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Research Article

Exploring the Biotechnological Future of Genetically Modified (GM) Crops in U.S. Agriculture: Regulatory Challenges, Scientific Foundations, and Pathways Forward

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Abstract:

The development of genetically modified (GM) crops have revolutionized U.S. agriculture by enhancing crop productivity and sustainability. However, there is a strong global consensus on the safety of GM crops-evidenced by over 4,400 risk assessments confirming no significant difference in risk between GM and non-GM crops, yet there are substantial societal, scientific, and governmental obstacles to the future expansion and integration of GM crops. This review looks at the current state of GM crop biotechnology in the U.S., focusing on the legal frameworks that control its development, the scientific discoveries that spur innovation, and the critical challenges that need addressing to ensure continued progress. The article outlines the foundational science behind GM technologies, including gene editing, precision breeding and transgenic approaches, which have made it possible to produce crop types that are more resilient and sustainable. Furthermore, the review covers the changing regulatory environment, with special attention to the difficulties in navigating federal regulations, public perception challenges, ethical considerations, and worries about the effects on the environment and human health. Lastly, the article proposes potential pathways forward, emphasizing the necessity of regulatory change, public and policymaker education, and research funding to realize the full potential of GM crops. By addressing these challenges, U.S. agriculture can continue to benefit from biotechnological advancements while maintaining safety, sustainability, and global competitiveness in the agricultural sector.

Key words: biotechnology; GMOS; regulatory process; safety; public health; environmental effects

1.Introduction

In the United States, biotechnology has revolutionized agricultural practices, such as, increasing crop production and variety diversification (Grossman, 2018). Along with other industries, the agricultural sector is experiencing the most significant impact from the blessings of biotechnology, or, in other words, genetic engineering (GE) technology.

For over 10,000 years, humans have employed conventional methods to alter crops and animals according to their preferences and requirements (Razzaq et al., 2021; U.S. FDA, 2023a). Examples of conventional methods for making these changes include cross-breeding, selective breeding, and mutation breeding. These breeding methods frequently entail combining the genes from two distinct sources (IAEA, 2022; Lee et al., 2015). Scientists trialed these methods to develop familiar crops, for instance, modern corn varieties and seedless watermelons (Thompson, 2023; U.S. FDA, 2023b; Melissa & Schleiger, 2022; Wieczorek et al., 2012). Scientists now use genetic engineering technology to transfer beneficial genes, such as insect resistance or drought tolerance, into plants with the blessing of this modern technology (Talakayala et al., 2020, Martignago et al., 2020, Gatehouse, 2008, Low et al., 2018, U.S. FDA, 2024a). In recent years, genome editing technologies have emerged as a powerful tool in agricultural biotechnology, facilitating the generation of innovative crop varieties devoid of foreign DNA integration. In contrast to conventional genetic modification that entails transgene insertion, techniques such as CRISPR/Cas9, TALENs, and ZFNs provide accurate modifications of an organism's pre-existing genetic material (Malzahn et al., 2017). This accuracy facilitates the overexpression or repression of particular genes to cultivate desired phenotypes while removing foreign sequences (Saravanan et al., 2022). Patel-Tupper et al. (2024) emphasized the advancement of disease-resistant crops using genome editing,

particularly enhancing bacterial wilt resistance in tomato plants. Hayes (2023) illustrated in Nature Biotechnology that genome editing may improve maize's drought resilience by altering genes associated with water stress response. Cisneros et al. (2023) illustrated the efficacy of genome editing in enhancing rice yield and nutritional quality in their article in Nucleic Acids Research. The capacity to develop genetically modified crops devoid of foreign DNA has considerable benefits for public acceptance, since traditional GMOs encountered resistance stemming from apprehensions over foreign gene insertion and its long-term consequences (Aziz et al., 2022). Genome editing can produce comparable or superior outcomes while alleviating these issues, potentially resulting in diminished regulatory restrictions and more consumer acceptance (Callahan, 2023). The objectives behind genetic modification remain consistent throughout history: enhancing crop yields, reducing crop loss, extending storage life, improving appearance, boosting nutrition, or a combination of these beneficial traits (Babe, 2022, Butler, 2023, Ramos et al., 2023). We also expect the application of genetic engineering (GE) and genetically modified organisms (GMOs) in agriculture to enhance resistance to diseases and pests, and secure food safety and availability (Hossain & Roslan, 2023).

Despite its potential, biotechnology in agriculture has been the subject of vigorous debate and scrutiny. Particularly, widespread skepticism (Fig. 1) (Pew Research Center, 2020) with GMO safety, environmental effects, and ethical implications are at the core of these arguments (Abushal et al., 2021; EFSA, 2011). Research indicates that 32% of Americans with high knowledge of science and research believe that researchers often tend to favor industries based on their research outcomes related to GM foods (Funk & Funk, 2024). Moreover, when biotech crops are close to related plants, whether they are weeds or wildflowers, they have the ability to exchange traits with each other through pollen (Ellstrand, 2003; Warwick et al., 2009; Poppy, 2004; Snow, 1997; Martínez-González et al., 2021). The assessment of genetically engineered organisms also considered the potential environmental effect on birds, mammals, insects, worms, and others, especially when it comes to insect or disease resistance traits (Naranjo, 2021; USDA, n.d.; Ghimire et al., 2023; Wei & Stewart, 2023).

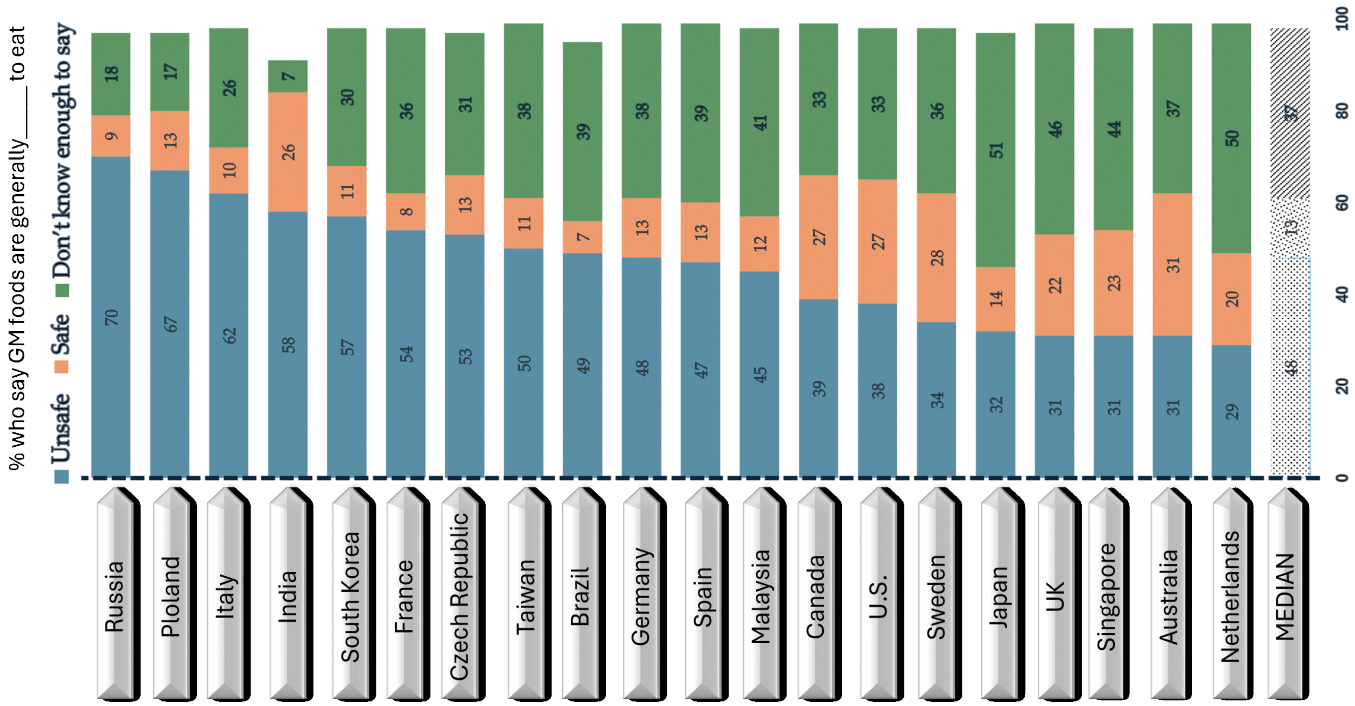

Figure: 1: Widespread skepticism about the safety of GM foods. Note that the respondents who did not give an answer are not shown. The data collected from the International Science Survey 2019-2020. Q20. (Pew Research Center, 2020)

On the contrary, GMO foods are equally healthy and safe as their non-GMO counterparts (Sims, 2020; Hollingworth et al., 2003; Teferra, 2021; Ghimire et al., 2023; U.S. FDA, 2023b). Basically, scientists have modified certain genes to improve their nutritional and dietary values. For instance, GMO soybean oil is healthier and can be used as a replacement for oils that contain transfat (Ghimire et al., 2023; Teferra, 2021; Shen et al., 2022). Studies have shown that GMO foods introduced in the 1990s, and are as safe as non-GMO counterparts (Shen et al., 2022; Klümper & Qaim, 2014; Bawa & Anilakumar, 2012). Moreover, studies indicate that GMOs used in animal feed are equally safe compared to non-GMO animal food (Norero, 2022; Shen et al., 2022; U.S. FDA, 2024b).

To address these challenges, regulatory frameworks play a key role in ensuring biotechnological progress, whether or not it adversely affects the environment or human health (Rozas et al., 2022, Tsioumani, n.d.). The U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA) are the principal regulatory agencies in the United States responsible for GMOs and biotechnology regulations.

The study aims to assess the scientific foundations, future directions, and regulatory challenges of biotechnology in American agriculture. We will review the current regulatory framework to find shortcomings and propose modifications for sustainable integration. We will also look at the scientific foundation of biotechnology, assessments of health and safety, and effects on consumers' and growers' socioeconomic situations. The study will also review EPA, FDA, and USDA's regulatory measures and offer evidence of the security and efficacy of modified species. Our goal in tackling ethical concerns and the broader consequences of biotechnological developments is to provide insightful analysis and

suggestions to the scientific community, industry stakeholders, and policymakers

2. Methodology

This review investigates agricultural biotechnology operations in the United States by examining peer-reviewed articles, regulatory documents, and key stakeholder perspectives. The literature search spanned from 1981 to March 2024, using databases such as Google Scholar, Sci-Hub, Pub-Med, Agricola for peer-reviewed articles and official documentation from the USDA, FDA, and EPA. In addition, relevant data were retrieved from reliable websites related to (agricultural) biotechnology regulation and policy. Boolean operators (AND, OR, NOT) were used to refine the search.

Inclusion criteria: consisted of studies focused on US agricultural biotechnology (mostly GM crops), regulatory frameworks, safety assessments, and socioeconomic impacts.

Exclusion criteria: removed unreliable sources and studies irrelevant to these topics. Articles were selected based on their relevance, and duplicate studies were removed using citation management tools, Endnote.

Semi-structured interviews were conducted with extension associates, field officials, and industry experts to gain practical insights into the regulatory landscape and its real-world implications.

3. Problem Statement

One of the main challenges to the seamless incorporation of biotechnology and genetically modified (GM) crops into the American agricultural system would be the intricate regulatory complexity and the fragmentation of regulations. As there is no dedicated legislation, the arrangement instead consists of borrowed portions of the existing laws, which makes the whole regulatory framework a very complex. While the Coordinated Framework established in 1986, U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA) divided the work under this "Coordinated Framework for the Regulation of Biotechnology" (Martin, A., 2022). Although this framework has functioned for decades, some researchers have pointed out potential gaps or overlaps in regulatory oversight, particularly when it comes to novel biotechnologies like genome editing (McHughen & Smyth, 2007; Montpetit, 2005). To improve the efficiency of the system, there may be a need for better coordination and streamlining between these regulatory bodies, especially as new biotechnologies continue to emerge.

The main challenges in biotechnology include resource allocation and regulatory effort prioritization. Regarding risk-based practice, there is a recognition of the need to align regulatory resources with risk levels. But still, the question arises as to whether the existing resource allocation practices are enough. The scientific and regulatory community generally agree on the mechanism of "product, not process" regulation, but further research is necessary to determine whether current legislation can effectively regulate biotechnology and determine its positive or negative impact on regulatory efficiency.

4. Regulatory Initiatives for Oversight of Agricultural Biotechnology in the United States

The US and Canada, in contrast to Europe, did not pass any new laws pertaining to the regulation of biotechnology. Instead, existing statutes were adapted to encompass new products and technologies. This strategy was driven by the idea that the nation already had enough human and juridical power in the appropriate agencies to ensure proper protection of the environment and society (Montpetit, 2005).

The Food and Drug Administration (FDA) published a policy statement in 1992 that described the safety and assessment procedure for foods made from novel plant kinds, including those made using the technique known as recombinant DNA (Federal Register Announcement of May 6, 1992," Kok et al., 2008). Since the first genetically modified crops were approved in 1994–1995 (U.S. FDA, 2023a; Rangel & Maurer, 2016), they have evolved and remain consistent with the oversight framework established by the U.S. Department of Agriculture (USDA).

4.1 USDA Oversight

Under a permit system, the USDA's Animal and Plant Health Inspection Service (APHIS) regulates managed field trials of prohibited genetically modified organisms and veterinarian products (Purchase, 1990). Meat and some poultry products are subject to safety regulations by the Food Safety and Inspection Service (FSIS), a division of the USDA (Brougher, 2011; Manchester et al., 1997). The genetic engineering method is the main emphasis of the process-based regulatory process at the USDA, which calls for permits and oversight for field testing of genetically modified organisms (Hoffman, 2021, McHughen, 2016). However, USDA regulatory mandates can easily be limited in scope to only environmental factors, resulting in whole categories of risk falling outside of regulatory scrutiny (Secchi, 2023).

4.2 FDA Authority

The FDA assures that genetically modified foods are safe for human and animal consumption. Under the Federal Food, Drug, and Cosmetic Act, the FDA evaluates food from GM crops with specific concern for allergens, toxicants, and the nutritional equivalence of the foods (Shen et al., 2022). Specifically, the Centers for Food Safety and Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) of the FDA, in particular, evaluate the safety of genetically modified crops, milk, and dairy products (Jarrell et al., 2015). In contrast to a process-based approach, the FDA evaluates the qualities and attributes of the food before imposing regulatory scrutiny based only on the biotechnology process. FDA connection is discretionary, but if harm becomes apparent, not participating could lead to a recall that is required and legal action (Tennyson, 2011). However, the lack of legal restrictions on the recommendations of the FDA to engage in a pre-commercial consultation results in wide criticism, with apportionment of allowances to GM food developers, while their compliance with the guidelines is purely voluntary. These regulatory lapses add to both fragmentation and public fear of the processes involved, which in turn contribute to minimal transparency (Naveen & Sonatakke, 2024).

4.3 EPA Involvement

The EPA is in charge of regulating chemical insecticides and herbicides and oversees the evaluation of genetically modified plants that have pesticidal, Plant-incorporated Protectant (PIP) genes incorporated into them (Murphy & Krimsky, 2003, Ehn RC, & Fox JR, 2019). The EPA basically follows two Acts-the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). Among other regulatory functions, the agency assesses potential environmental impacts of pest-resistant crops, for instance, Bt corn, to

ensure that those plants do not pose unintended risks to non-target species and the ecosystem. While EPA is focuses on the environmental impacts of GM crops, it does not look into larger issues of agricultural management or food safety, which fall under USDA and FDA, respectively (EPA, 2023). Moreover, FDA and EPA both adhere to identical standards for food safety. A thorough dossier must be submitted to the EPA and discussions with the FDA are part of the PIP evaluation process (McHughen & Smyth, 2007). Mandatory USDA and EPA requirements guarantee a rigorous review process (Spector, 1975).

Agency	Primary Responsibilities
USDA	It regulates the introduction of genetically engineered organisms(USDA (*n.d*).
	Assesses environmental impacts and manages field trials (USDA-APHIS (*n.d.)*
FDA	The FDA operates under the Federal Food, Drug, and Cosmetic Act (FFDCA). It oversees the safety of food and feed products derived from GMOs (US FDA, 2023).
EPA	The FFDCA evaluates safety and nutritional aspects (US FDA, 2023).
	Regulates pesticides produced by genetically modified plants (US EPA (*n.d*).
	evaluates environmental impacts and effects on non-target organisms (*US EPA*, 2024).

Table 1: Key regulatory responsibilities of each agency

5. Current GMO Approvals

(As of 2023) 645 GM crop events are listed by the Center for Environmental Risk Assessment, taking into account several breeding techniques. GM approval data, including additional crop varieties, is kept up to date in a database maintained by the International Service for the Acquisition of Agri Biotech Applications (ISAAA.org, n.d.). To ensure accessibility, every regulatory body-including the EPA, FDA, and USDA-maintains distinct databases for each of their decisions about specific GM incidents (Freese & Schubert, 2004). Most genetically modified crops (GM) occur in commodity crops such as soybean, canola, cotton, and maize. In 1996, the genetically modified (GE) seed was first commercially introduced in the United States as a major field crop. The United States has seen a remarkable adoption rate of genetically modified crops; in 2014, over 90% of planted maize and soybeans were GM varieties (Fernandez-Cornejo et al., 2014). Since the commercial launch in 1996, their (GM seeds) adoption rate has increased rapidly. Later, GM crops, mostly canola and sugar beets, were broadly adopted. By 2024 (the most recent year for which data are available), approximately 55% of the total harvested cropland was cultivated with at least one GM trait (Figure. 2) (USDA-ERS. n.d.).

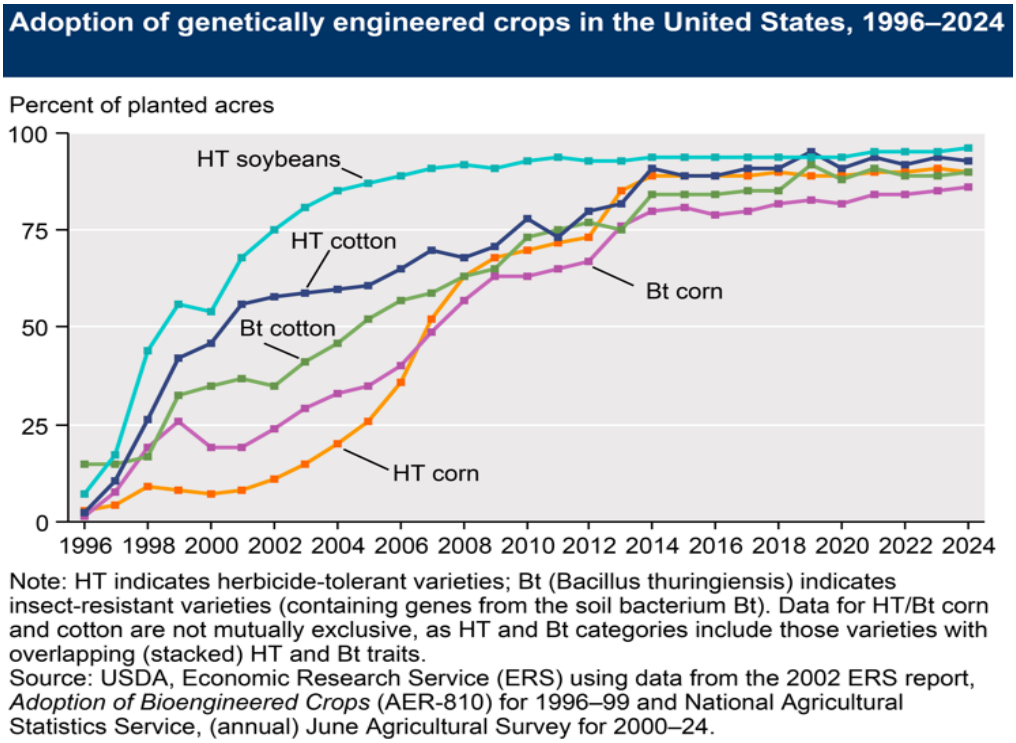

Figure 2: Recent trends in genetic engineering adoption

Herbicide tolerance and insect resistance are most common (Table 2) (USDA-ERS. n.d.). For detailed information, the table 2 can be viewed on the USDA ERS website here (Accessed October 10, 2024).

Genetically engineered (GE) corn varieties by State and United States, 2000–24

Insect-resistant (Bt) only (percent of all corn planted)

State/Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Illinois	13	12	18	23	26	25	24	19	13	10	15	14	14	4	3	1	2	3	1	1	2	2	2
Indiana	7	6	7	8	11	11	13	12	7	7	7	7	9	2	2	4	2	3	2	2	3	2	1
Iowa	23	25	31	33	36	35	32	22	16	14	15	13	12	5	4	5	3	5	3	4	3	4	3
Kansas	25	26	25	25	25	23	23	25	25	24	22	28	20	7	5	4	4	3	2	1	4	1	4
Michigan	8	8	12	18	15	15	16	19	15	13	11	11	8	4	2	2	3	1	2	3	2	3	2
Minnesota	28	25	29	31	35	33	28	26	19	23	18	16	19	3	2	2	3	2	1	2	4	2	3
Missouri	20	23	27	32	32	37	38	30	27	23	15	27	18	5	4	5	4	2	2	2	2	2	3
Nebraska	24	24	34	36	41	39	37	31	27	26	22	15	15	6	4	4	3	3	3	3	3	2	3
North Dakota 2/	.	.	.	.	.	21	29	29	24	22	22	26	17	5	6	6	4	5	2	3	3	3	3
Ohio	6	7	6	6	8	9	8	9	12	15	13	24	13	6	3	3	2	2	2	2	3	5	1
South Dakota	36	30	33	34	28	30	20	16	7	6	6	7	9	2	3	1	4	3	2	3	4	3	1
Texas 2/	.	.	.	.	.	21	27	22	20	21	18	22	20	16	12	10	8	6	6	6	8	3	5
Wisconsin	13	11	15	21	22	22	22	19	14	13	13	18	10	3	3	3	3	2	3	3	3	3	3
Other States 1/	10	11	14	17	19	19	20	20	20	20	21	20	18	6	6	4	5	4	4	3	4	3	4
United States	18	18	22	25	27	26	25	21	17	17	16	16	15	5	4	4	3	3	2	3	3	3	3

Herbicide-tolerant (HT) only (percent of all corn planted)

State/Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Illinois	3	3	3	4	5	6	12	15	15	15	15	17	16	7	5	4	4	4	5	4	4	4	4
Indiana	4	6	6	7	8	11	15	17	16	17	20	22	15	10	8	8	9	9	7	9	9	7	7
Iowa	5	6	7	8	10	14	14	19	15	15	14	16	15	14	8	8	9	8	7	7	8	9	8
Kansas	7	11	15	17	24	30	33	36	30	29	28	22	19	15	18	12	12	15	10	12	11	8	12
Michigan	4	7	8	14	14	20	18	22	24	20	25	24	26	15	15	16	18	15	11	11	13	12	11
Minnesota	7	7	11	15	17	22	29	32	29	24	28	29	22	10	10	13	10	10	9	8	9	8	4
Missouri	6	8	6	9	13	12	14	19	21	17	19	22	20	16	10	9	8	8	7	7	8	5	12
Nebraska	8	8	9	11	13	18	24	23	24	23	24	26	20	13	15	10	15	12	9	8	9	4	7
North Dakota 2/	.	.	.	.	.	39	34	37	34	30	34	32	36	20	22	21	25	21	21	15	13	12	17
Ohio	3	4	3	3	4	7	13	12	17	17	22	13	20	16	14	14	18	14	14	11	13	14	10
South Dakota	11	14	23	24	30	31	32	34	30	25	29	25	23	12	14	13	16	17	15	12	11	8	10
Texas 2/	.	.	.	.	.	42	37	37	31	30	27	24	21	20	17	12	11	13	12	9	8	9	8
Wisconsin	4	6	9	9	14	18	18	23	26	27	29	27	23	18	17	19	17	14	13	14	11	12	11
Other States 1/	6	8	12	17	21	19	25	33	32	30	30	30	26	21	19	18	18	17	15	13	14	15	14
United States	6	7	9	11	14	17	21	24	23	22	23	23	21	14	13	12	13	12	10	9	10	9	9

Stacked gene varieties (percent of all corn planted)

State/Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Illinois	1	1	1	1	2	5	19	40	52	59	52	55	53	78	83	88	87	86	89	88	88	86	87
Indiana	*	*	*	1	2	4	12	30	55	55	56	56	60	73	78	76	75	75	77	76	74	78	79
Iowa	2	1	3	4	8	11	18	37	53	57	61	61	64	72	83	80	80	80	83	81	79	80	82
Kansas	1	1	2	5	5	10	12	21	35	38	40	42	51	69	72	79	79	77	84	82	81	84	78
Michigan	*	2	2	3	4	5	10	19	33	42	44	52	52	71	76	74	70	71	72	75	74	76	81
Minnesota	2	4	4	7	11	11	16	28	40	41	46	48	47	78	81	78	80	82	83	80	79	84	86
Missouri	2	1	2	1	4	6	7	13	22	37	45	36	48	71	79	75	81	81	83	82	83	84	81
Nebraska	2	2	4	5	6	12	15	26	36	42	45	52	55	74	77	82	77	81	84	85	82	91	85
North Dakota 2/	.	.	.	.	.	16	20	22	31	41	37	39	43	69	68	70	66	67	69	78	76	77	74
Ohio	*	*	*	*	1	2	5	20	37	35	36	37	43	63	69	68	66	66	70	76	71	70	80
South Dakota	2	3	10	17	21	22	34	43	58	55	60	64	62	82	80	83	78	77	79	79	80	83	84
Texas 2/	.	.	.	.	.	9	13	20	27	33	40	42	44	53	62	67	71	77	75	80	76	80	79
Wisconsin	1	1	2	2	2	6	10	22	35	37	38	41	53	63	72	70	70	71	72	72	76	76	77
Other States 1/	1	1	2	2	6	6	10	14	22	28	31	36	41	61	66	68	68	70	71	75	73	73	74
United States	1	1	2	4	6	9	15	28	40	46	47	49	52	71	76	77	76	77	80	80	79	81	81

All GE varieties (percent of all corn planted) 3/

State/Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Illinois	17	16	22	28	33	36	55	74	80	84	82	86	85	89	91	93	93	92	95	93	94	92	93
Indiana	11	12	13	16	21	26	40	59	78	79	83	85	84	85	88	88	86	87	86	87	86	87	87
Iowa	30	32	41	45	54	60	64	78	84	86	90	90	91	91	95	93	92	93	93	92	90	93	93
Kansas	33	38	43	47	54	63	68	82	90	91	90	92	90	91	95	95	95	95	96	95	96	93	94
Michigan	12	17	22	35	33	40	44	60	72	75	80	87	86	90	93	92	91	87	85	89	89	91	94
Minnesota	37	36	44	53	63	66	73	86	88	88	92	93	88	91	93	93	93	94	93	90	92	94	93
Missouri	28	32	34	42	49	55	59	62	70	77	79	85	86	92	93	89	93	91	92	91	93	91	96
Nebraska	34	34	46	52	60	69	76	79	86	91	91	93	91	93	96	96	95	95	96	96	94	97	95
North Dakota 2/	.	.	.	.	.	75	83	88	89	93	93	97	96	94	96	97	95	93	92	96	91	92	94
Ohio	9	11	9	9	13	18	26	41	66	67	71	74	76	85	86	85	86	82	86	89	87	89	91
South Dakota	48	47	66	75	79	83	86	93	95	96	95	96	94	96	97	97	98	97	96	94	95	94	95
Texas 2/	.	.	.	.	.	72	77	79	78	84	85	88	85	89	91	89	90	95	93	95	92	92	92
Wisconsin	18	18	26	32	38	46	60	64	75	77	80	86	86	84	92	92	90	87	88	89	90	91	91
Other States 1/	17	20	27	36	46	44	55	67	74	78	82	86	85	88	91	90	90	91	90	91	91	92	91
United States	25	26	34	40	47	52	61	73	80	85	86	88	88	90	93	92	92	92	92	92	92	93	93

Note: HT indicates herbicide-tolerant varieties; Bt (*Bacillus thuringiensis*) indicates insect-resistant varieties (containing genes from the soil bacterium Bt). The stacked gene category includes those varieties with overlapping (stacked) HT and Bt traits.
* Data rounds to less than 0.5 percent.
1/ Includes all other States in the corn estimating program.
2/ Estimates published individually beginning in 2005.

Table 2: The data provides an overview of the adoption of herbicide-tolerant and insect-resistant corn, cotton, and soybeans, by State and for the Unites States, 2000–24.

6. Evolution of GM Crop Landscape

The field of genetically modified crops has evolved, with many GM events serving comparable purposes. Some genetically engineered crops were removed due to pressures from customers and businesses, but others-e.g., viral-resistant papaya-have efficiently addressed certain issues and saved the corresponding industries (Kour et al., 2022). Fresh GM crop sweet-sorghum participated in a fast-paced adoption in China, India, and the United States becoming a major portion of the worldwide production of cotton and entering the market (Raman, 2017). Since the introduction of GM crops, they have consistently contributing in global economic gain. Their cumulative economic contributions are substantial (Figure. 3) (Chaudhary & Singh, 2018). In particular, insect-resistant (IR) maize and IR cotton stand out with the highest cumulative economic benefits, with IR maize alone contributing approximately $33.40 billion and IR cotton contributing $11.10 billion. According to the recent reports, GM crops produced an estimated $261.3 billion in economic benefits from 1996 to 2019 (ISAAA - AFRICENTER, 2019). Moreover, before marketing and consumer access, GM products have to undergo strict safety and regulatory processes.

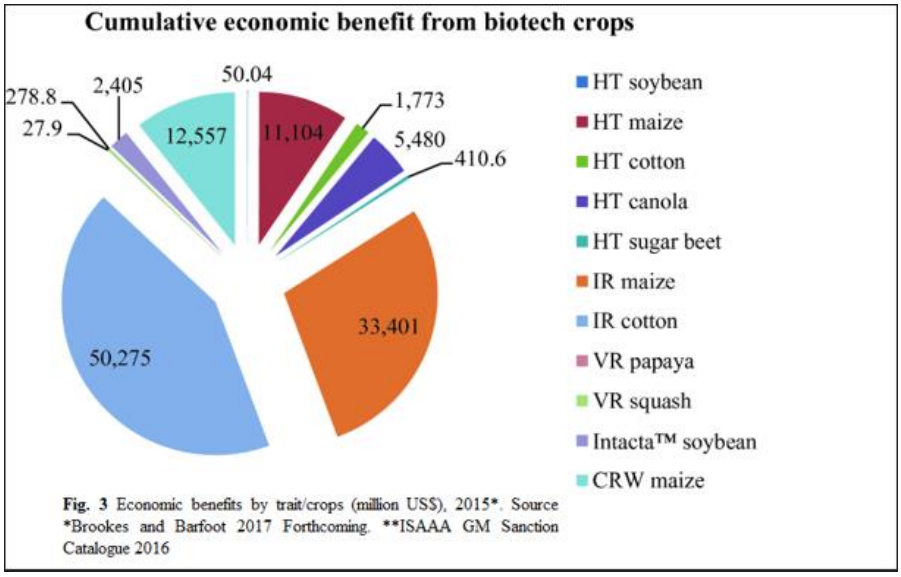

Figure 3: Economic benefits by trait/crops (million US$), 2015. The data sources are the Brooks and Bafoot 2017 Forthcoming and the ISAAA GM Sanction Catalogue 2016 (Chadhary & Singh, 2018)

7. Public Perception and Acceptance of GMOs

7.1 Socio-Cultural Factors

Public skepticism towards GMOs often arises from socio-cultural and ethical concerns. Many individuals express discomfort with the "unnaturalness" of genetic modification that goes against the sanctity of nature. These viewpoints are grounded in long-standing agricultural practices and cultural norms favoring organic, indigenous varieties of crops (Hund & Wald, 2020). Certain religious and ethical perspectives condemn the act of altering or tampering with the natural phenomena of life or disrupting the natural order of lives, guided by the belief that individuals should work in harmony with nature, rather than try to manipulate it (Hund & Wald, 2020). Misinformation and lack of clear communication of the technology can further increase these concerns.

7.2 Economic Factors

Skepticism towards GMOs is also rooted in economic issues, particularly in the developing world. For instance, small-scale farmers may object to GMO adoption, as multinational agribusinesses aggressively market and sell GMO seeds while exercising rights over the intellectual property of their seeds. These farmers cannot afford to pay for the high cost of GM seeds, which they may fear could eventually tie them to corporate-controlled farming practices (Naveen & Sontakke, 2024; Sandhu et al., 2024). Additionally, some consumers believe that GMOs primarily benefits agribusiness, rather than address global hunger or improve farmers' livelihood (Sandhu et al., 2024).

7.3 Political and Regulatory Factors

The politics of governing GMOs also serves as an important determinant of the public opinion. Citizens in several countries, and groups that represent them, are opposed to GM crops (Naveen & Sontakke, 2024; Turnbull et al., 2021). This is especially true for anti-GMO movements created by political parties, environmentalist groups, or consumer rights groups who demand that GM products be avoided or demand that the use of the technology be restricted or banned. Much of this pressure has effectively limited the technology's use within several members of the European Union (Bain & Dandachi, 2014). Inconsistencies in regulatory policies across the world too has lent a hand in fueling the apprehension surrounding GM crops. Although the United States uses a fairly liberal policy, EU, in the wave of popular anti-GM sentiment in its member countries has set in place regulations that leaves relatively less freedom for GM crops to be developed and used in its members. This fragmented policy contributed to the divergence of perception over the safety and wisdom of utilizing GMOs (Naveen & Sontakke, 2024; Turnbull et al., 2021).

8. Outreach Strategies to Enhance Public Acceptance

8.1 Education

Educational outreach should focus on increasing public awareness of demystifying GMOs by providing clear, reliable information regarding the science of genetic modification. The targeted public awareness campaigns should be grounded on science-based accounts of the safety procedures and regulatory framework regarding the production and consumption of GMOs and combat common myths (e.g., that GMOs are inherently unsafe) (Cornell Chronicle, 2022). In addition, infographics and forums hosted in local communities to establish a two-way conversation among scientists and communities will encourage members of the community to raise their questions and concerns (Biosafety Information Centre. (*n.d.*). Infographics can also be launched to the supermarket shelves or labels to inform consumers of the importance of re-examining the acceptance of GMOs and the benefits it may have for both the food security and environmental sustainability of the nation (Verma, S., 2024).

8.2 Engage with Cultural Values

Educational effort targeting different cultural groups should also ensure that the sensitivity of the region is properly maintained and that important ethical or religious concerns are taken into account. This might involve partnerships with community leaders, religious leaders, or public figures who are well-respected in the community. Community-based participatory research process also helps ensure that the voice of small farmers and vulnerable community members is heard as well. This makes sure that critical ethical and religious concerns are understood and that the citizens of that country understand the benefits of GMOs to the food security and environmental sustainability (Naveen & Sontakke, 2024; Fan et al., 2021).

8.3 Emphasizing the Role of Genome Editing

Genome editing, particularly the CRISPR-Cas9 approach may serve as a more acceptable approach for biotechnological development. Unlike traditional genetic modification where foreign genes are often inserted, genome-editing allows for the removal and editing of the genes to be modified without the insertion of foreign material (Javaid et al., 2022; Reardon, 2023). This may mitigate fears of "unnaturalness" of using foreign material in food. Educational efforts can point out the role and importance of genome editing to its ability to improve aide the crops in climate resilience, increased nutritional content, and reduce pests while not changing the crop's genetic identity (Ronald, P. & Cliegman, M., 2024). Scientists must especially point to the rigorous standards and principles that the product had to meet to gain its regulatory approval standards, and regulatory principles and safety standards which is often more streamlined than that for GMOs (Chaparro, T., 2024).

In addition, targeted social media campaigns can effectively promote the safety, advantages, and possibilities of GMOs and genome editing, engaging younger audiences via concise informative videos. Integrating biotechnology and genetic engineering into the school curriculum helps enhance scientific literacy and critical thinking. What's more, collaborations among governments, NGOs, and biotechnology firms can demonstrate practical instances of GMOs and genome-edited crops tackling food security, climate resilience, and nutritional deficiencies. These activities can transform the discourse from apprehension to optimism over the prospective advantages of biotechnology for society (Gene-Editing, 2024).

9. Review of the Scientific Basis for Agricultural Biotechnology Regulations

The inception of recombinant DNA technology in the early 1970s in the United States prompted immediate concerns about potential risks associated with genetic engineering (Bur & Wright, 1996). Scientists raised apprehensions, leading to the Asilomar Conference in 1975, where discussions addressed various risk scenarios related to recombinant DNA technology (Krimsky, 2005). In response, the National Institutes of Health (NIH) published the guidelines for research involving recombinant

DNA molecules in 1976 (NIH, 1987; Singer, 1977). While not codified into law, laboratories receiving federal funds adhered to them. Other labs, both public and private, voluntarily followed these guidelines, recognizing their prudence.

Certain limitations were eased as time passed on and the scientific and regulatory institutions gained greater familiarity with the technology and its offerings. When it was suggested that organisms with gene editing might be unleashed into the environment in the early 1980s, public opinion evolved (Devos et al., 2007).

The White House Executive Office organized an interagency working group to deal with these concerns, which examined the veracity of the allegations and suggested a regulatory strategy. The result was the 1984 draft of the "Coordinated Framework for Regulation of Biotechnology," that was finalized by the White House Office of Science and Technology Policy (OSTP) in 1986 (Shapiro & States, 1989; OSTP, 1986). This paradigm yielded several important findings (summarized from Payne & Medley, 1992) that will direct science and policy going forward:

- Biotechnology goods are not essentially different from conventional products or unmodified organisms.
- Regulation ought to put more emphasis on what is achieved than the method.
- Regulation ought to be case-by-case depending on the product's intended purpose.

The laws that are now in place give sufficient jurisdiction to regulate biotechnology products. Amazingly, it is believed that these foundational legal and regulatory safeguards were foreseen about 50 years ago, even before any genetically modified organisms were released or ingested by humans (Freese & Schubert, 2004).

In 1992, the Office of Science and Technology Policy (OSTP) released a position statement to strengthen the scientific foundation. This declaration stressed a risk-based, scientifically sound approach to biotechnology products, placing a greater priority on the traits of the product and how it impacts the environment than on the method of generation (Freese & Schubert, 2004).

10. Scientific Examination of Genetic Modification Risks

One of the main concerns surrounding GMOs is the possibility of unforeseen consequences, particularly those that may pose a risk. Thorough evaluations conducted by scholars, including the 2004 report from the United States National Academy of Sciences and the Institute of Medicine, provide a detailed analysis of the risks involved in plant breeding (Kessler & Economidis, 2001; NRC, 2004). It compares contemporary genetic modification techniques and those employed in earlier times. Unintended consequences are the main focus, seen as indicators of unforeseen risks. Modifying the DNA of a plant, animal, or microbe can have unforeseen consequences, potentially resulting in unintended or risky traits. including gene flow and cross-contamination, which may adversely affect the environment. An illustrative instance is Star Link Corn, a GMO-approved-only animal feed found in human food products in 2000, exacerbating public concern regarding the inadvertent dissemination of GM crops. A notable case is the herbicide-resistant Brassica napus (canola), wherein transgenes escaped wild relatives, resulting in the emergence of herbicide-resistant weeds, a phenomenon termed transgene escape, which complicates the management of invading species (Shen et al., 2022; Sabat & Tripathy, 2024). It is proven that genetic modification may influence the biochemical pathways in ways that are not predictable, resulting in unexpected changes, e.g., producing new metabolites that were not present in the original organisms (Sorochinskii, et al., 2011; Zheng et al., 2020, Goyal et al., 2021), which may adversely affect the environment. However, the standard breeding process successfully identifies and eliminates undesirable traits before introducing them to the market. Modern cultivars have been specifically engineered to thrive in optimal farming conditions, effectively minimizing the chance of undesirable traits (Benavente & Giménez, 2021; Sun et al., 2024).

The breeding techniques used in livestock, fiber, food, and industrial applications have a long history of safety, with only a few alleles causing harm (Bishop & Van Eenennaam, 2020; Dekkers, 2019). The infrequency of unfavorable outcomes among many new varieties highlights the general security of breeding methods. Although every breeding technique has its own potential effects, a comprehensive evaluation process has proven successful in identifying and minimizing any risks involved (Zilberman et al., 2018).

11. Health Risks

Naturally occurring toxicants found in food and feed plants include mycotoxins in cereals and glycoalkaloids in potatoes. Researchers are constantly developing plant cultivars free of these dangerous chemicals (Kumar et al., 2018, Hansen et al., 2021, WHO, 2023). One obvious sign of the attempts made to lessen or completely eradicate the presence of toxic compounds is the ongoing work to selectively breed plants (Asghar et al., 2024). Many aspects of human existence can be significantly disrupted by toxins and allergies. From mild coughing to a runny nose to severe symptoms including anaphylaxis (Cleveland Clinic, 2020), allergies trigger off immunological reactions. Toxins can throw off cell activities, induce inflammation, oxidative stress, and damage to key organs (Hoag, 2024). Toxins including heavy metals and mycotoxins can damage kidney performance (Ding et al., 2023) by creating oxidative stress and damaging renal cells). Long-term exposure to some toxins (BiologyInsights, 2024) can cause proactive kidney damage and diseases like chronic kidney disease (CKD). Generating DNA changes (Ding ewt al., 2023) allows various toxins—including aflatoxins—to be carcinogenic and increase a cancer risk. On the other hand, allergies have a complex relationship with cancer; some studies indicate a probable risk resulting from chronic inflammation (Cleveland Clinic, 2020), while others reveal a preventive role resulting from better immune monitoring. Allergies induce the immune system to react to innocuous molecules, which generates immunoglobulin E (IgE) antibodies and generates histamines (Cleveland Clinic, 2020). Toxins can lower immune system activity, therefore raising the body's susceptibility to diseases and infections (Hoag, 2024). By means of several pathways—DNA damage, protein synthesis inhibition, oxidative stress, and immunological suppression—mycotoxins produce their toxic consequences (BiologyInsights, 2024). Although totally getting rid of allergies and toxins is still a difficult task, plant breeders have made use of conventional breeding methods (Khan et al., 2020). Notably, in comparison to breeding methods, the growing environment frequently has a greater impact on the inherent hazards associated with food (NAP 20024; Jiang et al., 2021). Rarely do conventionally bred crops produce unexpected effects, such as the Lenape potato, which under some circumstances can have high selinene levels (Koerth-Baker, 2013; Bradshaw, 2019). Conventional

breeding methods have, nevertheless, been continuously shown to be rather safe (Thrupp 2000; Kaiser et al., 2020).

Contrary to popular belief, both conventional breeding techniques and genetic engineering can transmit genes between various species. Induced mutation, one of the modern breeding methods, has a continuously safe history (Parrott, 2010). Observations highlight the significant role of unintentional genetic impacts, underscoring the challenge of distinguishing between safe and dangerous breeding techniques. Recombinant DNA (rDNA) technologies are one of the breeding strategies that, according to Berg et al. (1975), presents fewer hazards in relation to serious health and safety issues. More research has confirmed that, in comparison to other breeding techniques, rDNA does not cause the genome to mutate more significantly. This confirms the general agreement that breeding methods ought not to be interpreted as justifications for regulatory action (McHughen, 2016; Anderson et al., 2016)

12. Risk Detection and Prevention Measures

To alleviate these risks, numerous detection and preventative measures have been developed. Molecular markers, like Simple Sequence Repeats (SSRs) and Single Nucleotide Polymorphisms (SNPs), are essential for detecting gene flow (Taheri et al., 2018). SSR markers have been successfully utilized to monitor gene flow from herbicide-resistant canola (Zhang et al. 2023), facilitating prompt interventions to avert further spread.

Alongside detection, measures for containment have been developed to execute gene flow. A conventional approach is an isolation or physical distance, which entails cultivating GM crops considerably from non-GM or wild varieties to reduce pollen dispersal (Price & Cotter, 2014). This approach has been used in Mexico to protect indigenous maize from contamination by GMO maize (Hu et al., 2022). Additional advanced strategy involves biological containment, such as Genetic Use Restriction Technologies (GURTs), which are commonly referred to as 'terminator technology.' GURTs assist prevent the unintended spread of transgenes through natural reproduction by ensuring that the seeds of GM crops are sterile after the first generation (Lombardo, 2014). By combining such approaches with regular molecular marker monitoring, a strong barrier against the unforeseen ecological effects of GM crops is created (Clark & Maselko, 2020).

13. Analysis and Findings: Regulatory Theory and Policy

The protection of our environment, community, and society as a whole is the goal of the regulatory bodies. Ideally, hazards to life, food and feed security, and ecosystems would all be eliminated by carefully targeted rules and efficient risk management strategies (Hasnas j., 2009, Pacheco-Vega, R., 2020). But to control and manage certain possible dangers, it is necessary to allocate human, financial, and temporal resources wisely for pragmatic reasons (US EPA, 2020). No nation can really control every facet of every potential threat in its entirety. As a result, a system of priority needs to be applied everywhere. The primary cause of the variances seen in this study between various jurisdictions is the differing priority policies and procedures.

Effective prioritization necessitates a careful evaluation of the risks connected to different hazards and concentrating resources on managing and reducing risks from those that pose the biggest danger.

14. Summary and Recommendations

Recognizing the merits of the 'product, not process' approach to biotechnology product regulation is crucial. Furthermore, it is critical for the United States to demonstrate that biotechnology regulation can be accommodated within the framework of currently enacted legislation, even if it needs modification or interpretation with some flexibility to properly address possible targets (McHughen, 2016).

McHughen (2016) also emphasized the significance of establishing strong working ties with various departments and agencies and creating appropriate Memorandums of Understanding (MoU), which allowed for logical cooperation in carrying out necessary tasks. Further enhancing the process is the idea of a "single desk" or "one-window shopping," in which a proponent applies to one department or agency, and that agency coordinates with any other agency to complete the regulatory evaluation for the product.

A regulatory shortage also occurs when hazards are not sufficiently identified and regulatory resources are not allocated in a manner commensurate with the amount of risk. As a result, mistakes are made in both commission and omission: comparatively higher-risks are under regulated, while lower-risk ones are overregulated. In addition to wasting resources, misallocating resources to address lower-risk issues exposes the environment and public health to possible harm from higher-risk but less obvious concerns (US FDA-Office of the Commissioner, 2024).

In order to successfully regulate and preserve public faith in the regulatory mechanism, it is obvious that effective prioritization and coordination are essential (US EPA 2016).

15. Conclusions

Having a clear understanding of biotechnology and genetically modified organisms (GMOs) in American agriculture is the first step in considering their potential impact on health and the environment. Without a doubt, strong legal and policy implementation through collaborative action and communication among the agencies, working towards a common goal with one another, can ensure the safe and sustainable development of this area. Aside from that, the specific creative approaches that enable biotechnology may focus on the good of people, localities, and the planet. We can achieve this by acknowledging the challenges highlighted in this study and implementing the measures suggested.

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