FDA Under Trump Should Continue Streamlining Regulations for New Plant Varieties

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September 9, 2025

The FDA plays a critical role in regulating genetically engineered crops through premarket review of New Plant Varieties (NPVs), ensuring food safety while supporting agricultural innovation. In 2024, FDA introduced Premarket Meetings, a faster review pathway for some gene-edited NPVs compared to the existing Premarket Consultation process. The six products that have utilized the Premarket Meeting pathway so far indicate that the new process is enabling a wider range of crop species from smaller developers to reach the market more efficiently. However, most NPVs still undergo lengthy and unpredictable reviews, often exceeding a year. This continues to particularly disadvantage smaller developers with limited resources.

Genetically engineered crops have historically contributed significantly to yield growth and farm income, while reducing pesticide use and environmental impact. To continue enabling these benefits, FDA's regulatory process must be predictable and proportionate to risk. The agency could improve efficiency by clarifying submission requirements, making NPV reviews through the Premarket Consultation pathway a two-step process, limiting the NPV characteristics that trigger Premarket Consultations to only those associated with unreasonable risk, and ensuring the Human Foods program has adequate resources to conduct NPV reviews. Only more risk-based factors like the presence of toxins or allergens should guide FDA's decisions rather than the type of genetic change.

FDA initiated Premarket Meetings under the Biden administration and the new process for review has remained in place since the start of the second Trump administration in 2025. By building on this progress to further optimize its review framework, FDA can accelerate the

availability of beneficial products, ensure that small and large developers alike are able to contribute to advances in biotechnology, and keep American innovation onshore.

I. Introduction

At least half of U.S. crop yield increases in corn, wheat, and soy in the 20th century were due to improved crop genetics. The U.S. has some of the highest corn, rice, and soybean yields, and continuing to increase these yields is important for maintaining American competitiveness, meeting rising food demand, and minimizing the environmental impacts of agriculture. Continuing to increase yields depends on continuing technological advances, including genetically engineered crops.

Genetically engineered crops with resistance to insect pests have also reduced farmers' spending on pesticides and increased crop yields and farmer income per hectare. Genetically modified insect resistant maize and cotton and herbicide tolerant canola and maize were responsible for between $30 and $111 of growth in average net farm income per hectare in the U.S. from 1996 to 2020.

New genetically engineered crops—including genetically modified and gene edited crops—are subject to premarket regulatory review at FDA before products from these crops can be sold in the U.S. for human or animal consumption. The agency calls these products New Plant Varieties (NPVs). FDA also includes conventionally bred crops under the umbrella of NPV, but they are not subject to the same premarket review as genetically modified and gene edited NPVs.

FDA reviews of NPVs benefit farmers, consumers, and the environment. Apples and potatoes with reduced browning and bruising help reduce food waste, reducing costs for consumers and greenhouse gas emissions. Drought tolerant wheat increases yields under poor growing conditions and improves yield stability across unpredictable environmental conditions, benefiting farmers economically and increasing the sustainability and dependability of food supply. Insect resistant and herbicide tolerant crops such as corn, soybean, and canola reduce pesticide use and help enable reduced tillage, saving costs for farmers, decreasing greenhouse gas emissions, and improving soil health.

II. FDA's role in regulating genetically engineered crops

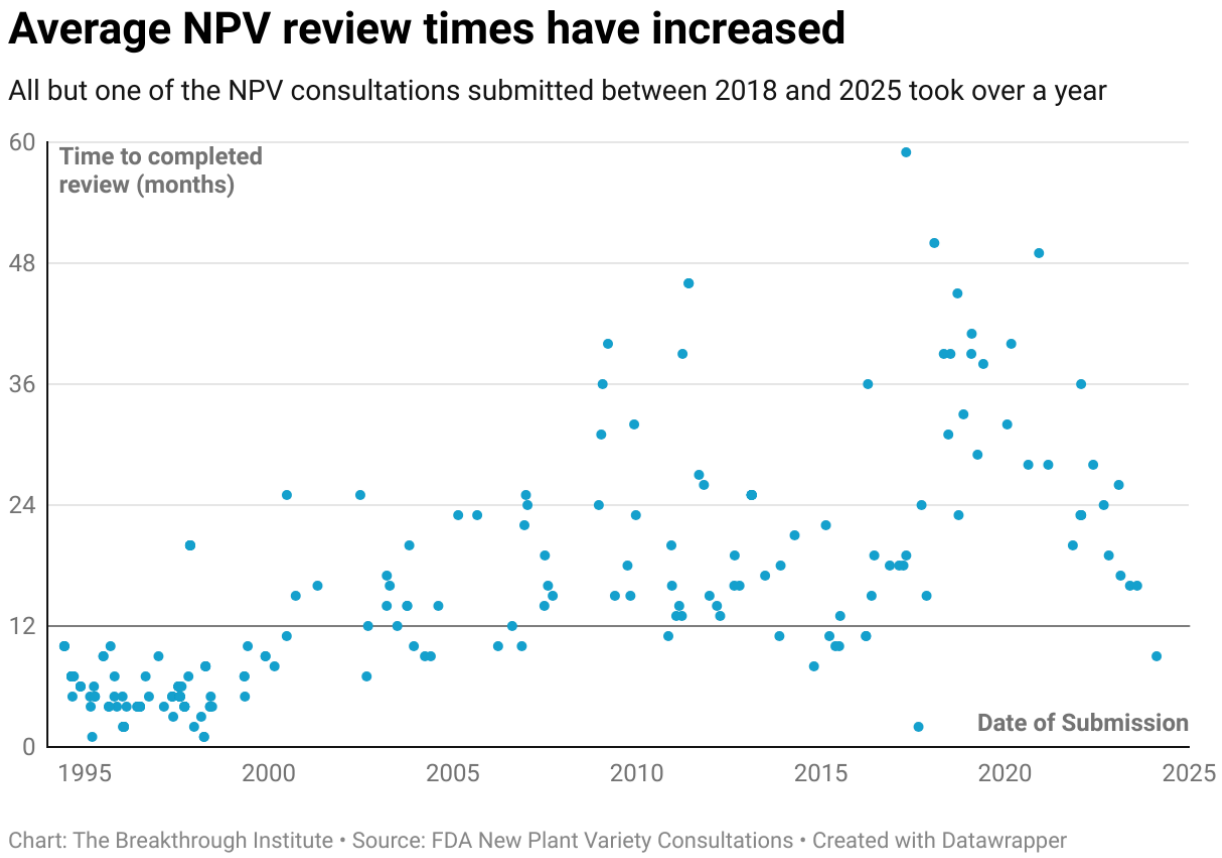
The purpose of FDA's premarket review of NPVs is to ensure that plants destined for the food supply are safe, including that they do not contain unapproved food additives. Under existing FDA regulations, any substance added to food must be approved as a food additive unless it is generally recognized as safe (GRAS). During an NPV consultation, FDA could decide that the plant contains an unapproved food additive, at which point the developer would need to either submit a food additive petition or establish that the substance is GRAS based on publicly available scientific evidence and expert consensus.

In addition to conducting premarket food additive reviews and NPV consultations, FDA also has postmarket authority it can apply if unapproved or unintended products enter the food supply and result in the adulteration of food. This postmarket authority is most frequently used to regulate the presence of environmental contaminants like lead, but could also be used to pull products from the market that the agency determines are unsafe or contain an unapproved food additive.

In order for beneficial products to get to market and for developers of NPVs to be able to plan to commercialize their products, FDA's review process must be predictable and timely. Long or unpredictable reviews particularly disadvantage small companies, as well as academic and nonprofit developers, that have limited resources or rely on graduate students and postdoctoral researchers with limited tenures. This pattern was evident at USDA as regulatory streamlining sped up reviews of genetically engineered crops under the SECURE rule. When Argentina reduced premarket oversight of gene edited organisms, these products—in many cases developed by smaller companies and academic labs—moved faster to commercialization and covered a larger diversity of organisms and traits.

Prior to 2024, all NPVs subject to FDA premarket review went through a voluntary process called New Plant Variety Consultations. Average review times increased, and all but one of the NPV consultations submitted to FDA between 2018 and 2025 took more than a year (figure below). Recent consultations for a genetically modified non-browning apple and non-browning potato took 28 and 16 months, respectively; and a genetically modified tomato with increased levels of

anthocyanins took 39 months. Gene edited high-oleic soybean took 15 months and gene edited potato with high tuber set took 23 months.



To address the bottleneck of long review times, FDA under the Biden administration established a new and improved review process in 2024. The new review process has remained in place since the start of the second Trump administration in 2025 and the current FDA has an opportunity to further build on this progress by setting timelines for reviews, clarifying requirements for applications, making Premarket Consultations a two-step process, narrowing the criteria that trigger Premarket Consultations compared to Premarket Meetings, and ensuring the Human Foods program has the staff and resources necessary to carry out these reviews.

III. FDA's new 2024 guidance streamlined NPV reviews

In February 2024, FDA published guidance to clarify how the agency's existing 1992 policy for products of New Plant Varieties (NPVs) applies to NPVs created using newer gene editing technology. So far the new policy has sped up reviews of some gene edited NPVs, supporting potentially beneficial products in reaching the market. The 2024 guidance addressed the problem of long review times by adding a new pathway for premarket review of some NPVs that is faster than Premarket Consultations. The new pathway, called Premarket Meetings, is available to NPVs that don't have any of the characteristics recommended for consultations—these characteristics include the presence of toxins and allergens. While Premarket Consultations require a lengthy submission from developers and a formal response from FDA, the database of Premarket Meetings simply lists the date of the meeting and limited information about the product and the developer.

The addition of Premarket Meetings in 2024 has given some gene edited NPVs a much faster path to market than the existing Premarket Consultation process. After publishing the guidance in February 2024, FDA completed 3 Premarket Meetings. After Trump took office in January 2025, FDA completed a fourth Premarket Meeting in March and two more in May.

Not only have Premarket Meetings given some products a faster path to market, but so far these products represent a wide variety of traits and crop species such as rice, strawberries, and mustard greens. In contrast, corn, soy, potato, cotton, and canola have historically been the main crops to complete the consultation process, making up 82% of all premarket consultations compared to 33% of premarket meetings.

FDA's Premarket Meetings for NPVs so far

VPM No. (sorted Z-A)	Date of meeting	Plant	Trait(s)	Designation(s)	Developer	Intended use
0005-B	May 29, 2025	Rice (*Oryza sativa*)	Herbicide tolerant rice 3	Mutations in certain genes involved in herbicide tolerance	Cibus, Inc	Human and animal food
0005-A	May 29, 2025	Rice (*Oryza sativa*)	Herbicide tolerant rice 1	Mutations in certain genes involved in herbicide tolerance	Cibus, Inc	Human and animal food
0004	Mar 14, 2025	Potato (*Solanum tuberosum*)	Reduced browning Reduced black spot	Potatoes with loss-of-function edits in certain *Ppo* genes, e.g., AP695 potato	J.R. Simplot Company	Human and animal food
0003	Dec 6, 2024	Canola (*Brassica napus*)	Pod shatter reduction	Mutations in certain genes involved in pod shatter reduction (PSR Canola)	Cibus, Inc	Human and animal Food
0002	Dec 4, 2024	Strawberry (*Fragaria x ananassa*)	Altered flowering for remontancy	Strawberries with loss-of-function edits in confidential gene "Gn1"	J.R. Simplot Company	Human food
0001	Aug 1, 2024	Mustard Greens (*Brassica juncea*)	Reduced pungency Reduced trichome number	GT225 GT226 GT241	Pairwise Plant Services, Inc.	Human food

Most recent premarket meetings as of August 7, 2025.

FDA's most recent Premarket Consultations for NPVs

BNF No	Food	Designation	Trait(s)	Developer[+]	Unique Identifier	Date Completed (sorted Z-A)
195	Corn	MON 94804	Altered plant architecture (short stature)	Bayer CropScience LP	MON-948Ø4-4	Mar 31, 2025
188	Corn	PY1203	Change in composition (express the phytase enzyme Phy02)	Agrivida, Inc.	AGV-PY203-5	Jan 10, 2025
181	Corn	FG259	Change in composition (express the AC1 beta-glucanase enzyme)	Agrivida, Inc.	AGV-FG259-5	Jan 10, 2025
199	Soybean	MON94637	Insect resistance	Bayer CropScience LP	MON-94637	Nov 27, 2024
200	Soybean	COR23134	Insect resistance Herbicide tolerance (ALS-inhibiting herbicides)	Pioneer Hi-Bred International, Inc.	COR-23134-4	Nov 6, 2024
192	Apple	PG451	Change in composition (reduced polyphenol oxidase activity)	Okanagan Specialty Fruits, Inc.	OKA-PGØØ4-1	Sep 19, 2024

Most recent premarket consultations as of August 7, 2025.

IV. Trump's FDA could further streamline NPV reviews

While some of the 2024 changes are beneficial, some are not and further changes are still needed to streamline reviews.

FDA should limit the NPV characteristics that trigger Premarket Consultations to only those associated with unreasonable risk. Specifically, the agency should stop recommending Premarket Consultations for plants based on the type of genetic change they contain. Rather, FDA should reserve full consultations for varieties with traits that plausibly pose an unreasonable risk, like an increase in toxins or allergens.

The 2024 guidance introduced a list of these NPV characteristics that stray from the guidelines in the 1992 policy by introducing categories focused on the type of genetic change rather than more risk-based characteristics. FDA should remove one of the new categories, "Modifications that introduce: (a) new genes and/or genetic elements that do not naturally occur in that species; or (b) additional copies of endogenous genes that are retained in the genome once genome editing is complete." This category is unnecessary because FDA's other categories cover the important, risk-based criteria of food that could endanger human or animal health, namely the presence of toxins, allergens, anti-nutrients, and changes in nutritional value. FDA should also continue its 2024 policy of not regulating "unintended" and "off-target" changes. Regulating these would further focus the trigger for lengthier regulatory review on the type of genetic change rather than more risk-based characteristics of the resulting product.

FDA should also introduce an initial step of consultations that looks for plausible pathways to unreasonable risk based on plant, trait, and mechanism of action, and only conduct full review if the agency finds any plausible pathway. Currently, all NPV Consultations require developers to submit significant amounts of data. Under the SECURE rule, USDA conducted two-step reviews that initially looked for plausible pathways to increased plant pest risk before requiring developers to submit extensive data. This process allowed faster review of most products while reserving more regulatory resources for higher-risk products. Adopting a similar process at FDA would help the agency better direct limited resources to those NPVs that are most likely to present risk.

In some cases developers have to update an NPV Premarket Consultation application multiple times before FDA considers it complete. In order to address this issue, FDA should clarify the requirements for developers' submissions to the agency. Having more clear expectations could help developers send the agency a complete submission the first time and reduce resources used by both the developer and FDA during a longer process.

Finally, FDA and Congress must equip the Human Foods program with the staff and funding necessary to carry out NPV reviews with sufficient expertise.

Overall, FDA's 2024 guidance has positively impacted the agency's review of genetically engineered crops by dramatically accelerating review of some low-risk gene edited crops through Premarket Meetings. The agency could further improve its processes by streamlining review of genetically engineered crops that aren't eligible for Premarket Meetings. The agency's premarket reviews have potential to further support commercialization of beneficial genetically engineered products, giving farmers access to better inputs and helping to maintain American leadership in biotechnology innovation on the world stage.