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Biotechnology in U.S. Crop Production: A Primer on Adoption, Costs, and Regulatory Structure

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Abstract

Genetically engineered (GE) crop varieties have achieved widespread adoption in major field crops, accounting for more than 90 percent of corn, soybean, and cotton acreage in the United States since 2013. This report examines adoption, costs, and the regulatory structure of agricultural biotechnology, focusing on both transgenic GE and emerging gene-edited crops. Major findings highlight that farmers pay higher prices for GE seeds relative to conventional seeds, primarily because GE seeds provide improved pest control, yield stability, and labor savings. Gene-editing technologies can enable faster and lower-cost development, and a wider variety of crop traits, than earlier genetic engineering methods. These traits may be especially well-suited for specialty crops, potentially bringing innovations to market with less time and expense than is required for traditional GE traits. Key challenges, like weed resistance to herbicides and insect resistance to pesticides, continue to spur innovations in new GE traits. A review of the literature suggests gene editing could reduce development costs by roughly 40–85 percent and decrease the time to commercialization by 25–38 percent as the technology adapts to a wider range of species and traits. The regulatory environment also plays a role: new products spent less time in regulatory review under revised USDA regulations for GE crops that were in effect from August 2020–December 2024.

Keywords: genetically engineered crops, agricultural biotechnology, seed industry, research and development, adoption

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A report summary from the Economic Research Service

Biotechnology in U.S. Crop Production: A Primer on Adoption, Costs, and Regulatory Structure

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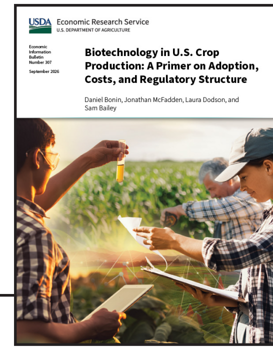

Key Points

- Genetically engineered (GE) crops have become a cornerstone of U.S. agriculture, with USDA data showing adoption rates exceeding 90 percent of planted acres for corn, cotton, and soybeans since 2013, as well as industry estimates showing similarly high adoption for sugarbeets and canola since 2018.
    - Herbicide tolerance (HT), insect resistance (IR), and, more recently, drought tolerance (DT), have simplified pest management, reduced crop losses, and supported conservation practices.
    - Farmers pay higher prices for GE seeds compared to conventional varieties, but these premiums reflect benefits such as improved pest control, yield stability, and labor savings. Per-acre cost differences are smaller than per-bag differences because GE traits can enable more efficient planting and management.
- Newer genetic engineering methods have the potential for faster and less costly development of GE traits compared to earlier methods, while also changing the kinds of traits being developed.
    - The economic literature suggests gene editing could reduce development costs by at least 40 percent and shorten commercialization timelines by 25 percent or more.
    - These advantages are particularly relevant for specialty crops, which face high pest and disease pressures but have smaller markets that could make traditional GE development less economically viable.
    - Additional traits aimed at product quality have been developed, including some consumer-oriented traits for apples, tomatoes, and potatoes.
- Regulatory changes like the Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient (SECURE) rule have allowed USDA, Animal and Plant Health Inspection Service to increase the speed of trait commercialization, decreasing approval times by two-thirds and doubling the number of approvals.

Why Does This Matter?

Biotechnology has reshaped U.S. crop production over the past three decades, bringing substantial benefits to trait developers and farmers, especially to those producing three major GE field crops (corn, cotton, and soybeans), as well as sugarbeets and canola. These benefits come at significant cost to trait developers, who invest millions of dollars over multiple years to commercialize a new GE trait. The GE regulatory structure helps shape these outcomes, as do newer GE technologies like gene editing, which offer a pathway to lower costs, faster development timelines, and could help expand innovation to other crops and traits. A better understanding of these dynamics is crucial for policymakers, farmers, industry stakeholders, and researchers seeking to foster a system that supports efficient technological advancement. As global food systems face mounting pressures from many sources, the ability to develop and deploy beneficial GE traits will be important for sustaining U.S. agricultural productivity and competitiveness. In particular, weed resistance to widely used herbicides (e.g., glyphosate) and insect resistance to insecticidal proteins (e.g., *Bacillus thuringiensis* (Bt)) continue to erode the effectiveness of existing GE traits, spurring demand for new solutions. Other stressors (e.g., drought, viruses, fungi) underscore the need for traits that improve resilience without sacrificing yield potential. Farmers' options for planting crops with new GE traits may be limited by development costs, consumer acceptance, and the timing of multi-market regulatory approvals for internationally traded GE crops.

A Few More Details

This report relies on data from three USDA agencies, the Economic Research Service (ERS), the National Agricultural Statistics Service (NASS), and the Animal and Plant Health Inspection Service (APHIS), and summarizes and consolidates information from economic literature and agency regulations. Information about average GE seed prices and herbicide-resistant weed management practices is drawn from the field-level version of the Agricultural Resource Management Survey (ARMS), which is produced jointly by USDA, ERS and USDA, NASS. Specifically, we use ARMS data for corn production in 2016 and 2021, cotton in 2019, and soybeans in 2023. Adoption rates of GE seeds for years 2000–25 come from the USDA, ERS Adoption of Biotechnology data product, which draws on the USDA, NASS June Agricultural Survey. We analyze public USDA, APHIS GE product review records to examine differences in confirmation and approval patterns under primarily two different regulatory structures (SECURE versus pre- and post-SECURE). The USDA, APHIS data are also used to create a visualization of how the two regulatory structures differ, including the timing and duration of various stages throughout the regulatory processes.

Biotechnology in U.S. Crop Production: A Primer on Adoption, Costs, and Regulatory Structure

Introduction

Biotechnology—particularly genetically engineered (GE) crops—has dramatically transformed U.S. agriculture over the past three decades.[1] Farmers began adopting GE corn, soybeans, and cotton in 1996, and GE versions of these three crops now account for the vast majority of their acreage. More broadly, the United States has been a global leader during this time in the scientific development of GE traits, acres planted to GE crops, production of GE commodities, innovation in GE regulatory systems, and liberalization of trade rules to promote international trade in GE commodities (MacDonald et al., 2023; National Academies of Sciences, Engineering, and Medicine (NASEM), 2016; Qaim, 2009).

In field crops, the primary traits have been herbicide tolerance (HT) and insect resistance (IR), which have helped simplify weed and pest management, reduce crop losses, and facilitate practices like conservation tillage (NASEM, 2016). The rapid adoption of GE technology reflects its significant on-farm benefits, including higher effective yields and more flexible management of field operations. The biotechnology toolbox has continued to expand, with transgenic methods now complemented by gene editing techniques such as CRISPR,[2] which can precisely modify a plant's own genes (see box, "Modern Biotechnology").[3] Newer approaches promise to introduce beneficial traits more rapidly and at lower cost, potentially broadening the range of crops—especially fruits and vegetables—and traits improved through biotechnology.

This report provides a brief economic overview of the role of GE crops, both transgenic and gene-edited, in U.S. agriculture, with a focus on adoption trends, economic costs, and the regulatory structures governing these biotechnologies (biotech). We begin by documenting the extent of GE adoption in major U.S. field crops and the associated cost implications—for instance, higher seed prices due to technology premiums. Next, we compare the development pipelines for transgenic versus gene-edited traits and present costs of GE trait development from economic literature. Further, we also explore challenges faced by farmers and associated opportunities for new GE traits, from managing insect and weed resistance to developing stress-tolerant and specialty crop varieties. The report briefly notes data limitations and knowledge gaps; overcoming such limitations and filling these

[1] USDA's *Agricultural Biotechnology Glossary* defines biotechnology to be "A range of tools, including traditional breeding techniques, that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses." Genetic engineering is defined as "Manipulation of an organism's genes by introducing, eliminating, or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques" (USDA, n.d.). However, for the purposes of this report, biotechnology and genetic engineering are used interchangeably. The glossary terms are included for general purposes and may not represent specific definitions that apply to any law or regulation of any Government agency.

[2] CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) is one of three primary gene editing techniques that have been used in trait development for crops in the United States and elsewhere.

[3] Transgenic methods refer to genetic engineering that produces transgenic organisms. A transgenic organism results from the insertion of genetic material from another organism using recombinant DNA techniques, which are procedures that are used to join DNA segments in a cell-free environment (e.g., in a test tube outside living cells or organisms). See USDA's Agricultural Biotechnology Glossary (USDA, n.d.) for additional details.

gaps could improve decision making within the current regulatory structure and better inform other processes that will shape the trajectory of biotech innovation in U.S. agriculture. Throughout this report, most emphasis is on U.S. field crop production and the economic and institutional factors that influence biotech adoption and impacts.

Broadly, GE crops have generated benefits and costs to both producers and consumers over the past three decades. These benefits and costs have been widely studied by economists during this period. At the same time, benefits and costs of regulatory approaches pertaining to GE crops have not been studied nearly to the same extent (NASEM, 2016) for several reasons, including some we mention later in this report. In shaping the rules and incentives to innovate and develop, regulatory structures partly determine the availability of GE products, and thus the extent of benefits and costs in the broader agricultural economy due to these technologies. A comprehensive enumeration of these benefits and costs, in addition to an economic analysis of how regulatory structures impact product innovation, are beyond the goals of this report: providing decision-makers with a succinct overview of (1) the current status of GE crop adoption in the United States, (2) GE seed prices (costs) and a presentation and discussion of results from other studies that quantify trait development costs, and (3) select challenges faced by farmers that present opportunities for GE trait innovation. Information on the broader economics of how regulatory systems can impact innovation can be found in the appendix.

Modern Plant Biotechnology

Desired genetic modifications in a plant can be introduced via genetic engineering techniques (including gene editing) and conventional breeding methods which are still widely used in crop improvement. Tools from molecular biology, such as genotyping by sequencing and molecular mapping, are used for faster and more precise selection of desirable traits leading to shorter times for crop development. Some traits, such as improved yield, require the simultaneous combination of many genes and these traits have typically been most successfully improved through conventional breeding. Many crops grown in the United States, specifically wheat[1] and rice, are only the product of conventional breeding (Wu et al., 2021).

Conventional genetic engineering uses techniques to randomly insert DNA into the recipient organism. If the DNA is derived from an organism that is not sexually compatible with the recipient, the introduced DNA is known as a transgene. If the DNA is from a sexually compatible species, it is known as a cisgene. While many early GE crops contain transgenes, such as Bt corn and cotton, Simplot's Innate™ potatoes were engineered with cisgenes derived from other potatoes (NASEM, 2016). Examples of conventional genetically engineered (GE) crops include herbicide tolerant (HT) corn, cotton, and soybeans.

Gene editing (also called genome editing) uses techniques such as transcription activator-like effector nucleases (TALENs) and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) to introduce, eliminate, or rearrange DNA at a precise location (Ye et al., 2022). The reagent reads a specific genetic sequence and then makes an edit at that sequence—and only that sequence—in the target organism's genome. The edit may be the insertion of new genetic material, but it may also be a simple

[1] In August 2024, a variety of wheat genetically engineered to be drought tolerant was approved for production in the United States by regulators, but as of September 2025 it is not yet commercialized (Polansek & Ingwersen, 2024).

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deletion or mutation to disable the targeted gene (Matres et al., 2021). Gene-edited drought tolerant corn is an example of the former and soybeans with a more shelf-stable oil are an example of the latter.[2]

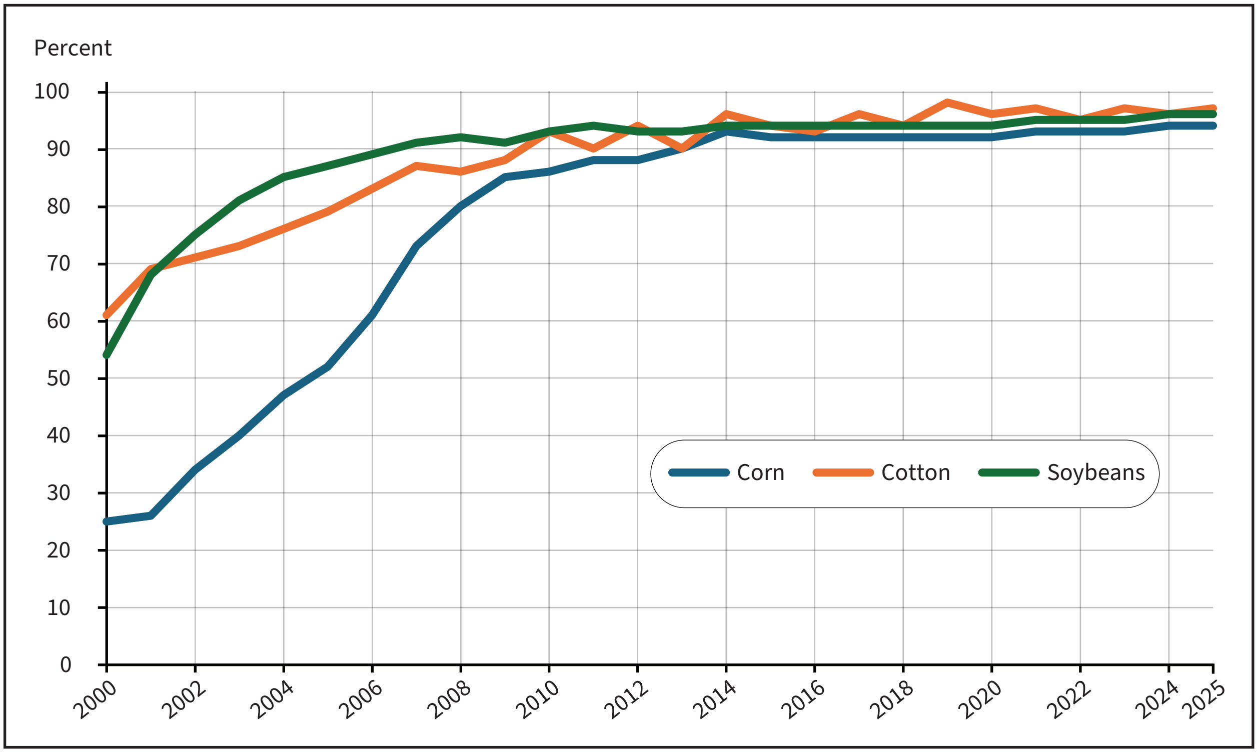
[2] For gene-edited drought tolerant corn, researchers used a gene that is already present in corn and copied it to a different part of the genome where it increased proteins produced by nearby genes (Shi et al., 2017). The desired change required the gene to be in a specific spot in the genome, so conventional breeding and conventional genetic engineering would be insufficient, despite the genes involved being native to corn. Regarding soybeans with more shelf-stable oil, the FAD2KO soybean was brought about by deleting nucleotides in two genes and sold under the brand name Calyno in 2019 and 2020 (Gilyard, 2023).

GE Field Crop Adoption in the United States

Since 2013, USDA has reported that more than 90 percent of planted corn, upland cotton, and soybean acres have included GE technology (figure 1). External data sources report that by 2018, roughly 100 percent of sugarbeet and canola acres planted in the United States were genetically engineered (International Service for the Acquisition of Agri-biotech Applications, 2018). Nearly all GE acres for field crops include input-focused traits, such as herbicide tolerance (HT), insect resistance (IR), or in the case of corn, drought tolerance (DT). In recent years, most commercially available seeds contain multiple GE traits (i.e., combinations of different HT and IR traits).

GE HT technology has provided farmers with a method of weed control that allows crops to survive applications of an herbicide while nearby weeds are killed. One of the first available HT traits for corn, cotton, and soybeans was tolerance to herbicides containing glyphosate. As glyphosate tolerant seeds were widely adopted in the 2000s, this reliance on a single mode of action (i.e., specific chemical method of weedkilling) increased resistant weed populations—weeds that survive glyphosate applications—and created new challenges for crop production (Livingston et al., 2015). As glyphosate resistant weeds have become more common, growers have needed alternative herbicide and trait technologies, such as glufosinate tolerant corn, cotton, and soybeans, which have been available since 2009. More recently, HT traits have expanded to include tolerance to 2,4-D choline, dicamba, and isoxaflutole, which help growers overcome glyphosate resistant weed populations and weeds resistant to herbicides with other modes of action.

Figure 1
U.S. adoption of genetically engineered corn, cotton, and soybeans, 2000–25



Note: Each crop-specific line represents adoption of any herbicide tolerant (HT) or insect resistant (IR) trait, which includes crop varieties with combined HT and IR traits. The IR data in this graph only includes traits that are derived from *Bacillus thuringiensis* (Bt).

Source: USDA, Economic Research Service Adoption of Biotechnology data product, using data from the USDA, National Agricultural Statistics Service June Agricultural Survey (2000–25).

Genetically engineered IR corn and cotton typically contain genes from the soil bacterium Bt (*Bacillus thuringiensis*) to produce insecticidal proteins, such as *Cry* or *Vip* proteins, to kill targeted insect pests (table 1).[4] This subset of IR crops is often referred to as "Bt crops." Early Bt crop varieties produced a single Bt toxin for distinct lepidopteran pests, such as the European corn borer. However, the development of pest resistance to Bt toxins prompted the development of Bt crops that produce more than one toxin (Carrière et al., 2015). These "pyramided" Bt crops were introduced to thwart resistance by producing two or more distinct Bt toxins that kill the same pest. Bt crop pyramids for corn that protect against coleopteran pests, such as the corn rootworm, have also been introduced.[5] More recently, GE corn has included IR traits beyond Bt technology, such as RNA interference, which allows for an alternative method of insect control that does not have the existing resistance issues to Bt (table 1).

Environmental stressors, like drought, also create significant risks for U.S. farmers and can significantly impact yields and profits. For decades, conventional methods of plant breeding have introduced corn plants that are increasingly resistant to drought stress. GE drought tolerant (DT) seeds first became commercially available on a limited basis in 2012.

[4] The insecticidal activity of Bt is due to the presence of insecticidal crystal proteins (*Cry*) and/or vegetative insecticidal proteins (*Vip*), which damage a susceptible insect's digestive system when ingested. The *Cry* and *Vip* proteins have similar but distinct modes of action, and cross resistance between the two proteins is expected to evolve quite slowly (Van Rie & Jansens, 2019).

[5] Lepidopterans are an order of winged insects that includes moths and butterflies. Coleopterans are an order of beetles that includes boll weevils, ladybugs, and fireflies. Collectively, Lepidoptera and Coleoptera are the two largest orders of insects.

Adoption of DT corn has been rapid: By 2021 more than 26 percent of U.S. corn acreage, as surveyed in the Agricultural Resource Management Survey (ARMS), was planted with a DT trait (USDA, ERS, 2021). Genetically engineered DT corn generally contains other GE traits (e.g., herbicide tolerance or insect resistance).

Table 1
First U.S. commercial sales of genetically engineered (GE) input-linked traits for corn, cotton, soybeans, canola, sugarbeets, and alfalfa[1]

Crop	Type	Genetically engineered trait	First sales	Trade name of first sale
Corn	HT	Glufosinate tolerance	1996	LibertyLink®
	IR	Single *Cry* protein *Lepidoptera*	1997	YieldGard® Corn Borer
	HT	Glyphosate tolerance	1998	Roundup Ready®
	IR	Single *Cry* protein *Coleoptera*	2003	YieldGard® Rootworm
	IR	Pyramided *Cry* proteins *Coleoptera*	2005	Herculex® Rootworm
	IR	Pyramided *Cry* proteins *Lepidoptera*	2009	Genuity® VT Triple Pro
	IR	*Vip* protein *Lepidoptera*	2010	Agrisure Viptera 3110
	DT	Drought tolerance	2013	DroughtGard®
	HT	2,4-D choline tolerance	2018	Enlist®
	IR	RNAi resistance to rootworm	2024	VT4PRO® w/RNAi Technology
Cotton	HT	Glyphosate tolerance	1996	Roundup Ready®
	IR	Single *Cry* protein *Lepidoptera*	1996	Bollgard®
	IR	Pyramided proteins *Lepidoptera*	2003	Genuity® Bollgard II®
	HT	Glufosinate tolerance	2004	LibertyLink®
	IR	*Vip* protein *Lepidoptera*	2015	Widestrike® 3
	HT	Dicamba tolerance	2015	Bollgard II® XtendFlex®
	HT	2,4-D choline tolerance	2016	Enlist®
	IR	Modified *Cry* protein *Hemiptera*	2023	ThryvOn®
	HT	Isoxaflutole (HPPD) tolerance	2024	Avant™ Flex
Soybeans	HT	Glyphosate tolerance	1996	Roundup Ready®
	HT	Glufosinate tolerance	2009	LibertyLink®
	HT	Dicamba tolerance	2016	Roundup Ready 2 Xtend®
	HT	Isoxaflutole (HPPD) tolerance	2019	Balance™ GT
	HT	2,4-D choline tolerance	2019	Enlist E3®
Canola	HT	Glufosinate tolerance	1998	LibertyLink®
	HT	Glyphosate tolerance	1999	Roundup Ready®
Sugarbeets	HT	Glyphosate tolerance	2007	Roundup Ready®
Alfalfa	HT	Glyphosate tolerance	2005	Roundup Ready®

HT = herbicide tolerance, IR = insect resistance, DT = drought tolerance.

[1] Several companies have been researching genetically engineered traits for other genetically complex crops (e.g., wheat, rice) and for other trait-crop combinations (e.g., Bt soybeans), though these are not currently commercialized. A host of factors underlies commercialization of such crops, including consumer acceptance, insect exposure, and the role of potential resistance pressure on gene pools. We leave these topics for future work.

Note: The emphasis of this table is primarily GE traits that are linked to inputs such as pesticides, though there are several other notable non-input-related traits (e.g., high oleic soybeans) that were excluded from this table. Also excluded are traits that were commercialized and then either removed or are no longer produced (e.g., bromoxynil resistant cotton).

Source: USDA, Economic Research Service using information from Babcock et al. (1999), DiFonzo & Porter (2025), Duke (2014), Fernandez-Cornejo et al. (2016), Graham (2023), Heckel (2023), McFadden et al. (2019), Nandula (2019), Wechsler (2018), and Van Rie & Jansens (2019).

Genetically engineered seeds have provided profound economic benefits to farmers. Beyond their direct effects, such as herbicide tolerance or insect resistance, GE seed traits are also valuable because they allow farmers to alter other management practices like reducing chemical inputs and labor requirements. For example, past work has demonstrated that IR corn and cotton have often been more profitable than conventional seeds, HT crop adoption has increased off-farm household income and improved time flexibility, average insecticide use has declined with the adoption of IR seeds, and HT crops have facilitated the uptake of less environmentally toxic chemicals (i.e., glyphosate) in place of more toxic herbicides, in addition to uptake of conservation tillage, which comes with its own substantial soil health benefits (Fernandez-Cornejo et al., 2005, 2014; Marra & Piggott, 2006; NASEM, 2016; Perry et al., 2016; Bowman et al., 2025). In many instances, GE crops have increased U.S. crop yields (Xu et al., 2013; Lusk et al., 2019), and some IR crops have been shown to reduce aflatoxin risk to nearby crops (Yu et al., 2024).[6] In a more aggregate context, Ciliberto et al. (2019) found the total surplus to GE traits in the United States during 2007–11 to be between $3.7 billion and $5.2 billion. When considered in a global context, similar benefits from GE crops emerge, particularly expanded farm revenues and higher yields (Scheitrum et al., 2020; Ala-Kokko et al., 2021; Hansen & Wingender, 2023).

However, benefits conferred from GE traits come at higher costs to farmers in the form of relatively high prices. Table 2 provides the average price of a bag of seed with the specified GE trait, as reported in the ARMS data (USDA, ERS, 2019, 2021, 2023). Since most modern GE seed contains multiple traits, these averages do not represent the markup for the specific trait listed.

Table 2

Price paid by U.S. farmers for seed with particular genetically engineered traits (2019, 2021, 2023)

	Price of seed (U.S. dollars)											
		Herbicide tolerance (HT)					Insect resistance (IR)					Other
Crop	**Non-GE**	**GLY**	**GLU**	**DIC**	**24D**	**ISO**	**Any**	**CB**	**RW**	**EW**	**AW**	**DT**
Corn per bag	198	253	262		255			255	259	259	254	268
per acre	76	99	100		96			99	101	100	100	100
Cotton per bag	174	514	533	538	542		528					
per acre	48	86	91	87	103		87					
Soybeans per bag	57	61	61	59	61	59						
per acre	67	69	67	65	70	54						

GLY = Glyphosate; GLU = Glufosinate; DIC = Dicamba; 24D = 2,4-D, Choline; ISO = Isoxaflutole; CB = Corn Borer; RW = Corn Rootworm; EW = Corn Earworm; AW = Fall Armyworm; DT = Drought Tolerance.

Note: Blank cells indicate that either the particular crop did not exhibit the specific trait in that year or that ARMS did not collect information that would lead to a reliable price estimate. One bag of corn seed has about 80,000 kernels, while bags of cotton and soybean seeds are about 50 pounds.

Source: USDA, Economic Research Service and USDA, National Agricultural Statistics Service, Agricultural Resource Management Survey (ARMS), years 2019 (cotton), 2021 (corn), and 2023 (soybeans).

[6] The economics literature contains mixed findings on the extent to which GE crops have brought about higher average yields than non-GE crops in the United States, in part because nearly all commercialized GE traits have not been expressly designed to maximize potential yield. Yield advantages for GE corn (Xu et al., 2013; Lusk et al., 2019) and GE cotton (Cattaneo et al., 2006; Hansen & Wingender, 2023) in the United States are a generally robust finding, while GE soybeans may not exhibit higher average yields relative to conventional varieties (Xu et al., 2013; Hutchins & Irwin, 2026). A distinct but related literature thread examines the effects of GE traits on yield variability and yield risk, with findings that are also mixed (Lusk et al., 2019; Goodwin & Piggott, 2020; Aglasan et al., 2023; Shi et al., 2013).

Seed with particular GE traits almost universally cost more than non-GE seed, the only exception being HT soybeans that tolerate isoxaflutole. Per-bag GE soybean prices are within 10 percent of non-GE soybean prices, with the per-acre costs being essentially the same (excepting isoxaflutole). Similarly, GE cotton seeds cost more than three times as much as non-GE cotton seeds per bag, but that difference is reduced to about double the cost per acre. GE corn seeds cost about 30 percent more than non-GE corn seeds, with drought-tolerant varieties having the highest average cost. While per-bag prices are higher for GE seed, the seed traits allow farmers alternative management practices which mitigate the higher price of GE seeds on a per-acre basis. For example, HT soybeans can be placed further apart, reducing the amount of seed needed. The consistently higher prices for seeds with GE traits indicate that farmers are willing to pay more for GE traits and suggest that trait developers are recouping at least part of their GE research and development (R&D) investment in the form of higher seed prices.[7]

An Overview of U.S. Regulatory Oversight of GE Crops

The United States has regulated genetically engineered crops under the Coordinated Framework for the Regulation of Biotechnology (CF) since 1986. The CF facilitated the introduction of biotechnology products by distributing regulatory responsibilities between the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA), each operating under its own preexisting statutory authorities, which are not specific to biotechnology. To address emerging issues and be responsive to new scientific, market, and other conditions (and as a result of gained experience), the CF has evolved over time through modifications from administrative and legislative actions. For example, regulatory amendments for USDA, Animal and Plant Health Inspection Service (APHIS) occurred in 1988, 1990, 1993, 1994, 1997, and 2005 (Hoffman, 2021). A 1992 update to the CF laid out three fundamental principles of scope, provided a rationale for the risk-based regulatory approach established in 1986, and clarified implementation options, among other things. In this same year, FDA released its Statement of Policy: Foods Derived from New Plant Varieties, which clarified FDA's interpretation of the Federal Food, Drug, and Cosmetic Act with respect to biotech foods. In 1994, EPA proposed a set of regulations to help establish its scope for plant pesticides (Office of Science and Technology Policy (OSTP), 1992; FDA, 1992; EPA, 1994).

Other modifications to the CF have occurred since this time, and each agency continues to maintain its own regulations, rules, guidance, and policies in line with its statutory authority. Table 3 lists examples of GE crops with traits for which one or more agencies play a role. This table makes clear that the agencies hold distinct but overlapping regulatory roles (Shams et al., 2024). However, a key feature of the system is that each agency abides by a set of principles in their regulation of GE crops (see box, "Principles for the Regulation of Biotech Products").

[7] At least two complicating factors arise when attempting to link GE R&D portfolios to seed price increases. First, increased market power among trait developers (afforded by patents and Plant Variety Protection Certifications (PVPCs) and, later, mergers in this industry) has allowed seed companies to expand their crop R&D, commercialize new varieties, and charge higher prices (MacDonald et al., 2023). Brand and technology switching costs borne by farmers also play a role in increased prices for GE seeds (Luo et al., 2023). Second, trait developers receive royalties from seed companies that are licensed to use the trait, which provides developers with greater leeway on seed pricing strategies. Several traits are licensed separately from seed and incorporated into multiple varieties and crops, and it is not uncommon for a single variety to have multiple GE traits licensed from multiple companies. Anticompetitive licensing practices have been alleged in recent years, which might play a further role in driving up seed prices, but scant publicly available information is available since licensing contracts are private, as are the details of relevant litigation settled out of court (Moschini, 2010; MacDonald et al., 2023).

Table 3

Examples of modified organisms subject to regulations under the Coordinated Framework, by Federal agency

	Insect resistant food plant	Herbicide tolerant food plant	Fungal resistant plant not for human food	Altered appearance of o rnamental non-food plant
Example	**Rootworm-resistant corn**	**Glyphosate-tolerant soybean**	**Aphanomyces root rot-resistant alfalfa**	**Blue petunia**
EPA	Yes	No	Yes	No
FDA	Yes	Yes	Yes*	No
USDA	Yes	Yes	Yes	Yes

EPA = U.S. Environmental Protection Agency, FDA = U.S. Food and Drug Administration, USDA = U.S. Department of Agriculture.

Note: A "Yes" in a cell indicates the agency has regulatory oversight. EPA determines the safety of complementary herbicides (e.g., glyphosate) but not the plant itself (e.g., glyphosate-tolerant soybeans) for crops that do not have plant incorporated protectants (PIPs). Although corn and soybeans are largely feed crops, the CF makes a distinction between food for humans and food for animals where appropriate. In this example, corn and soybeans can be considered field crops used for food for animals and/or humans.

* FDA regulates fungal resistant plants not for human food if the product goes into animal food.

Source: USDA, Economic Research Service using information from *The Coordinated Framework for the Regulation of Biotechnology: Plain Language Information on the Biotechnology Regulatory System*, by USDA, EPA, and FDA, 2023.

Principles for the Regulation of Biotech Products

In 2023, the U.S. Department of Agriculture, U.S. Environmental Protection Agency, and U.S. Food and Drug Administration provided a joint, plain language summary of the system that is designed to be accessible to the public and to new entrants to the regulatory system. This document notes that the U.S. biotechnology regulatory system should be based on science, proportionate to the risks posed, and based on the product (not the process used to develop the product). Existing laws provide necessary authorities for agencies to regulate biotechnology and agencies have separate responsibilities. Agencies coordinate as needed, and the regulatory status of a product with one agency does not affect the regulatory status of that product with other agencies. Meeting with regulatory agencies early in product development can help developers determine the process or processes that are most relevant for a product (USDA, EPA, and FDA, 2023).

These ideas expanded upon and clarified a set of principles in the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology (CF), which we reproduce below as a bulleted list. These principles are designed to provide guidance for the three regulatory agencies.

- Federal statutes and regulations regulate products based on specific uses. This approach means that products with the same use are subject to the same types of oversight by the relevant regulatory agencies.
- Biotechnology products have applications in many areas, such as medicine, agriculture, energy, manufacturing, and environmental protection.
- The intended introduction of biotechnology products into the environment can be subject to Federal oversight under Federal statute(s) related to such products and their intended application.
- Each agency uses its existing statutory authorities and regulations to ensure the safety of the biotechnology products for their intended applications.
- Underlying statutes define the boundaries of the scope of oversight afforded to each regulatory agency.

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- It is the characteristics of the biotechnology product, the environment into which it will be introduced, and the application of the product that determine its risk (or lack thereof).
- Exercise of agency oversight within the scope afforded by statutes should be commensurate with the risk posed by the introduction of the biotechnology product and should not turn on the fact that it was created or has been altered by a particular process or technique.
- To the extent permitted under relevant statutory provisions, following a risk-based approach to regulation, the regulatory system should distinguish between those biotechnology products that require a certain level of Federal oversight and those that do not.
- Because the overarching U.S. regulatory framework for biotechnology products relies on several different existing Federal laws, statutory nomenclature for certain actions may seem inconsistent; notwithstanding those seeming inconsistencies, the reviews conducted by each of the regulatory agencies are intended to be of comparable rigor to the extent allowed by law.
- The agencies endeavor to operate their programs in an integrated and coordinated fashion; together, they should cover the full range of plants, animals, and microorganisms derived from biotechnology.
- Future scientific developments will lead to further refinements of the CF. Experience with earlier basic scientific research has shown that as science progresses, regulatory regimens can be modified to reflect a more complete understanding of the potential risks involved. Refinements to the CF should consider any such updates to regulatory processes (Office of Science and Technology Policy, n.d.).

Although each agency has updated its policies since this time, no other joint document has been developed by the agencies that updates these principles.

The Coordinated Framework for the Regulation of Biotechnology (CF)

Under the CF, each agency has a distinct role in the regulatory system. EPA registers all crops with "plant-incorporated protectants" (PIPs), such as Bt and RNAi crops, which confer insect resistance (EPA, 2024). PIPs are pesticides concentrated in plant tissues, and the EPA has regulatory authority regarding pesticide registrations. However, the EPA does not regulate the plants themselves.[8]

The FDA regulates GE crops used for human and/or animal food for food safety under the Federal Food, Drug, and Cosmetic Act (FDA, 2024c). Since 1994, the FDA has encouraged developers to engage in voluntary premarket consultations with the agency to help firms ensure their product meets relevant safety requirements. Developers routinely take part in voluntary premarket consultations prior to marketing. These consultations help to resolve issues such as potential allergenicity and toxicity of any newly introduced proteins in food from the plant, whether any newly introduced substance in

[8] The herbicides must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Seeds resistant to specific herbicides may be sold even if it is illegal for farmers to apply those herbicides post planting. Such an incident occurred in 2016. USDA, APHIS deregulated dicamba-tolerant cotton and dicamba-tolerant soybeans in January 2015. At the end of 2015 and beginning of 2016, Monsanto sold these seeds in anticipation of the EPA registering dicamba for post-emergent, over-the-top soybean and cotton use in the 2016 growing season. However, the EPA did not permit such use until late 2016, meaning there was a full year when farmers could plant the dicamba-tolerant seed but could not take advantage of that trait (Gullickson, 2020).

food from the plant requires premarket approval as a food additive, and whether certain toxicants and nutrients or anti-nutrients have been changed in a way that is relevant to food safety or nutrition.[9]

The Plant Protection Act of 2000 gives USDA the authority to regulate movement and dissemination of organisms that could be considered “plant pests or noxious weeds.” Except for a period from August 2020 to 2024 (discussed in more detail in the section, “The Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient (SECURE) Rule”) USDA, APHIS regulates a genetically engineered organism if the organism itself, a donor organism (source of inserted genes), or a vector species used to introduce genetic material into the recipient organism is on a list of plant pests and plant pest DNA remains in the modified organism (USDA, APHIS, 1987).[10] A common method for inserting genetic material uses a bacterium called *Agrobacterium*, which is on the list of plant pests, so any crop created with this technique is automatically placed under review if plant pest sequences remain in the final product. Developers request permits or notifications to conduct field tests that are closely monitored by USDA, APHIS inspectors. To come out of USDA, APHIS regulation, applicants can submit a petition to deregulate the plant, which allows it to be grown without USDA, APHIS authorization.

Many GE crops grown in the United States fall under the jurisdiction of USDA, APHIS, so this pipeline from permit (for movement and field tests) to deregulation to market is one that many developers undertake. That is, it is often the case that GE crops are first field tested under USDA, APHIS authorization, though only a small subset are then petitioned for non-regulated status, and an even smaller subset will ultimately be commercialized. However, some of the steps in that pipeline are not strictly required by statute but are typically customary (figure 2).

This pipeline is changing with newer technologies (e.g., gene editing). For example, the current non-regulatory and voluntary Am I Regulated? (AIR) process enables developers to obtain confirmation that their organism does not meet the definition of a regulated article. For gene-edited organisms, the AIR process confirms that such organisms which are not plant pests and do not contain plant pest sequences are not regulated. As a result, most gene-edited organisms are not regulated.

Since December 2024, permits and notifications have taken 11–36 days for USDA, APHIS to process (USDA, APHIS, 2026a). Petitions for deregulation prior to the Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient (SECURE) rule tend to take longer: The median time from when the petition was first submitted to when USDA, APHIS declared the article nonregulated is 526 days or a little over 17 months.[11] Since 2011, developers have also had the (voluntary) opportunity to send a letter of inquiry to USDA, APHIS to check whether their article falls under its regulations (e.g., the AIR process). Across the entire time period (2011–20 and since 2025), the median time between when the developer sent the letter and when USDA, APHIS responded is 79 days (2.6 months) (USDA, APHIS, 2026b). Figure 2 (upper panel) shows the steps a developer would go through with APHIS from field testing to deregulation.

[9] FDA ensures that GE foods or foods having GE ingredients meet the same safety standards as all other foods—standards that are set and enforced regardless of how the foods are created (FDA, 2024b). The safety standard for food additives and generally recognized as safe (GRAS) substances is considered a reasonable certainty that the substance is not harmful under the conditions of its intended use (OSTP, n.d.).

[10] In accordance with the National Bioengineered Food Disclosure Law (in effect since 2023), the Agricultural Marketing Service (AMS) maintains a list of bioengineered foods. Note that a bioengineered food disclosure is a marketing label, and does not convey any information about the health, safety, or environmental attributes of bioengineered food as compared to non-bioengineered counterparts. This regulation requires that products indicate the presence of genetically engineered ingredients but puts no restrictions on cultivation or sales (USDA, AMS, n.d.). For these reasons, we will not address these regulations in detail in this report.

[11] A regulated article is an organism or product that has been altered or produced using genetic engineering (1) that has one or more of its components derived from a plant pest or an unclassified or unknown organism; or (2) that USDA, APHIS “determines is a plant pest or has reason to believe is a plant pest” (USDA, APHIS, 2020).

The Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient (SECURE) Rule

After the CF was implemented, several revisions took place, notably those in 1992 which introduced the petition process, though the rules remained largely the same for more than 30 years. A 2017 CF update was designed to further clarify the roles and particular focus areas of the three regulatory agencies, and a subsequent executive order called for regulatory streamlining such that GE products would be regulated in a more risk-proportionate way (Shams et al., 2024; Hoffman, 2021). In May 2020, USDA, APHIS issued a revised rule (the Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient (SECURE) Rule), with phased implementation between August 2020 and April 2021.[12] In December 2024, a district court vacated (i.e., overturned) USDA, APHIS's 2020 rule. We will refer to that period (August 2020–December 2024) as the "SECURE era." Modified organisms that had been determined not subject to regulation during the SECURE era were allowed to remain nonregulated post-vacatur, but the agency has since implemented regulations similar to those in place prior to the SECURE era.[13] For simplicity, we call the regulations in place prior to August 2020 (and after December 2024, where relevant) the "legacy regulation," even though there are some differences.

The USDA, APHIS revisions in the SECURE Rule were made to "change the basis for (USDA) APHIS regulatory review from one in which GE plants are regulated based on the use of plant pests in their development, to one in which (USDA) APHIS reviews the GE plants themselves for plant pest risks" (USDA, APHIS, 2020). Under this rule, a plant was exempt from regulation if it could have, in principle, been produced through conventional breeding methods, or if the plant-trait-mechanism of action combination (PTMOA) has already been determined not subject to regulation by a previous ruling (USDA, APHIS, 2024b). A new plant variety was considered to be achievable through conventional breeding if it satisfied one of the following: (1) the modification is the result of disabling a gene, (2) the modification is the result of a single base pair substitution, or (3) the modification is the result of introducing a gene that already exists in the plant's gene pool.[14] If a plant did not meet one of the exemptions listed above, the developer had to apply for a permit for field tests or could ask for a regulatory status review (RSR). The RSR differed fundamentally from the petition process in that the regulatory trigger was no longer based on the use of a plant pest in the engineering, and the process employed a problem formulation approach to identify whether a plausible pathway to increased plant pest risk exists for the engineered plant, which also helped to make the regulatory process more accessible to small and mid-sized enterprises. If USDA, APHIS determined that no plausible pathway existed, the plant was not subject to regulation; otherwise, the developer could request that USDA, APHIS undertake a plant pest risk assessment to evaluate whether the plant was unlikely to pose an increased plant pest risk. Figure 2 (lower panel) shows the steps a developer would take under the SECURE Rule.

In May 2023, the EPA released a new rule on how it would regulate plant-incorporated protectants. It exempted from registration genetically engineered crops whose pesticidal properties were either (1) solely the result of gene insertion from another sexually compatible plant or (2) solely the result of "loss-of-function," which refers to an existing gene getting knocked out but with no inserted gene or alteration of other genes (Pesticides, 2023). This new rule thus largely followed the framework issued by USDA, APHIS.

[12] In accordance with their oversight roles under the CF, EPA issued a new regulation in 2023 and FDA issued new guidance in 2024.

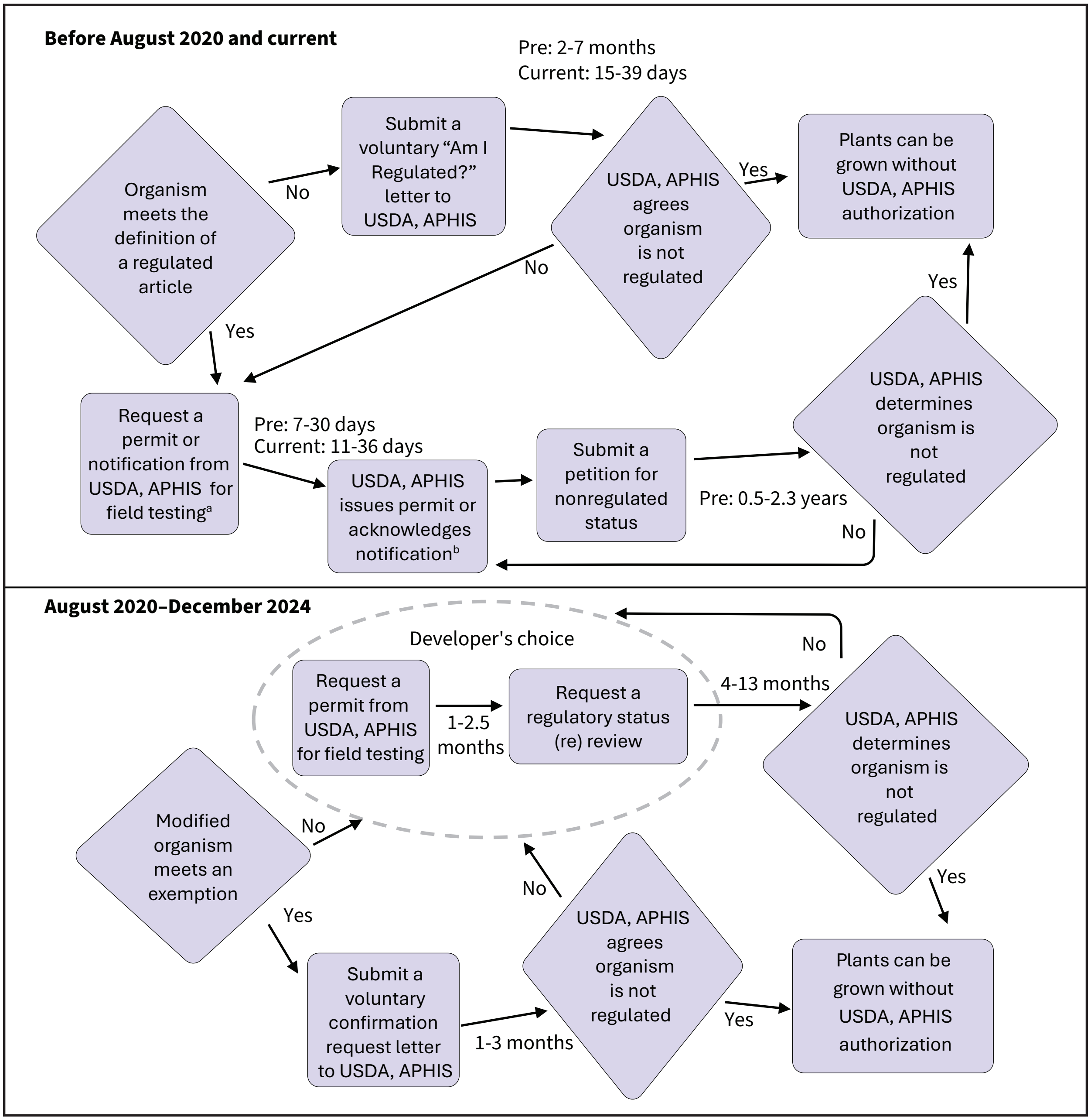
[13] While the two regulatory structures are similar, there are some differences. Compare USDA, APHIS (2020) and USDA, APHIS (2025b) for more information.

[14] In November 2024, USDA, APHIS updated and clarified the types of modifications that can be made to plants that qualify for exemption to include plants containing multiple edits (USDA, APHIS, 2024a).

In February 2024, FDA issued guidance describing how firms can voluntarily engage FDA before marketing food from genome-edited plants. The guidance reaffirms that the risk-based approach the FDA has taken for foods derived from new plant varieties also applies to foods from genome-edited plants. The guidance describes two processes through which developers may inform FDA of the steps they have taken to ensure the safety of foods from their new genome-edited plants: voluntary premarket consultations and voluntary premarket meetings. The recommended pathway for engagement is based on a food's risk-based characteristics. The voluntary premarket meeting pathway is recommended for developers to inform the agency of their foods when a voluntary premarket consultation is not warranted based on the food's risk-based characteristics. The agency expects this voluntary premarket meeting pathway to take less time than a voluntary premarket consultation, including because the meeting pathway is recommended for foods that are less likely to raise safety questions. The FDA continues to suggest voluntary premarket consultations for foods that have certain risk-based characteristics, as described in the guidance (FDA, 2024a).

In July 2021, a coalition of non-governmental organizations and organic farmers filed a complaint against USDA, APHIS in the U.S. District Court for the Northern District of California for its 2020 rule. The plaintiffs argued the agency's rule was "arbitrary and capricious" under the Administrative Procedure Act (APA) because USDA, APHIS had ignored public comments and its own past notices in developing the rule, particularly earlier USDA, APHIS notices that announced it would consider GE crops as potential "noxious weeds" in regulating them. The court acknowledged USDA, APHIS was not bound by its prior declarations, but because it had given no explanation for its change of position, the rulemaking did in fact violate the APA. A summary judgment on December 2, 2024, vacated the rule. As previously mentioned, modified organisms that had been determined not subject to regulation under the rule were allowed to remain nonregulated, but all future modified organisms must go through the same process as they did before August 2020 (National Family Farm Coalition versus Vilsack, 2024). As of December 2024, USDA, APHIS returned to its earlier processes for Am I Regulated letters, permits and notifications, and petitions (USDA, APHIS, 2025a).

Figure 2
Flowchart of steps for developers of genetically engineered (GE) crops to obtain deregulated status from USDA, APHIS in the U.S. regulatory system before and after the time the SECURE rule was in effect (2020–24)



Abbreviations: Pre = before August 2020; SECURE = Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient.

Note: For Am I Regulated? (AIR letters), confirmation letters, petitions, and regulatory status review (RSR), the time range of each step is the 25th percentile and 75th percentile of the duration between when the developer filed the request and when USDA, Animal and Plant Health Inspection Service (APHIS) responded. The date of filing is the submitted date as reflected in the USDA, APHIS-designated AIR number, confirmation letter number, petition number, or RSR number. In general, this duration may not coincide with the total elapsed calendar time between the company's dated submission and the USDA, APHIS response letter (e.g., situations in which the company initially files an incomplete submission). For permits and notifications, the time ranges are the 25th and 75th percentiles of the duration between the received date and issue date. The permits/notifications data only include those with statuses that are issued, acknowledged (notifications only), superseded, and denied. The analysis is limited to release permits and excludes courtesy permits.

[a] Following field-testing authorization, there is no fixed timeline for submission of a petition. Developers may conduct field testing for multiple years before seeking nonregulated status, and not all field-test organisms proceed to a petition.

[b] Petitioning USDA, APHIS for nonregulated status only applies to modified plants. The data used to calculate petition duration are from the pre-SECURE era only. However, to date, two petitions in the post-SECURE era have a deregulated status.

Source: USDA, Economic Research Service elaborations of the Coordinated Framework for the Regulation of Biotechnology, with permit, AIR, and petition data from USDA, Animal and Plant Health Inspection Service (APHIS). Permits and notifications for the SECURE and post-SECURE era are from USDA, APHIS eFile data. Permits and notifications prior to the SECURE era are from USDA, APHIS ePermits data.

Pre-SECURE and Post-SECURE Status Determinations

USDA, APHIS made determinations of nonregulated status of modified organisms under SECURE (August 2020−December 2024) at a higher rate than it had under the legacy regulation (before August 2020). Figure 3 shows modified organisms determined to be nonregulated by petitions and RSRs, as well as the number of modified organisms that were confirmed to be not regulated by AIR or confirmation letters.[15] The number of modified organisms determined to be nonregulated by an RSR in the first year of the program was higher than the number of modified organisms determined to be nonregulated by petition in all but 7 years. In the first full calendar year of SECURE, RSR determinations of "not regulated" were made for 27 modified organisms, more than twice as many as had previously been petitioned in any year. There were also consistently more confirmation letters than AIR letters, with the notable exception of 2020 which saw a spike that summer.

The processing times also fell. As previously noted, between 1992 and 2020 the median successful petition took 526 days (roughly 1.5 years) from the time the requestor sent its first letter to the final determination. In 2010, the average approved petition had been in process for more than 3 years. Process times fell since that peak but rarely below 1 year. Between 2021 and 2024, the median process time for RSRs was 222 days.[16] It is also important to note that determinations of nonregulated status during this time (August 2020−December 2024) did not end with commercialized products in many instances. The SECURE changes, as well as greater use of new technologies (e.g., whole genome sequencing and gene editing), enabled a substantial shift in the timing of regulation relative to product development. The confirmation request process under SECURE enabled products to be submitted to USDA, APHIS early, often before they had been created, although products may also be submitted early to USDA, APHIS under the current AIR process.

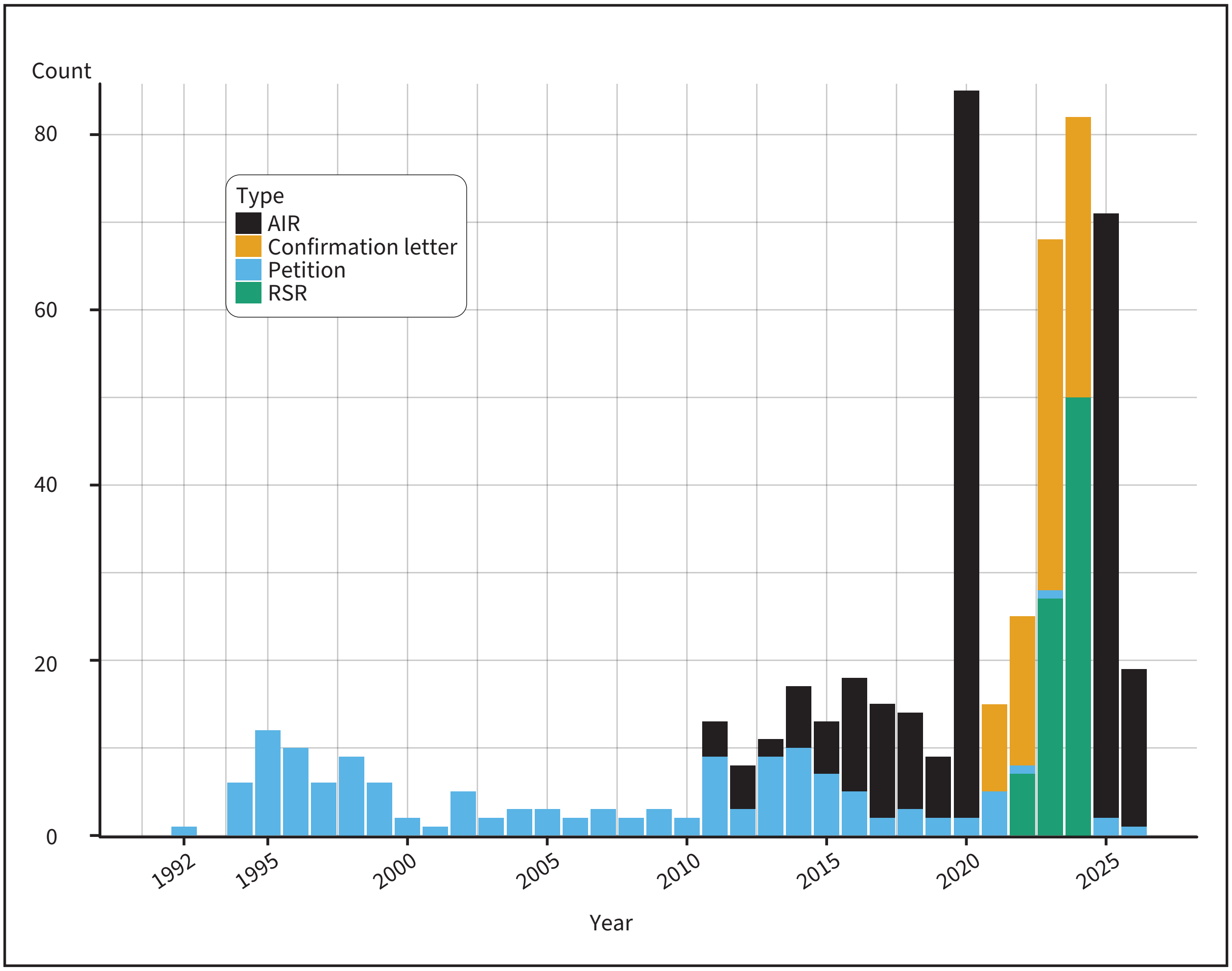
Two caveats apply when analyzing durations between the developers' submissions and USDA, APHIS's decision. First, not all submissions are deemed complete when first filed, in which case the developer is asked to revise and resubmit its filing. These revisions could be minor, taking a short amount of time (e.g., several weeks), or more substantial in nature, requiring a longer amount of time (e.g., 1 year or longer)—all depending on the content of the submission.

Second, litigation or other forms of opposition (e.g., very large numbers of public comments) can significantly lengthen the timeline. For example, after USDA, APHIS issued a determination of nonregulated status for herbicide-tolerant sugarbeets in 2005, a group of organizations sued the USDA in 2008 to challenge USDA, APHIS' determination. The court ruled in 2009 that USDA, APHIS should have prepared an environmental impact statement (EIS), rather than a limited environmental assessment review, in its decision-making leading to the 2005 determination. The court officially vacated USDA, APHIS's determination in 2010, though it did not formally prohibit farmers from planting sugar beets. USDA, APHIS published the EIS in June 2012 and then issued a determination of non-regulated status the following month (Cowan & Alexander, 2013; Fernandez-Cornejo et al., 2016). While the duration of time for the USDA, APHIS evaluation of these GE sugarbeets was extreme (8.7 years between November 2003 and July 2012), the influence of such outliers on our estimates is reduced due to our use of interquartile ranges.

[15] A never-regulated/deregulated modified organism appears on the chart in the year that USDA, APHIS sent a reply, not necessarily the year the requestor sent its application.

[16] The RSR completion time is right censored, as we do not observe the end dates for certain applications. The lack of end dates corresponds to situations where the clock paused while USDA, APHIS waited for the submitter to indicate their desire to move forward and to provide any additional information APHIS needed to complete its analysis.

Figure 3
Number of never-regulated/deregulated modified organisms by year, 1992 through March/April 2026



AIR = Am I regulated; RSR = regulatory status review.

Note: The plotted data do not include modified organisms if they are not plants or the plant species is listed as "confidential business information." As of publication, the most recent data for AIRs are through March 23, 2026, and the most recent data for petitions are through April 6, 2026.

Source: USDA, Economic Research Service calculations using information from USDA, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services.

The types of crops deregulated under SECURE differed from those under the legacy regulation. Table 4 shows the top 11 crops by frequency of developed traits declared to be never-regulated or deregulated before, during, and after the SECURE rule. Some crops ranked highly in each time period, most notably corn and soybeans. However, before August 2020, the top five never-regulated or deregulated crops were mostly field crops, whereas under SECURE there was also a cover crop and specialty crop—pennycress and blackberry—in the top five.[17] Over the 28.5 years from 1992 to August 2020, there were 53 distinct species cleared from regulation. Over the nearly 4.5 years during August 2020 to December 2024, there were 42 distinct species cleared—21 percent fewer in a period about one-seventh as long. The kinds of traits differed as well, with traits related to product quality and disease resistance

[17] Pennycress, an oilseed crop being developed as alternative source for biofuels and animal feed, has been gene edited to (1) lower erucic acid (a health concern for livestock), (2) reduce undigestible fiber content (thus improving metabolizable energy for animal feed), (3) decrease glucosinolate levels (toxic at high levels), and (4) lower seed shatter (to increase yields). The developers also envision pennycress as a cover crop to be used in corn-soybean rotations (McGinn et al., 2019; CoverCress, 2024).

increasing under SECURE, despite the smaller number of total modified organisms in that period. There were also nearly as many traits related to agronomic properties in the SECURE era as there had been prior. In 2025 and early 2026, there were relatively more modified organisms with agronomic properties or product quality traits than herbicide tolerance, insect resistance, and disease resistance traits.

Although the current regulatory environment is similar to what existed prior to SECURE, it may be too early to observe changes in the types and quantities of traits being developed, since the development pipeline is long and the overturning of SECURE was unanticipated. It may also be that the types of traits being developed have been changing for mainly non-regulatory reasons, like applications of new technologies (e.g., gene editing) or changing market conditions.

Table 4

Top 11 never-regulated and deregulated modified organisms before (1992–August 17, 2020), during (August 18, 2020–December 2, 2024), and after (December 3, 2024–March 23, 2026) SECURE regulations, by crop and trait

Crop	Legacy	SECURE	Post-SECURE	Trait	Legacy	SECURE	Post-SECURE
Corn	47	22	9	HT	70	41	8
Soybean	35	56	8	IR	36	4	3
Canola	13	14	3	DR	19	22	10
Potato	20	12	4	PQ	70	111	22
Cotton	18	5	1	AP	39	38	40
Tomato	18	6	14				
Blackberry	0	20	0				
Rice	6	6	5				
Tobacco	8	0	0				
Pennycress	5	27	12				
Camelina	3	7	0				

SECURE = Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient Rule.

Note: These are counts of individual requests sent to USDA, APHIS by the developer. Modified organisms that are ultimately commercialized may be the subject of multiple requests, and not all requests for deregulation are necessarily commercialized. Not all modified organisms are able to be classified as herbicide tolerant (HT), insect resistant (IR), product quality (PQ), agronomic property (AP), or disease resistant (DR) for various reasons (e.g., company-withheld information about the exact nature of the trait(s)). The most recent publicly available information about Am I Regulated (AIR) letters is from March 23, 2026, while the most recent publicly available information for petitions for determination of nonregulated status is from April 6, 2026.

Source: USDA, Economic Research Service calculations using information from USDA, Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services.

Costs of Trait Development: Evidence From the Literature

Obtaining regulatory approval is only one part of the process developers go through when bringing a new trait to market. The exact cost of trait development depends on which breeding techniques are used and their associated timelines. Among the newest of these techniques is gene editing, which has several advantages in speed and cost over conventional breeding and conventional genetic engineering, but all three remain relevant for developers today. Conventional breeding is still used to improve the underlying genetics of crops, while gene editing is finding relatively more use in developing traits for specialty crops and product quality improvements compared to conventional genetic engineering (e.g., mustard greens with reduced bitterness, pennycress with improved feed digestibility and other traits), as well as being commonly used in row crops (often in combination with conventional genetic engineering techniques).

Monetary Costs of Trait Development

Developing and commercializing any new variety, genetically engineered or otherwise, is a lengthy and expensive process (table 5). In both gene editing and conventional genetic engineering, the initial phase involves researchers identifying organisms that display the trait of interest and the part of the organism's genome that is responsible. With conventional genetic engineering, there is still a large degree of randomness in where the genetic material inserts into the genome and how it is expressed in different individuals. Gene editing enables a precise change to the organism's DNA, such as a deletion or substitution, which can be a much faster and cheaper process because of the precision of tools like CRISPR and transcription activator-like effector nucleases (TALENs). Once researchers have successfully identified and brought a trait into a breeding line, they begin initial field testing. If regulatory approval is required for full commercialization, researchers begin collecting the data to send to regulatory agencies (Kalaitzandonakes et al., 2023). Finally, the best performing elite lines with the new traits are tested in larger plots in a wider variety of locations in final premarket testing. Companies will also conclude any regulatory steps necessary at this point before commercialization.

Kalaitzandonakes et al. (2023) estimate the total time from proof of concept to commercialization, including review by regulatory agencies in multiple countries, is 12–13 years for both conventionally bred and transgenic (conventional genetic engineering) crops and 8–9 years for gene-edited crops. Chen et al. (2019) estimate 8–10 years for conventional breeding, 8–12 years for conventional genetic engineering, and 4–6 years for gene editing. Gao (2021) has the same estimates for conventional breeding and conventional genetic engineering but estimates an even faster process for gene editing, 2–5 years. In all three studies, though, conventional breeding and conventional genetic engineering take roughly the same amount of time, and gene editing is anywhere from 25 percent to 83 percent faster than conventional breeding.

Table 5
Conceptual overview of time required to develop a new crop variety

	Conventional breeding	Conventional genetic engineering	Gene editing
Proof of concept	2–3 years	4–6 years	3 years
Initial field testing	3 years	2–3 years	n/a
Integration into elite lines	5 years	3–4 years	2–3 years
Premarket testing	2–3 years	2–3 years	3 years
Average total	**13 years**	**12 years**	**8–9 years**

Note: These estimates are conceptual in nature, based on average times and ranges reported in a synthesis of the literature (Kalaitzandonakes et al., 2023). Actual times may deviate and change with changes in technology (e.g., development of Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology for gene editing) or regulation (e.g., phase-in of the Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient (SECURE) rule in August 2020 or its vacatur in December 2024). Since field testing does not occur between proof of concept and integration into elite lines for gene editing, we indicate this as "n/a" in the respective row and column.

Source: USDA, Economic Research Service using information from The Economics and Policy of Genome Editing in Crop Improvement by N. Kalaitzandonakes, C. Willig, and K. Zahringer, The Plant Genome, 2023.

The direct monetary costs of developing new traits are also high. Table 6 lists several studies that have attempted to estimate costs for conventional genetic engineering and gene editing. Three important points must be borne in mind. First, most of the published studies in table 6 are based on surveys or interviews with large agribusiness companies like Bayer or Corteva. Second, several of the studies explicitly assume regulatory approval is sought by the trait developers in at least two countries (Kalaitzandonakes et al., 2007; Phillips McDougall, 2011; AgbioInvestor, 2022). Regulatory costs for firms that do not plan to export (e.g., producers of gene-edited specialty crops) may be much lower. For example, in correspondence with the National Academies of Sciences, Engineering, and Medicine (NASEM) Committee on Genetically Engineered Crops, Okanagan Specialty Fruits company documents show its regulatory costs for the Arctic Apple, a genetically engineered apple that prevents browning, were only $50,000 ($62,200 in 2023 dollars) (NASEM, 2016). Third, the studies do not provide a cost comparison involving development of the same (or similar) novel trait using conventional plant breeding. Allocating costs to specific R&D projects is highly difficult, especially with conventional plant breeding since it is usually pipeline-based, involves the production of many varieties simultaneously, and has no equivalent discrete regulatory endpoints (Kalaitzandonakes et al., 2023). Older literature using spreadsheet budget modeling estimated development costs per conventionally-bred variety (Dreher et al., 2003), but this literature has generally not been updated in recent years.

Because of the variety of research methods used, it is difficult to compare total development costs over time. However, some studies have similar methodologies. Phillips McDougall (2011) and AgbioInvestor (2022), both commissioned by the trade group CropLife International, are comparable, and the estimates of USDA, APHIS (2020) build directly on the work of Kalaitzandonakes et al. (2007). Phillips McDougall (2011) and AgbioInvestor (2022) show that R&D costs fell by more than $60 million (in 2023 terms) during the 2010s, though the AgbioInvestor study stresses that the time to move to commercialization increased from 13.1 to 16.5 years.[18]

Many studies do not fully enumerate the cost categories associated with regulatory compliance for GE traits, though major costs include molecular characterization, compositional testing, protein production and characterization, and production of tissues, as well as facilities and management overhead and any relevant intellectual property (IP) protection costs.[19] The costs attributable to navigating regulation have decreased relatively less than other development costs according to Phillips McDougall (2011) and AgbioInvestor (2022), though their estimate of $45 million is higher than most others that range from $3 million to $25 million. There are some direct fees paid to regulatory agencies, but regulatory costs are predominantly due to data collection and analysis, as well as employing regulatory specialists and lawyers. The studies generally do not make clear what share, if any, of these costs would have been incurred even in the absence of a particular regulatory system.

[18] This number is on the high end of estimates for total development time, as discussed above.

[19] Comparable regulatory cost categories are not as well developed for conventionally bred traits, which generally do not undergo equivalent regulatory processes. For gene edited traits, published studies mainly estimate total costs and tend to characterize only broad differences (e.g., with or without a GE-style regulatory review phase) (Lassoued et al., 2019; Bullock et al., 2021).

Table 6

Monetary costs of developing a new genetically engineered (GE) or gene-edited trait before the SECURE rule

Source	Time period	Method	Cost range, regulatory (U.S. dollars, millions)	Cost range, total (U.S. dollars, millions)	
				Conventional GE	Gene editing
Kalaitzandonakes et al. (2007)	Late 2000s	Interviews, submitted dossiers	9.5–22.2 (HT corn) 10.8–23.6 (Bt corn)	--	--
Phillips McDougall (2011)	2008–12	Survey	46.9	181.8	--
Lassoued et al. (2019)	2019	Survey	--	--	11.9–27.8
USDA, APHIS (2020)	Mid-2010s	Estimates are based on literature review	2.7–14.5 (USDA, APHIS alone) 5.1–22.3 (2+ agencies)	--	--
Bullock et al. (2021)	Late 2010s	Interviews, survey	21.7–54.3	56.5–139.1	8.7–26.1
AgbioInvestor (2022)	2017–22	Survey	44.9	115	--
Kalaitzandonakes et al. (2023)	2016–22	Survey, industry data	14–21	50–65	12–40

Note: All amounts are deflated to 2023 dollars with the National Institutes of Health Biomedical Research and Development Price Index. All studies use surveys and interviews or are meta-analyses of surveys and interviews. All study periods take place prior to adjustments to the Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient Rule (SECURE) rule, which was in effect during 2020–24. Kalaitzandonakes et al. (2007) studied total compliance costs, including permits and stewardship, for insect resistant and herbicide tolerant corn. Phillips McDougall (2011) and AgbioInvestor (2022) asked about any "biotechnology-derived trait" and do not include stewardship costs. Lassoued et al. (2019) surveyed experts in academia, government, and industry. Bullock et al. (2021) surveyed eight firms involved in GE and gene editing. Dashes in cells indicate the study did not report the particular estimate. Kalaitzandonakes et al. (2007) itemized compliance costs for certain geographies (United States, Canada, European Union); Phillips McDougall (2011) inquired about resources for submissions in 1–2 countries/jurisdictions for cultivation and 5–7 countries/jurisdictions for import approval. AgbioInvestor (2022) inquired about resources for submissions for cultivation approval in at least two countries and import approvals from at least five countries. Lassoued et al. (2019) and Bullock et al. (2021) used survey data from participants located in the United States and other countries to construct averages. The USDA, APHIS (2020) estimates were designed to parse out the regulatory costs specific to USDA regulation using Kalaitzandonakes et al. (2007) and are U.S. costs only. It is unclear from Kalaitzandonakes et al. (2023) if costs are only reflective of the U.S. regulatory system or also include those of other countries.

Source: USDA, Economic Research Service, using sources listed in the table's first column.

In cases where conventional genetic engineering and gene editing costs are estimated separately, the latter is always much lower: Bullock et al. (2021) estimate gene editing is from 53 percent to 94 percent less expensive and Kalaitzandonakes et al. (2023) report it is from 20 percent to 80 percent less expensive. Lassoued et al. (2019) use a different methodology than AgbioInvestor (2022) but cover roughly the same period, and their estimate for gene editing is 75–90 percent less than conventional genetic engineering. These ranges cover scenarios where gene edited plants are not subject to regulation and scenarios where they are subject to the same regulations as GE plants.

Opportunity Costs of Trait Development

It should be noted that any GE regulatory system has the potential to create opportunity costs for technology developers because the resources these companies allocate to navigating the regulatory process could have been put to other uses (Zilberman et al., 2015; Van Eenennaam et al., 2021). The magnitude and distribution of these costs can have implications for the structure of GE seed markets, among other factors that influence the relationship between regulation and innovation (see appendix for additional details). Much past work has explored the linkages between certain components of regulation, especially intellectual property rights (IPR), and innovation in GE seed markets, repeatedly finding that expanded IPR protections (through patents and PVPCs) have led to greater innovation in

GE seeds (Fernandez-Cornejo, 2004; Fuglie et al., 2011; MacDonald et al., 2023).[20] Although regulatory approval costs are typically characterized as fixed costs that can create barriers to market entry by new seed developers (Fuglie et al., 2011), past work has shown development of marketing and distribution networks, combined with certain firm characteristics, have tended to be stronger determinants of industry concentration than regulation (Heisey & Schimmelpfennig, 2006).[21]

One prominent synthesis of NASEM findings indicated that while regulatory approval has economic and social costs that can slow innovation and the deployment of beneficial products, such regulations are necessary for biosafety and consumer confidence (NASEM, 2016). But quantifying and comparing both the direct and indirect costs and benefits from regulatory systems is notoriously difficult. For example, it is challenging to capture the cost of a loss of public trust in a product, industry, or legitimacy of a regulatory system, and it is likewise challenging to quantify the benefit of harm avoided to public health and the environment due to a strong system (Millstone et al., 2015; Thompson et al., 2015). Similarly, it is also challenging to quantify the benefits from the U.S. regulatory system serving as an international standard and model for other countries' regulatory systems (e.g., trade facilitation of GE products) (NASEM, 2016). These benefits are potentially large and positive, though they have largely gone uncaptured in this literature, which has tended to study direct costs, such as those shown above (NASEM, 2016).[22]

Select Challenges Facing U.S. Farmers and Opportunities for Trait Innovation

Having provided an overview of GE crop adoption trends, the current regulatory structure, and GE trait development costs, we last turn to opportunities for new trait development as a response to pressing challenges affecting U.S. farmers. Innovating new biotech crop traits is crucial for sustaining productivity gains in the face of significant environmental and economic pressures (Huffman & Evenson, 2006; Ortiz-Bobea & Tack, 2018; Lee et al., 2022). U.S. crop producers experience a wide array of challenges throughout the growing season from both biological stresses (e.g., pest infestations, disease outbreaks) and non-biological stresses (e.g., extreme heat, drought, flooding). Some of these challenges relate to the near-universal adoption of GE crops, including weed and insect resistance to certain pesticides and herbicide drift (Dodson et al., 2021; Brown et al., 2022). However, new innovations in GE traits, ongoing trait development, and adjustments to farmer behavior can significantly mitigate these challenges.

[20] PVPCs, similar to patents, are a form of IPR that grants their owners the right to exclude others from marketing and selling their varieties and manage the use of the protected varieties by other breeders (USDA, Agricultural Marketing Service, 2025).

[21] A combination of market incentives and regulation can also influence the kinds of trait research performed at universities. Direct channels include the possibility that (1) compliance costs can make certain projects infeasible at scales appropriate for some university research laboratories, (2) permitting can shape what kinds of field trials are undertaken, (3) liability can shape what kinds of research university committees will approve, and (4) IP protection can play a role in the varieties available to researchers. Indirect channels may arise if (1) university technology transfer offices tend to prefer projects with concrete commercialization pathways, or (2) if researchers are not able to get grants to develop GE traits in certain crops (e.g., lower-acreage specialty crops) due to industry expectations about not being able to recoup regulatory compliance costs (NASEM, 2016). Collaborations between university researchers and biotechnology firms, as well as public-private collaborations (e.g., Fuglie & Toole, 2014), can help overcome some of these barriers. However, such collaborations tend to reinforce the trend that some university GE research portfolios have begun to mirror those of private firms working on major crops (Welsh & Glenna, 2006; Glenna et al., 2011).

[22] The NASEM study further finds that not having government regulations of GE crops would be problematic for safety, trade, and other reasons and would erode public trust (NASEM, 2016), which underscores the significant value that EPA, FDA, and USDA, APHIS have in their oversight of biotech products.

Decades of widespread use of glyphosate-tolerant corn, cotton, and soybeans have led to substantial concerns about weed resistance to glyphosate. As of 2025, the International Survey of Herbicide Resistant Weeds has identified 17 glyphosate-resistant weed species affecting U.S. crop-production areas (Heap, 2025), causing millions in annual economic losses (Ye et al., 2022; Van Deynze et al., 2022). Industry innovation has responded to glyphosate-resistant weed species by creating crops tolerant to other herbicides (such as dicamba and 2,4-D choline), which can be stacked with other HT traits, to give growers new tools against resistant weeds. A similar dynamic exists with insect pests: widespread use of Bt crops has eroded the efficacy of certain insecticidal proteins due to resistance. As one example, the western corn rootworm has developed resistance to multiple Cry proteins; in some U.S. Corn Belt regions, certain rootworm populations are now resistant to nearly all commercially available Bt corn traits, threatening the effectiveness of current insect-protected crops (Gassmann, 2021). In response to insect pest resistance, biotechnology companies have been developing seeds by pyramiding new insecticidal proteins and RNAi.

At the same time, U.S. farmers are also increasingly adopting a more holistic approach to managing weed resistance. In 2016, operators of 30 percent of U.S. glyphosate-tolerant (GT) corn acreage indicated they tend to use herbicides other than glyphosate every year (typically in addition to using glyphosate); by 2021, this number had increased to 38 percent (table 7). In 2021, operators of 85 percent of U.S. GT corn acreage indicated they use herbicides at the recommended label rate as a glyphosate resistance management strategy, up from 74 percent in 2016.[23] Other resistance management practices with widespread use include tillage and crop rotations, which were used on 45 percent and 80 percent of GT corn acres in 2021, respectively.

Table 7

Glyphosate resistance management strategies used on glyphosate-tolerant corn acres, 2016 and 2021

	Used in year...		Tend to use every year	
Resistance management practice (percent)	**2016**	**2021**	**2016**	**2021**
Use herbicides other than glyphosate	70.3	72.3	30.3	38.2**
Use tillage	43.6	45.1	56.9	56.0
Use recommended label application rate	73.7	85.1***	26.8	29.9
Rotate crops	74.1	80.3*	26.5	33.4**

Note: Table entries are reported in percent of U.S. planted glyphosate-tolerant corn acres in the respective year. Asterisks denote a statistically significant difference in means between years 2016 and 2021, making use of delete-a-group jackknife standard errors. Significance is denoted as ***p<0.01, **p<0.05, and *p<0.10.

Source: USDA, Economic Research Service and USDA, National Agricultural Statistics Service, Agricultural Resource Management Survey (ARMS), years 2016 and 2021.

[23] Standard economic models predict farmers increase herbicide use as resistance increases (Lichtenberg & Zilberman, 1986). Even though label rates derive from efficacy and safety concerns, manufacturers are increasingly providing information about glyphosate-resistance management in their published labels (e.g., additional applications or application of an herbicide with a different mode of action).

New Biotech Products and the Coordinated Framework

An important question about the Coordinated Framework (CF) is the extent to which it should be updated to adjust to biotech products using newer GE methods, such as gene editing and RNA interference. One way to think about this is by asking the following series of questions:

1. Do these newer GE methods bring about new risk endpoints?

2. Do gene-editing and similar technologies create "different-in-kind" products, or are these methods mostly different ways to reach similar products?

3. In light of the first two questions, what regulations (if any) require being revisited?

Similar questions were taken up by a panel of experts who published their findings in a 2017 National Academies of Sciences, Engineering, and Medicine (NASEM) study, *Preparing for Future Products of Biotechnology*. The committee considered risk-assessment endpoints related to human health and environmental outcomes (e.g., illness, injury, death, or loss of ecosystem function) for expected future biotech products in various degrees of complexity and novelty. They considered gene-edited crop products from various methods (e.g., Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), transcription activator-like effector nucleases (TALENs), zinc finger nucleases (ZFNs)) and gene-edited animals, cell-cultivated products from cellular agriculture systems (Raszap Skorbiansky et al., 2024), and a variety of other products that are in early-stage conceptualization (e.g., ever-blooming plants, bioluminescent trees, plants with gene drives for control of insect pests, genomically engineered microbial communities).

They concluded that the endpoints for these new products are not new compared with those that have been identified for existing biotech products, but the intermediate steps along the paths to those endpoints have the potential to be more complex, more ambiguous, and less well characterized. The report finds that many products will be similar to existing biotech products, but they may be created through new processes and some products may be wholly unlike products that exist today. The scale, scope, complexity, and tempo of biotechnology products are likely to increase in coming years, but the CF is sufficiently flexible to cover a wide range of these biotech products. However, regulatory gaps for some products and capacity limits at agencies based on the expected scope and scale of these future products could emerge. To help address these challenges, the report stresses the importance of greater clarity to the public and product developers about the regulatory process, improved coordination among the three regulatory agencies, and expanded capabilities, tools, and expertise available to regulatory staff (NASEM, 2017).

Another lens by which to answer these questions is a process-focused, regulatory operations approach. A process-focused evaluation could be operationalized by starting from descriptive system goals (e.g., clarity, predictability, transparency, coordination, and administrative efficiency) and then mapping how a typical product moves through the agencies' entry points, information requests, review steps, and decision documents, with attention to where handoffs occur and how similar information is requested or evaluated across steps. From that map, an analyst could identify where desired outcomes are not being met (e.g., uncertainty about jurisdiction or evidentiary expectations), where administrative steps appear duplicative or sequential when they could be parallel, and where information that would be useful for future decisions is not routinely captured in a reusable form (such as non-confidential rationales, standardized summaries of endpoints considered, or process/timeline metrics). This kind of approach is also consistent with the NASEM (2017) report, which emphasized strong problem formulation and the value of triage/stratified review—

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rapidly handling familiar product types while reserving more scrutiny, where warranted, for biotech products without comparators.

Although U.S. agencies have taken multiple steps after 2017 to clarify pathways for such biotech products, the NASEM (2017) conclusions remain applicable because they focus on system-level capacity and process needs under increasing product volume and diversity (e.g., predictable, transparent, and scalable risk analysis), rather than on any real or perceived unique nature of a single technology.

A continuing frontier for trait innovation is tolerance to various non-biological stresses. Droughts, heat waves, and soil salinity continue to negatively impact crop yields, and ongoing biotechnology research offers avenues to improve how crops endure these stresses. Although development and commercialization have been slower for these abiotic stress-related traits than those related to pest management, there are some promising GE traits, including drought tolerance. Several studies indicate that commercialized DT corn hybrids can modestly outperform conventional non-DT corn under water stress, with benefits that vary by location, growing conditions, and other factors, although yield benefits are small or negligible under non-stress conditions (Adee et al., 2016; Messina et al., 2022; Lee et al., 2024; McFadden et al., 2026).[24] Adoption of DT corn has been gradual, with more acres planted to DT hybrids produced by advanced conventional breeding rather than genetic engineering (McFadden et al., 2024).

New discoveries, relying on transgenic GE methods and gene editing techniques, are accelerating the development of stress-tolerant crops (e.g., DT soybeans and DT wheat), with researchers identifying genetic pathways that control water use efficiency, root development, and temperature tolerance (Shi et al., 2017; Ribichich et al., 2020; Sheridan, 2021). The main development challenges lie in the complex genetics of stress responses—many genes often contribute to traits like drought tolerance—and ensuring that improvements in stress tolerance do not come at the expense of yield potential under favorable conditions. As research continues, public and private investments in stress-tolerant GE traits could be key to bringing more of these innovations to market. Since the 1990s, over 1,000 organizations (companies, universities, agencies, etc.) have filed in the United States for plant biotech field testing permits from USDA, APHIS, with research on traits related to fungal resistance, virus resistance, nutritional quality, digestibility, altered coloration, reduced oxidation (e.g., browning), delayed flowering, self-pollination, seedlessness, increased root depth, and a variety of other traits (Huffman & Evenson, 2006; Fernandez-Cornejo et al., 2014; NASEM, 2016; McFadden & Huffman, 2017; USDA, APHIS, 2026b).

Beyond major field crops, there are significant challenges for biotech innovation in many specialty crops (e.g., fruits and vegetables). U.S. specialty crops often have smaller (though substantial) market sizes, often with low export volumes, making it difficult to justify the R&D and regulatory costs of developing GE traits. Additionally, markets for food crops that are directly consumed raw or fresh have complex considerations related to storage, transportation, and producer adaptation to evolving food safety standards (Astill et al., 2019). These factors, among others, have resulted in fewer GE traits in specialty crops compared to corn, soybeans, or cotton, limiting researchers' abilities to provide

[24] Drought tolerance produced using conventional breeding methods was first commercially introduced in U.S. corn hybrids in 2011. GE drought tolerance was introduced in hybrids in 2012 but did not become broadly available until 2013 (McFadden et al., 2019). Several field-trial studies incorporate both conventional DT and GE DT hybrids in their assessments of crop performance under water-stress conditions. However, there is currently limited evidence on whether the genetically-engineered DT trait outperforms the conventionally-bred DT trait at scale in the United States.

greater analysis of GE specialty crops. Currently, GE varieties have been planted only on a small scale in a handful of fruit and vegetable crops to date (notably papaya, potato, tomato, squash, and apple), despite the need for innovation: Many specialty crops face severe disease and pest pressures (e.g., citrus greening, blight) that biotechnology could help address. Tools like gene editing, combined with streamlined regulatory structures, could help reduce development costs and result in greater commercialization of valuable GE traits (Paarlberg et al., 2024; Atimango et al., 2024). However, there may be room for the regulatory system to be responsive to the entry of gene-edited and other biotech products that result from newer GE methods (NASEM, 2017) (see box, "New Biotech Products and the Coordinated Framework").

One other significant challenge in these markets, albeit less directly "producer-facing in most instances, is consumer acceptance of foods made from GE crops—a major topic of research in agricultural economics over the past 30 years (Fox, 1995; Hobbs & Plunkett, 1999; Huffman & Tegene, 2001). Studies published in the past 10 years suggest U.S. consumers, on average, still tend to discount GE foods relative to non-GE alternatives. However, the size of that discount is highly context-dependent and shaped by private-benefit framing, food label format, the nature of the labeling system (e.g., mandatory versus voluntary), and information about agricultural production (McFadden & Huffman, 2017; Waterfield et al., 2020; McFadden & Lusk, 2018). While no single estimate adequately captures variation across food products, U.S. region, or time, the literature indicates an average willingness-to-pay discount (as a percentage of the non-GE food price) in the lower double digits (e.g., Kalaitzandonakes et al., 2018). Many of these same studies, in addition to external polls, suggest that a fraction of U.S. consumers attempt to avoid purchasing GE foods (NASEM, 2016).[25] Beyond differences in consumer demographics (particularly age, education, and income), heterogeneity in consumer preferences is also affected by cultural worldview (Kemper et al., 2018), perceptions of the technology developer (Lusk et al., 2018), information provision (McFadden & Huffman, 2017; McFadden & Lacy, 2023), viewpoints surrounding naturalness (Scott et al., 2018), and reactions to mandatory labeling (Fan et al., 2022; Magnier et al., 2022; Caputo et al., 2025).

Less is known about consumer demand for gene-edited foods given their more recent introduction into the marketplace, but the literature is rapidly evolving (Yang & Hobbs, 2020; Marette et al., 2021; Meerza et al., 2024). For instance, recent U.S. evidence from orange juice studies shows that information can reduce aversion to CRISPR-based products, but the effect depended on how information is communicated. Infographic and video formats were found to be more effective than text alone, and gain-framed messages reduced aversion more than loss-framed messages (Hu et al., 2022; Orivri et al., 2025). Evidence from models of markets for non-browning apples indicates that even when some consumers value gene-edited products positively, market success depends on the size of the accepting consumer segment and other factors (Marette et al., 2023). A broader review of 74 consumer studies concluded that consumers generally prefer gene-edited foods to GE foods—but that this preference varies by product, price, context, perceived risk, trust, information, and other factors—and does not necessarily translate into higher willingness-to-pay for gene-edited products relative to GE products (Han et al., 2026). Some consumers may be less concerned about gene editing than genetic engineering, although consumer uncertainty about the technologies can effectively reduce their willingness to pay for both product types (Ding et al., 2023). Many of the current studies in this literature involve hypothetical scenarios, stemming largely from the fact that few gene-edited foods are currently widely available, which points to a broader knowledge gap to be addressed in future research.

[25] Related demand challenges exist for U.S. exports of GE crops in other countries, which involve wide variation in consumer preferences within and across countries (Wuepper et al., 2019; Muringai et al., 2020; Nes et al., 2022; Beckman et al., 2024).

Discussion and Conclusion

Biotechnology has become an integral part of U.S. field crop production. Adoption rates have exceeded 90 percent of planted acres for corn, cotton, and soybeans since 2013. U.S. sugarbeets and canola have also been predominantly genetically engineered, since at least 2018. U.S. farmers pay higher prices for seeds with GE traits, largely reflecting the improved pest control and simplified crop management they afford. Importantly, the cost differences between GE and conventional seeds tend to be smaller on a per-acre basis than they are when comparing the prices of seeds directly (e.g., per bag), in part because GE traits can enable more efficient planting and management.

Newer and more precise technologies like gene editing—an alternative to conventional genetic engineering methods—have begun to be applied to many major field and specialty crops. Gene-edited crop traits can often be developed faster and at lower cost than transgenic GE traits, an observation that is especially relevant to specialty crop developers that serve smaller markets (Bullock et al., 2021). Compared to earlier GE technologies, development of gene-edited crops may cost roughly half as much and be brought to market up to 4 years faster. Adjustments to the U.S. regulatory structure, involving USDA, EPA, and FDA, like those in effect during the era of the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) Rule (2021–24), may ultimately help broaden the range of GE traits and crops by reducing the costs of meeting regulatory requirements. During the 2021–24 period, more GE traits were cleared annually than during 1992–2020, and they were mostly related to product quality, compared to the earlier pronounced focus on GE pest resistance.

Despite the advances to date, important data gaps constrain ongoing research related to the impacts of GE trait development and adoption. One major gap is the lack of detailed R&D expenditure data by crop and trait from the private sector. Firms invest substantially in developing new traits, but granular information on which crops or trait areas are being initially developed is not necessarily publicly disclosed, making it difficult to assess how development efforts align with the needs of U.S. agriculture (e.g., developing traits for public-good objectives or for smaller-market crops). Another data gap regards tracking the adoption of GE crops beyond corn, cotton, and soybeans. Acres planted to GE crops like alfalfa, canola, sugarbeets, and various specialty crops are not annually surveyed by USDA (Fernandez-Cornejo et al., 2016), creating uncertainty about their usage and potential growth.

Several broader knowledge gaps merit attention. First, there are few comprehensive analyses quantifying the costs of navigating the U.S. regulatory system and even fewer with a focus on benefits. Cost analyses that do exist tend to focus on major field crops produced by large multinational companies, and they tend to include the time and costs incurred for regulatory reviews with major trading partners. Greater availability of regulatory cost data could inform efforts to make oversight more efficient. Second, international dimensions of crop biotechnology are also not fully understood. There is a lack of direct, detailed information from trait developers about the costs of obtaining international approvals for new GE traits, which can be substantial but are often only known to trait developers—if at all. These international dimensions can influence which traits are developed, since a trait not accepted by several major export markets may be less attractive to commercialize due to international regulatory asynchrony risk (Stein & Rodriguez-Cerezo, 2009). Third, the impacts of import restrictions on GE crop imposed by some countries remain an open question (Nes et al., 2022; Beckman et al., 2024). Crops with traits developed through gene editing may be treated differently by trading partners than those with similar traits developed by transgenic methods. Fourth, certain aspects of consumer acceptance of foods made from GE crops are not well understood, including the role of mandatory labeling, like the National Bioengineered Food Disclosure Standard, in shaping consumer preferences. Knowledge gaps surrounding U.S. consumer demand for gene-edited foods are also currently significant but expected to diminish as they become more widespread in the marketplace. Addressing these knowledge gaps could be important for informing U.S. and international policy surrounding the development and commercialization of future GE traits.

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Appendix: Innovation and Regulation

The relationship between regulation and innovation has been a central topic in economics throughout the 20th and 21st centuries. Economists have examined how different types of regulations influence the rate and direction of innovation, from market and competition rules to environmental, safety, and intellectual property laws. Overall, a nuanced picture emerges: Some regulations can spur innovation (by creating new incentives or markets), while others can potentially hinder it (through certain kinds of compliance costs or constraints), and the effects often depend on regulatory design, industry context, and time horizon (Blind, 2016).

Regulatory Design, Flexibility, and Predictability

There are competing perspectives on how regulation affects incentives to innovate. Some traditional models emphasize that regulatory compliance imposes costs on firms, potentially diverting resources away from research and development (R&D) and risk-taking. In this view, a heavily regulated sector could be expected to see less innovation because firms face higher costs and constraints, reducing their ability and willingness to invest in new products or processes (Blind, 2012). On the other hand, there are theories highlighting circumstances where regulation might encourage innovation. A well-known idea is the Porter Hypothesis, which argues that properly designed regulations can trigger innovation offsets: Firms, compelled to meet new standards, innovate in ways that not only comply with the rules but also improve their productivity or open up new opportunities. The short-term costs of compliance may be outweighed by dynamic gains if regulation induces firms to modernize technologies and become more competitive (Porter, 1991; Ambec et al., 2013). Another insight is that regulation can shape the direction of innovation: For example, labor regulations might encourage labor-saving innovations (Aghion et al., 2023).

One emerging consensus among economists is that how a regulation is designed often matters more than how much total regulation exists. Researchers have identified several regulatory attributes that substantially affect innovation outcomes, especially flexibility and predictability.

Highly stringent regulations can impose greater immediate costs, which can deter innovation if firms become overwhelmed by compliance burdens. However, stringent rules can also force innovation when firms must substantially improve technology to meet tough standards (e.g., catalytic converters for automobiles). Disproportionately strict regulations may have diminishing returns (or even negative effects) on innovation if compliance becomes too expensive, but moderate stringency coupled with clear goals could push firms to innovate. On the other hand, flexible, performance-based regulations (which set goals or standards but allow firms to find their own methods to achieve them) are generally more innovation friendly than prescriptive regulations that mandate specific technologies or processes. For example, an emissions rule that sets a limit per unit of output encourages firms to invent or apply any method to meet that limit, whereas a rule that mandates a particular technology, application, or other solution could discourage alternative (perhaps better) solutions. Voluntary or market-based regulatory approaches can also provide flexibility that stimulates creative compliance solutions (Wu & Babcock, 1999).

Regulations that increase information flow (e.g., transparency rules) can indirectly foster innovation by enabling consumers to value new attributes (e.g., organic food products). Moreover, the predictability and stability of the regulatory system is crucial for its functionality. Empirical surveys and case studies across industries often report that uncertainty or frequent changes in regulations slow down new R&D initiatives as firms adopt a “wait and see” approach rather than investing aggressively under less predictable conditions. Stable regulations and sufficient lead time for compliance can encourage innovation by providing a reliable backdrop against which the returns to innovation can be realized.

Competition, Entry Regulation, and Innovation

Market regulations (those governing entry, competition, and firm behavior in industries) can have a large impact on innovation. Broadly, reducing excessive entry barriers and monopoly protections tends to increase competitive pressure, which can be a strong driver of innovation. Many studies have reinforced the idea that competition policy and deregulation in previously protected sectors often boost innovation and productivity. For example, deregulation of U.S. telecommunications and airline industries in earlier decades led to new entrants and business models that drove innovative services (Bloom et al., 2019).

However, this relationship is not linear in all cases. Starting from very low competition (e.g., a monopoly), more competition spurs innovation. But beyond a point, additional competition can reduce the payoff to innovation and potentially hinder investment in R&D (Aghion et al., 2005). The optimal point varies by industry. Regulatory policy that maintains a healthy level of competition, for instance through antitrust enforcement or preventing anti-competitive mergers, is generally seen as innovation-enhancing in the long run, because it prevents complacency. On the other hand, overly restrictive licensing and permitting, for instance, could protect established firms and reduce the entry of innovative startups.

Labor market regulations also tend to have mixed effects on innovation. Strong worker protections might reduce a firm’s flexibility and raise labor costs, potentially reducing funds available for innovation. They can also discourage entrepreneurs from scaling up (Aghion et al., 2023). Conversely, some studies argue that job security provisions could encourage human capital investment and knowledge sharing, which over the long run might support more innovation that relies on skilled, stable teams (Acharya et al., 2013). The net effect is context dependent: Highly rigid rules could hurt innovation by making firms too cautious, but moderate protections combined with active policies (e.g., retraining) could be compatible with strong innovation.

Regulations as Innovation Drivers

Certain regulations, especially those related to public health and safety, have been traditionally considered to involve deep trade-offs. For example, achieving safer outcomes was thought to come at the expense of innovation and growth, because firms must divert resources to compliance (e.g., installing safety equipment) that could otherwise go into R&D. However, new research has found positive links between well-designed health and safety policies and innovation.

Regulations in areas like pharmaceutical approvals, medical device standards, and workplace safety have nuanced effects on innovation. In pharmaceuticals, regulatory rigor has a dual effect: Safety and efficacy standards ensure high-quality innovations reach the market (which maintains public trust in new drugs), but lengthy and costly trial requirements can slow down development cycles and raise the bar for R&D investments. On one hand, accelerated approval pathways and better regulatory science can speed up innovation, and when regulators provide clearer guidance or expedited routes, companies respond with more innovation. This is sometimes the case with orphan drugs that are designed for the treatment of rare diseases (Franco, 2013).[26] On the other hand, long approval timelines and uncertainty in regulatory outcomes can increase the cost of innovation. Some studies estimate that each additional year of regulatory delay can significantly reduce the present value of a drug innovation, especially deterring smaller innovators.

Beyond formal regulations, the legal liability environment can also act as a form of regulation. Stricter liability rules through legislation or court precedents can push firms to innovate safer products. For instance, the threat of lawsuits over product defects has spurred innovations in automobile safety, as firms try to reduce liability risks. Yet, if liability costs become too unpredictable or disproportionately large, they might also deter firms from pursuing certain innovations due to fear of lawsuits. Economists have tended to emphasize that finding the right liability balance is integral to well-functioning markets for R&D in both products and processes (e.g., Shavell, 2009; Galasso & Luo, 2022).

Intellectual Property and Legal–Judicial Settings

The legal and institutional environment, including intellectual property (IP) laws, courts, and contract enforcement, significantly affects innovation incentives. This aspect of regulation is about creating the rules of the game for innovation: How well can innovators capture returns, how easily can ideas circulate, and what legal frictions do they face? These are important questions that economists have been studying for more than a century, though focus in recent years has been placed on patent systems and how changes in IP systems impact innovation.

Stronger patent protection (longer or broader patent rights) should, in principle, increase the incentive to invent by rewarding successful innovators with temporary monopolies. However, this logic can fail under certain conditions (Lerner, 2009). One issue is cumulative innovation: Many industries, including the agricultural sector, have innovations that are sequential or combinatorial (e.g., new innovations build on previous ones). If patents are too strong or too broad, they can block follow-on innovators and raise the cost of cumulative innovation (Galasso & Schankerman, 2015). Another issue is competition: Granting very strong exclusive rights might reduce the competitive pressure that also drives innovation. Additionally, patent enforcement frictions matter a lot; if obtaining and defending patents is costly or if patent litigation becomes rampant, the intended benefits of strong IP protection might be undermined (Mezzanotti, 2021). However, patent protection clearly remains important in R&D-intensive industries (like pharmaceuticals, pesticides, and genetically engineered (GE) seed), where firms argue that without patents they cannot recoup large R&D costs.

A significant concern that emerged in the last 15 years is the rise of patent litigation (including "patent trolls") and its effect on innovators. Lawsuits over IP have surged in recent years, and the threat of costly litigation can be a deterrent to small innovators or startups (Huang et al., 2025). If a firm fears a new product will invite a lawsuit or an injunction from a patent holder, it might choose not to pursue that innovation. For instance, a landmark U.S. Supreme Court decision in 2006 (*eBay v. MercExchange*) curtailed the automatic issuance of injunctions in patent infringement cases. This meant that patent holders could no longer as easily shut down an infringing product entirely; courts gained flexibility to award damages instead of injunctions. The result was a reduction in the bargaining power of so-called patent trolls (Scott Morton & Shapiro, 2016). Similarly, studies of judicial efficiency (how quickly and consistently courts resolve disputes) indicate that faster, more predictable courts tend to correlate with

[26] Applications of costly genetic-engineering or gene-editing technologies to provide disease immunity in specialty crops is somewhat analogous to the development of orphan drugs (i.e., high R&D outlays that must be recouped over relatively low sales volumes).

greater firm productivity (Chemin, 2020). When firms trust that legal disputes (whether patent, contract, or antitrust) can be resolved in a timely manner, they are more willing to take innovation risks.

Beyond IP, the general legislative and judicial environment plays a role. Economists have looked at macro-level indicators (e.g., contract enforceability, investor protection laws) and have found that strong legal institutions correlate with higher innovation and patenting (Seitz & Watzinger, 2017). The reasoning is that a reliable legal environment protects entrepreneurs and investors from expropriation and lowers the risks associated with innovating. For example, if a new venture knows that contracts will be honored and not easily voided, or that an investor's rights are secure, they are more likely to invest in uncertain innovative projects. Conversely, unpredictable legal changes or arbitrary enforcement can scare off innovative investment.

Timing and Adaptive Regulation

The immediate effect of a new regulation can often be a dip in innovation or productivity, reflecting a short-run cost shock. For example, when a stringent new standard is imposed, firms may initially reallocate budgets to compliance, hire lawyers or consultants, and delay some R&D projects. However, over the long run, firms may rebound by "innovating their way out" of the compliance costs (i.e., developing new methods that not only meet the standard but eventually save money or open new market opportunities). The time lag for positive innovation effects can range from a few years to a decade or longer, making it challenging for economists to capture the full impact in short evaluation windows. This is one reason why the empirical findings are heterogeneous; some studies looking only shortly after a regulatory change might conclude it hampered innovation, whereas others examining a longer horizon might find innovative adaptation.

If laws and rules change too frequently (e.g., oscillating policies), firms may adopt a "stop-start" approach to innovation, which is inefficient. A stable multi-year regulatory outlook is generally better for nurturing innovation than a volatile one. Concepts like "adaptive regulation" have gained attention as ways to handle fast-moving technologies (e.g., artificial intelligence). In such systems, regulators allow limited trials of innovations, learning and adjusting regulations as data arrive. Adaptive, iterative approaches can encourage innovation by giving firms space to experiment, while still protecting public interests. Rather than freezing rules in place for long periods (which could become outdated), an adaptive regulatory timeline involves frequent feedback between innovators and regulators. This could reduce uncertainty because firms see a pathway to eventual regulation that will accommodate their innovations (Organization for Economic Cooperation and Development, 2024).

A related timing issue is the pace at which legislation or courts respond to innovation. Sometimes technology evolves faster than laws, leading to gaps in which innovations can initially operate outside existing regulations. This can create periods of uncertainty or conflict. The literature notes that when the legislative process is slow to adapt, either innovation is stifled (if legal ambiguity scares firms) or innovation charges ahead in a gray zone until regulation catches up (which can also be risky for investors). Neither extreme is ideal from an economic efficiency standpoint. Meanwhile, the judicial system often becomes the arbiter when laws lag behind. A judiciary that is informed and efficient can thus play a role in either facilitating innovation (e.g., by clarifying ambiguities) or hindering it (e.g., if decisions add confusion or excessive liability) (Anderlini et al., 2013).