-edited PVP grant |

**Table 2**: Seven examplary transgenic PVP grants (yellow) are summarized in the table below for comparison to the edited lettuce discussed above (green). The PVPs on transgenic plants summarized here include the oldest grant, the two most recent grants, and sample grants from the remaining crops (cotton, maize, potato, and rape). The modified traits include tolerance to the herbicides dicamba and glyphosate, synthesis of insecticidal Bt proteins from the bacterium *Bacillus thuringensis*, and changes to starch related genes to reduce acrylamide potential and improve storage capabilities. The transformation methods, when provided, were transgenic expression cassette insertion in each of these cases. Recent grants demonstrate a trend towards varieties with multiple transgenic traits, e.g., resistance to multiple herbicides, resistance to herbicides combined with Bt protein synthesis, and synthesis of multiple Bt proteins. These new varieties are often the result of breeding plants with a single transgenic trait with plants with a different transgenic trait; while these varieties are the direct result of conventional plant breeding methods, they inherit their progenitors' transgenic status.

## Options for plant IP protection and changes to PVPs

Although this article focuses on PVPs, it is useful to keep in mind that PVPs are one of three non-mutually exclusive forms of IP available for plants in the United States. The other two forms are utility patents and plant patents. Utility patents can have any number of claims, and can cover many different aspects of a plant, including, but not limited to, plant lineages, parts, cells, varieties, and even sometimes traits. Plant patents are restricted to asexually propagated plants, and contain only one claim, which is limited to the particular plant described in the plant patent and clones thereof. Somewhat similarly, PVPs are limited to the protected variety, but have slightly broader coverage than plant patents in that they contain provisions regarding essentially derived varieties (EDVs). This means that permission must be granted by the Certificate holder in order to sell varieties deemed to be "essentially derived" from the protected variety, so long as the protected variety is not itself an EDV. A more in-depth discussion of EDVs may be found here.

## What do we expect going forward?

We expect the number of PVPs granted on plants produced using biotechnology—whether transgenic or not—to only increase going forward. Given the recent updates to USDA's regulatory process for assessing plants developed using genetic engineering under the SECURE rule, which we have summarized in a previous post, and the increasing technological ease with which such edits may be made, it is likely that there will be an increase in development of such plants in the United States. This is likely to be particularly true for certain "simple" types of gene editing, such as targeted DNA breaks that are repaired without a template, and targeted single base pair substitutions, both of which are exempt from regulation under the SECURE rule.

Not only will significantly more gene edited plants likely be produced going forward, but the recent expansion in PVP coverage to also include asexually reproduced plants (summarized in a previous post) means that nearly all such plants are now potentially eligible for PVP coverage. We expect that the combination of these two factors will lead to a significant increase in both the number and proportion of PVPs granted on transgenic and gene edited plant varieties—though it remains to be seen how closely USDA will publicly track each of these categories.

As these technological and regulatory changes continue to settle in, it will be interesting to see how the industry adapts to the new regulatory atmosphere, and how use of the various forms of plant IP available in the United States continues to morph in parallel.