When Law Governs Science

A literature review on the impact of regulation on plant breeding with genetically modified crops in the EU and the U.S.A.

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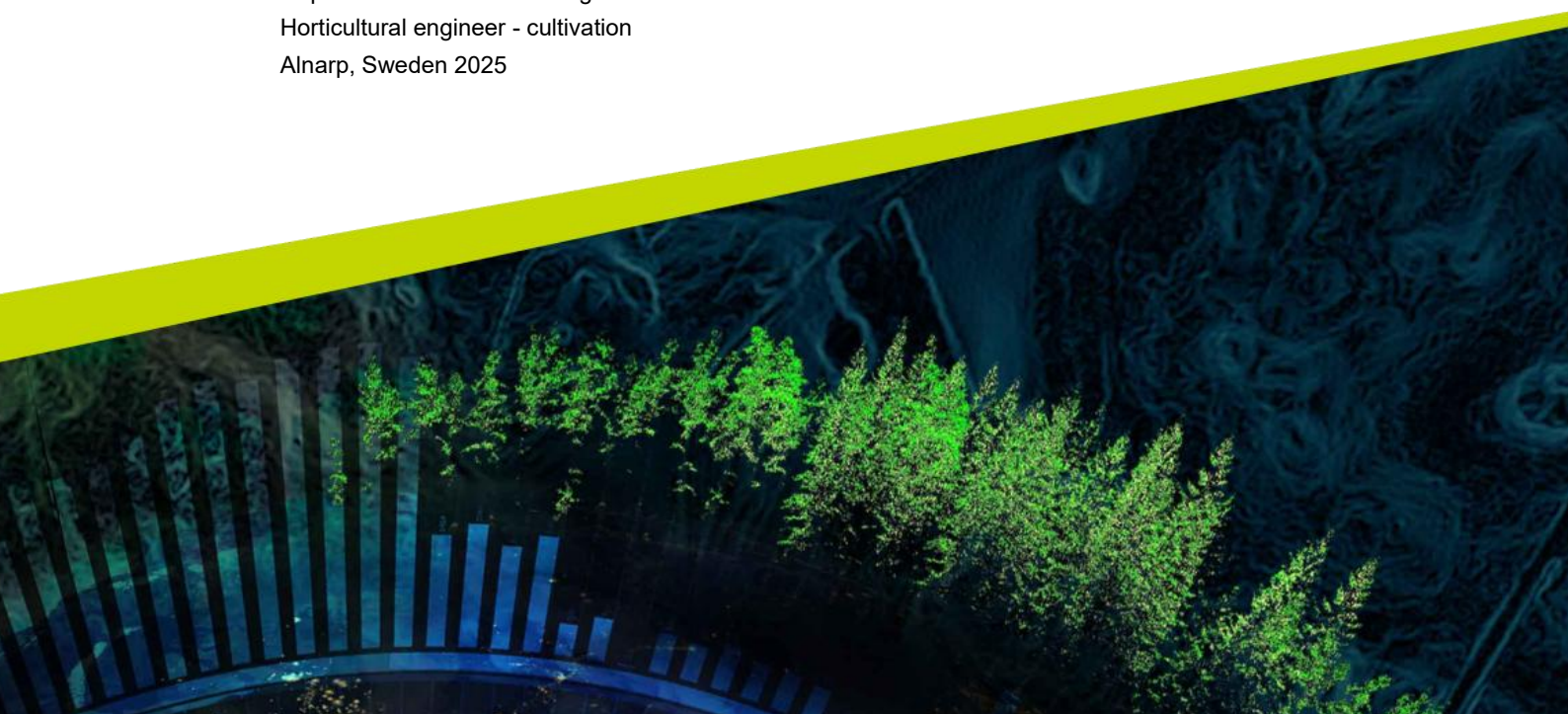

When Law Governs Science: A literature review on the impact of regulation on plant breeding with genetically modified crops in the EU and the U.S.A.

När lagen styr vetenskapen: En litteraturstudie om regleringars påverkan på växtförädling med genetiskt modifierade grödor i EU och U.S.A.

John Allmark

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Abstract

This thesis analyses how the contrasting regulatory frameworks in the European Union (EU) and the United States (U.S.) have shaped the diffusion and adoption of genetically engineered (GE) crops within the context of plant breeding.

A comparative and theory-guided literature review, peer-reviewed studies, legal texts, official statistics, and grey literature published between 1996 and 2025 were examined. Initial keyword strings were expanded through an AI-based search assistant, and documents were subsequently selected via structured academic and judicial databases (Scopus, EUR-lex, Connected Papers, Web of Science, and Google Scholar) with a defined set of inclusion criteria. The analysis employed social science models (Renn's risk governance, Rogers' Diffusion of Innovation, and Agricultural Innovation System) to organise and interpret the findings.

Results reveal a clear adoption gap. GE maize and soybeans account for 93 and 96 percent of the U.S. crop area, respectively, yet comprise less than 1 percent of the EU maize area and none of its soybean area.

Field trial activity has experienced a staggering decline since the 1990s, coinciding with higher compliance costs, increased approval timeframes, regulatory uncertainties, and an unfavourable legal environment. This has resulted in the relocation of private R&D away from the Union to more lenient jurisdictions. Conversely, the U.S. has a product-centric and trait-based approval process that only reacts if explicit pest, pesticide, or food safety issues are triggered and has witnessed consistent field trial activity.

The findings support the theory that the EU's strict process-oriented framework leads to reduced field trials, increased regulatory complexity, and limits the observability that would aid in the diffusion of innovation over time.

While this framework seemingly restricts innovation and the adoption of GE crops for cultivation, it paradoxically permits large-scale imports of the same GE commodities. This inconsistency complicates trade and undermines domestic breeders.

In summary, the EU's policy highlights the need for reform to align risk assessment with product characteristics, streamline field trial application requirements, and to restore coherence between cultivation and import policies.

Keywords: European Union, GMO regulation, genetic engineering, genetically modified crops, maize, plant breeding, policy, precautionary principle, soybean, and United States.

Table of contents

1. Introduction

1.1 Plant breeding, genetic modification, and genetic engineering

Plant breeding has long relied on crossing and selecting plants with desirable traits, such as higher yield or increased disease resistance, gradually improving crops over generations. However, traditional breeding is limited to the naturally occurring genetic variation within cross-compatible species, to overcome these limitations, modern genetic engineering permits the direct modification of an organism's DNA to introduce novel traits or enhance existing ones (EFSA 2024b).

In the context of plant breeding, genetic modification (GM) and genetic engineering (GE) are often employed interchangeably in public discourse to describe crops developed through non-traditional methods. Scientifically, however, the terms are distinct.

The United States Department of Agriculture (USDA) defines genetic modification as *"the production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods."* In contrast, genetic engineering refers to the *"manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology."* The EU's definition of a genetically modified organism (GMO), as laid down by directive 2001/18/EC, states that *"'genetically modified organism' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"* (Parliament & European Union 2001).

Although the term was not originally classified as scientific but rather introduced as strictly a legal term by lawyers and legislators, its widespread use in public and regulatory contexts has blurred its meaning, leading to its adoption even in scientific usage (Parliament & European Union 2001; Edminster 2015). In this sense, GMOs have become an umbrella term encompassing conventional techniques such as mutagenesis and advanced molecular methods, such as recombinant DNA technology (USDA 2013).

Within genetic engineering, a variety of biotechnological methods are used. These include:

- Cisgenesis, where genes are transferred within the same species or from a closely related one.

- Gene editing involves the deletion, insertion, silencing, or repression of specific gene sequences using precise molecular tools such as zinc-finger nucleases, transcription activator-like effector nucleases, and the CRISPR/Cas systems.
- Transgenesis, where a gene from an unrelated species is introduced.

(*Method of the Year 2011,* 2012; Edminster 2015).

1.2 Regulatory and Societal Context: EU and U.S. Perspectives

1.2.1 Regulatory Frameworks: EU vs. U.S.

This paper examines how the regulatory systems in the European Union and the United States have developed in different directions and analyses how the regulatory and societal differences influence the application of biotechnology in each region.

A clear contrast exists: the United States has generally been more accepting of agricultural biotechnology and has moved toward a more flexible, product-based model, adopting a case-by-case regulatory approach that focuses primarily on the characteristics of the end product rather than the process by which it was made, as shown in USDA documents such as Movement of Certain Genetically Engineered Organisms (2020c; b).

In contrast, the European Union enforces a precautionary and process-focused regulatory framework that imposes strict requirements on any crop developed through genetic engineering.

In the United States, GE crops have been cultivated commercially since 1996 and are extensively adopted across major agricultural regions. While U.S. regulatory agencies assess GE crops for safety, they are considered substantially equivalent to conventional foods. Consequently, over 90 percent of maize, upland cotton, and soybean production in the U.S. consists of GE varieties (USDA - Economic Research Service 2025a).

In contrast, European regulations are notably more restrictive, necessitating extensive safety assessments, traceability, and labelling for any GE organism. Political obstacles have further hindered the approval process (Global Research News 2015). Only one GE crop, MON 810 maize, has been approved for cultivation within the EU, and even this approval has faced bans in several member states (France-Presse 2015; European Commission 2025).

Historically, these regulatory disparities reflect more profound differences in public perceptions, philosophical approaches, and agricultural needs. Scientists, private sector leaders, and policymakers significantly shape public attitudes and can either support or hinder the adoption of biotechnology (Gates 2018; European Commission 2021; Scheufele et al. 2021; Fischer et al. 2025).

Other studies explore the historical and cultural factors influencing perceptions of technology and nature. For instance, the widely cited comparative analysis, "The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*"* provides a historical account of the political pressures that shaped the different regulatory philosophies (Lynch & Vogel 2001).

It is sufficient to note that these historical trajectories have a significant impact on contemporary attitudes towards GMOs and GE crops in the United States and Europe (Ujj 2016).

The governing philosophies behind regulatory practices differ in practice. The EU applies the Precautionary Principle, and although the U.S. does not reference the principle as a legal concept, it does follow precautionary measures as *"common sense"* (Zander 2010).

According to the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), the Precautionary Principle is an anticipatory model designed to protect humans and the environment from uncertain risks posed by human actions. It shifts the burden of action from post-damage liability to pre-damage risk assessment (COMEST 2005; European Union 2012b). The EU's stronger take on the precautionary principle permits regulators to restrict a technology despite scientific uncertainty, provided the measure is proportionate and subject to regular review (COMEST 2005).

Conversely, the United States emphasises the characteristics of the final product, the Office of Science and Technology Policy (OSTP) argues that if a GE product is substantially equivalent to its conventional counterpart, it should be regulated as such under existing food laws (OSTP 1986; FDA 2024b).

The U.S. argues that *"the EU version of the precautionary principle slows scientific and technological development and hinders international trade. Where the EU is considered risk-averse, the U.S. requires firm scientific evidence of harm before recognising the need for regulation."* (Zander 2010).

More recently, Eriksson et al. (2020a, b; c) identified issues and possible reforms that offer a tangible path forward to modernising the EU's GMO structures to reflect actual risks, not simply the creation process of the products.

1.2.2 Global adoption of genetically engineered crops

As of the early 2020s, genetically engineered technology in crops has been adopted in 76 countries and regions, with 27 actively cultivating GE crops across approximately 206.3 million hectares of farmland. Since their commercial introduction in 1996, GE crops have expanded by a factor of 121 and now represent approximately 13.4 percent of total global agricultural land (AgBioInvestor 2022; Cheng et al. 2024).

However, adoption is highly concentrated in a few major agricultural producers:

- United States: The world's largest cultivator of genetically engineered crops, with tens of millions of hectares planted. Key crops include maize, soybeans, and cotton, with over 90 percent of the area for each crop planted using GE varieties.
  As of 2024, approximately 94 percent of maize and 96 percent of soybean fields in the United States are genetically engineered.

- Brazil: Second only to the United States, Brazil cultivates over 60 million hectares of GE soybeans and maize. Adoption rates for both crops are on par with, or even slightly exceed U.S. levels.

- Argentina: Among the top GE-producing countries, Argentina grows over 20 million hectares of GE crops, with virtually 100 percent of soybean and maize area comprising genetically engineered varieties.

- Other Major Adopters:
  - Canada: Widely uses GE technology in canola, maize, and soybeans.
  - India: Focuses exclusively on GE cotton, with around 11.2 million hectares cultivated and a 95 percent adoption rate.

- Minimal or No Use: European Union: In stark contrast, the European Union only allows the cultivation of one GE crop – the insect-resistant maize variety MON 810. Even this is limited to a minimal area: fewer than 100,000 hectares, primarily in Spain and Portugal, with most EU countries opting out entirely.

(AgBioInvestor 2022)

1.3 Regulations and application

1.3.1 Overview of EU GMO legislation

The European Union's framework for GMOs consists of a series of Directives and Regulations that govern deliberate release into the environment, contained use (e.g., laboratories and greenhouses), traceability, and labelling, as well as provisions that allow individual Member States to restrict or prohibit cultivation of GMOs within their territories (European Commission 2016a).

In this section, I will clarify the differences between directives and regulations, outline the decision-making process within the European Commission, explain the scientific role of the European Food Safety Authority (EFSA), and examine how these institutions interact in practice.

The European Union's legislation on GMOs aims to protect human and animal health and the environment while ensuring uniform procedures for the authorisation and traceability of GMOs within the Member States (European Commission 2016a).
This legislation consists of directives and regulations, which form the basis of EU GMO regulations.

Directives are legislative acts that set out objectives that all EU Member States must achieve. However, each country must design its national laws to reach those objectives (European Commission 2016b).

For example, Directive 2001/18/EC has been implemented in Sweden through the Environmental Code (Miljöbalken, SFS 1998:808), specifically in Chapter 13, which governs the handling and release of GMOs (Sverige 1998). This illustrates how EU-level legislation is transposed into national legal frameworks across the Union.

Regulations are binding laws that must be applied in their entirety throughout the EU without the need for domestic legislation. In addition, regulations can supplement existing directives with binding details that apply directly to all Member States without them having to write their laws (European Commission 2016b).

Clarifying how distinct types of organisms are classified under EU GMO legislation is important in this legal framework.
Organisms produced by conventional breeding techniques, such as selection or crossbreeding, are not considered GMOs and, therefore, fall outside the scope of GMO-specific legislation.

Organisms produced by classical mutagenesis, using radiation or chemical agents to induce genetic changes, are legally defined as GMOs. They are, however, exempt from the obligation of the GMO legislation due to their long history of safe use at the time of the Directive 2001/18/EC enactment. However, the European Court of Justice ruled that plant breeding techniques based on newer forms of mutagenesis fall under the current EU GMO legislative framework in its 2018 ruling.

Organisms developed using established recombinant DNA technologies are considered GMOs and are fully subject to the provisions of the EU GMO legislation. (Parliament & European Union 2001; European Commission 2018).

1.3.2 The decision-making process within the European Commission & the role of EFSA

The EU GMO approval process involves several steps and actors:

Application: Companies wishing to cultivate or place a GMO on the EU market as food or feed must apply to a competent authority in a Member State. The regulatory framework depends on the intended use: cultivation falls under Directive 2001/18/EC or, if the scope covers food and feed (including cultivation for those purposes), Regulation 1829/2003 (Parliament & European Union 2001, 2003).

The application must include a comprehensive scientific dossier containing a molecular characterization of the genetic modification, comparative compositional analyses,
a toxicological and allergenicity assessments, and, where applicable, an environmental risk assessment (Parliament & European Union 2001; EFSA Panel on Genetically Modified Organisms (GMO) 2011; European Commission 2013).

In the EU, the application process for GMO approval is defined by evolving regulatory requirements that increasingly emphasize transparency and scientific robustness.
For instance, the 2018 revision of Directive 2001/18/EC introduced a more structured framework for environmental risk assessment, highlighting the EU's effort to make risk evaluations more consistent and evidence-based (European Commission 2018).

Applicants must also provide a publicly accessible summary of the release, known as a Summary Notification Information Format (SNIF), intended to facilitate public scrutiny.
This document is made available in both English and the local language to ensure accessibility, and it forms part of a broader public consultation process that is

mandatory before field trials or commercial releases can proceed. The SNIF allows citizens, scientists, and Member States to provide input, making it a concrete expression of the EU's precautionary and participatory regulatory philosophy (Parliament & European Union 2002).

A risk assessment by EFSA: The national authority forwards the application to the European Food Safety Authority (EFSA), a decentralized agency responsible for *"providing scientific advice and communication on existing and emerging risks associated with the food chain"* (European Union 2021).

Members of EFSA's scientific panels are selected based on a policy on declarations of interest, with scientific excellence and independence as key selection criteria.
Applications are assessed, and the most qualified candidates are submitted as a shortlist to EFSA's management board, which makes the final decision (EFSA 2024a).

The EFSA is responsible for a scientific risk assessment of GMOs. Specifically, the GMO Panel comprises European scientists with expertise in "Food and feed safety assessment, environmental risk assessment and molecular characterization and plant science." These experts evaluate potential risks to human and animal health and the environment (EFSA 2025).

Risk management: EFSA's scientific opinion is the basis for the European Commission to draft a proposal to either authorize or reject the GMO (EFSA 2024c). This proposal is then submitted to the Standing Committee on Plants, Animals, Food, and Feed (PAFF), which is composed of representatives from all EU Member States and chaired by a European Commission representative. The committee applies the principle of qualified majority voting, meaning that at least 55 percent of Member States representing at least 65 percent of the EU population must vote in favour or against the proposal, as laid out in Article 16(4) of the Treaty on European Union (European Union 2012a).

In the case of PAFF voting, *"No opinion"* or no qualified majority being reached, the proposal may be forwarded to an Appeal Committee, where a second round of voting occurs under the same legal conditions. The Appeal Committee consists of representatives from the Member States and allows having a second discussion at a higher level of representation (European Commission 2022a)

If a qualified majority still cannot be achieved, the final decision rests with the European Commission, which is legally obliged to adopt or reject the proposal (European Commission 2015a; b).

1.3.3 Overview of the U.S. GMO Legislation

The United States regulates GMOs under a Coordinated Framework for the Regulation of Biotechnology, which relies on existing statutes and federal agencies rather than dedicated GMO-specific legislation.
Initially established in 1986 by the White House Office of Science and Technology Policy (OSTP), the Coordinated Framework outlines the federal policy for overseeing the development and use of biotechnology-derived products. According to the Unified Website for Biotechnology Regulation, this framework is designed to *"cover the full range of plants, animals, and microorganisms derived from biotechnology in an integrated and coordinated manner"* (FDA et al. 2020).

Under the Coordinated Framework, three federal agencies, the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture, exercise their regulatory authority to assess and manage the health and environmental risks associated with biotechnology (FDA et al. 2020).

1.3.4 U.S. Regulatory Agencies

This section will clarify each agency's role under the Coordinated Framework, describe the relevant regulatory procedures, and examine the underlying risk assessment philosophy.

Environmental Protection Agency (EPA)

The EPA's role in regulating genetically modified plants is triggered when such plants have pesticide properties or are designed to interact with pesticide use. This includes so-called plant-incorporated protectants (PIPs), where genetic modification enables the plant to produce its protective substance against pests and must be registered as a pesticide with the EPA.

In addition to regulating PIPs, the EPA oversees genetically modified microbial pesticides, including bacteria, fungi, viruses, protozoa, and algae, and herbicides used with herbicide-tolerant crops (EPA 2024).

The EPA's authority comes primarily from two statutes: the Federal Insecticide, Fungicide, and Rodenticide Act, which governs pesticide registration and use, and the Federal Food, Drug, and Cosmetic Act (FFDCA), which sets either tolerance limits or exemptions for pesticide residues permitted in food products derived from genetically modified plants.
In all, the EPA focuses on the pesticidal aspects of genetically modified plants so that they meet the safety standards of pesticides, essentially *"that its use will not pose unreasonable adverse effects to the environment or human health"* (FDA et al. 2020; EPA 2025).

Food and Drug Administration (FDA)

The FDA is responsible for ensuring the safety of food and animal feed, including products derived from genetically modified plants. This authority is grounded in the FFDCA and was clarified in the agency's 1992 Statement of Policy, which states that foods developed through genetic engineering are to be evaluated under the same food safety standards that apply to conventional foods (FDA 2024b).

Under the FFDCA, all food and feed products, whether they are genetically modified, must be safe, unadulterated, and truthfully labelled. This includes ensuring that no unexpected allergens, toxins, or harmful substances are present and that any material differences from conventional products are communicated to consumers (U.S. Code 1938a; b).

This safety evaluation is based on the nutritional composition of the product. However, in most cases, genetically modified crops contain substances substantially equivalent to those already approved. Therefore, if a genetically modified plant does not introduce new nutritional components or additives, e.g., novel proteins, it does not typically require formal FDA approval (FDA 2024b).

The FDA's oversight relies on existing statutory requirements and a voluntary consultation process between developers and the agency before commercialization. Although voluntary, this consultation has become widely adopted and functions as a de facto regulatory expectation (FDA 2024b; a).

Within the Coordinated Framework, the FDA's mandate is limited to food and feed safety. The agency ensures that genetically modified plants are safe to eat under the same standards applied to all food. Notably, the FDA does not assess the environmental impacts of GM crops or evaluate the genetic engineering process itself. However, it does enforce truthful labelling under the National Bioengineered Food Disclosure Standard, which mandates that certain bioengineered ingredients must be disclosed to consumers (U.S. Code 2016; FDA et al. 2020).

U.S. Department of Agriculture (USDA)

The Animal and Plant Health Inspection Service (APHIS) is the agency within the broader USDA executive department responsible for protecting agriculture from pests and diseases. Under the authority of the Animal Health Protection Act and the Plant Protection Act (PPA), the USDA regulates both biotechnology-derived and conventional products that may pose risks to agricultural plant and animal health (U.S. Code 2004, 2008; FDA et al. 2020).

APHIS oversees the planting, environmental release, and interstate movement of genetically engineered plants under the PPA, as part of the Agricultural Risk Protection Act. This regulatory function is carried out through its Biotechnology Regulatory Services program, which focuses on genetically engineered plants that may present a plant pest risk to agriculture or the environment (USDA 2025).

Entities seeking to grow, test, or transport genetically modified plants must first obtain a permit or, if eligible, file a notification with APHIS. Permits include specific requirements regarding the nature of the organism and measures to prevent its spread or establishment in the environment.
Notifications are a streamlined alternative for modified plants that *"meet specific eligibility criteria and pre-defined performance standards."* After adequate research and data collection, developers may submit a petition for *"nonregulated status."* If granted, the plant is no longer considered a regulated article and can be freely cultivated like any conventional crop (USDA 2020a, 2025).

In 2020, USDA introduced the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule to modernize its biotechnology oversight. This updated framework aimed to shift regulatory focus from the genetic engineering process itself to the characteristics of the final product.
The rule adopted a science-based, risk-informed approach intended to concentrate oversight on organisms with plausible plant pest risks (USDA - Animal and Plant Health Inspection Service 2020).

However, this rule was vacated by a federal court in 2024 following a lawsuit filed in 2021. The plaintiffs argued that APHIS violated procedural requirements under federal law when adopting the SECURE rule, particularly in relation to regulatory authority and environmental review. The court found APHIS' actions to be arbitrary and in conflict with provisions of the Plant Protection Act and the Administrative Procedure Act, resulting in the rule being nullified (*National Family Farm Coalition et al v. Vilsack et al Summary* 2024).

In summary, USDA's role through APHIS is to ensure that genetically engineered plants do not pose plant pest risks, introduce new plant diseases, or become invasive, thus safeguarding plant health and the environment.

1.3.5 Regulatory procedures and decision-making within the U.S.

The United States uses a decentralized approval process model, in which each agency independently regulates specific aspects of biotechnology-derived products under its statutory mandates. This system means that a GMO may be subjected to regulations by the USDA's APHIS, the EPA, and the FDA, or in some cases, none, depending entirely on the traits and intended use of the product (FDA et al. 2020).

Rather than requiring a unified application or centralised approval process, each agency conducts its review. These include APHIS permits or notifications for environmental release, the FDA's voluntary food and feed safety consultation process, and the EPA's evaluation of pesticidal traits under pesticide law. Importantly, these agencies do not assess the genetic engineering method itself but

focus on the characteristics and risks of the final product (EPA 2024; FDA 2024a; USDA 2025)

Previous research suggests that regulatory frameworks that concentrate oversight on plausible risks and streamline review procedures can significantly reduce approval times and support the further development of biotechnology (Smart et al. 2015).

Importantly, the U.S. approach is product-centric. A genetically modified plant is regulated according to its traits and intended use rather than the breeding method. Suppose a GM plant does not trigger any agency statutes (for instance, it does not pose a plant pest risk, does not produce a pesticide, and its characteristics are substantially equivalent to conventional crops). In that case, it may require no pre-market approval in the U.S. under current rules (OSTP 1986).

These diverging regulatory approaches raise critical questions about how policy frameworks shape the development and use of agricultural biotechnology. By focusing on two of the world's most significant genetically engineered crops, maize and soybeans, this thesis investigates how the United States and the European Union differ in implementing GMO legislation and what consequences this holds for research, commercialization, and field trials.

2. Subject matter and scope

The differences outlined in the introduction chapter show that the European Union and the United States have adopted divergent legislative frameworks for regulating genetically engineered organisms (GEOs). The EU employs a precautionary, process-oriented approach that subjects new biotech crops to exacting risk assessment and risk management.
In comparison, the U.S. utilizes a more lenient, product-centric approach that focuses on the characteristics of the final product rather than the process by which it was created.

This divergence in regulatory philosophy has created two distinct environments for how agricultural biotechnology is being used and implemented. The underlying issue defining this study is the uncertainty about how these different policy environments affect real-world outcomes. Thus raises the question of whether the EU's stricter regulations limits research and slow down innovation, whereas the U.S. system allows for expedited experimentation and commercialization. In short, to what extent these disparities have practical impacts on plant breeding, scientific research directions, and the pace of commercialization of genetically engineered crops to market?

This thesis aims to systematically examine how the differences in the implementation of regulations of gene-engineered crops between the EU and the U.S. have influenced plant breeding, research, and commercialization. By analysing these two radically different systems, this study seeks to highlight the relationship between policy framework and agricultural biotechnology's innovation.

This research could be important for several reasons.
Biotechnology and agriculture stakeholders must understand how regulatory policy affects their ability to develop and commercialize new crop varieties.
As gene-editing technologies continue to advance, insights from this comparison could inform future policy decisions, ensuring that the balance between safety and innovation is respected. Examining these differences can contribute to the broader discussion on how governance can support or hinder scientific progress and agricultural sustainability.

To address these aims, this study is guided by the following research questions:

1. How are GMO regulations applied in practice in the EU and the U.S.?

2. What are the practical consequences of these differences in application, risk assessment, and approval regarding field trials, research, and crop development?
3. How have these differences manifested in maize and soybean as case studies?

This thesis recognizes that proving direct causality between a given regulatory framework and a specific outcome is difficult due to several contributing factors, including public perception, funding landscapes, and market forces.
However, clear patterns can be observed in adapting biotechnologically developed crops and the region's regulatory stance. While such correlations cannot prove direct causation, they suggest that regulatory influences significantly shape research and commercialization successes.

3. Methodology and Material

I designed this thesis to be a theory-guided literature review on the comparison on how the EU and the U.S. regulates GE crops and how these regulatory differences impact real-world innovation outcomes.

The thesis includes a case study of gene-edited maize and soybean to highlight the real-world impacts of regulatory decisions.

The data collection strategy involved structured document analysis of the following: official statistics, EU and U.S. legal texts, peer-reviewed field studies or literary reviews and grey literature. This data had the primary window between 1996 and 2025 (with exceptions regarding historical background context).

The search databases for these included Scopus, EUR-lex, Connected Papers, Web of Science and Google Scholar. Initial keyword strings were expanded with the help of an AI-based search assistant, after which all suggested documents were manually screened and all final sources cited in this thesis were retrieved from the original repositories when able.

In this work, I have used two AI-powered language tools: OpenAI ChatGPT (GPT-o3) and Grammarly. ChatGPT was used to sketch an overall outline (headings, subheadings and logical order), and to get suggestions on how my own formulations could be clarified and tightened up linguistically. Additionally, its deep research function was used for generating niche web-based sources outside of peer-reviewed research papers (e.g. AgBioInvestor, Global Research News). Grammarly complemented this by automatically identifying spelling errors, punctuation and stylistic inconsistencies in the finished text.
All ideas, analyses and source interpretations are my own; the AI tools have only served to streamline the structural work and raise the linguistic quality without introducing new substantive content.

Each suggestion has been critically reviewed and, where necessary, adjusted by me to ensure academic correctness, correct reference management and consistent professional terminology.

The criteria for inclusion of sources are as follows:

1. Topical relevance, including GMO or GE regulation (legal texts, policy analyses, compliance costs), risk assessment and governance (scientific opinions, precautionary-principal applications), innovation and adoption outcomes (field-trial data, farm-level impacts, trade flows).

2. Jurisdictional focus, material analyses of the European Union or the United States or the trade links between them.
3. Primary window 1996 - 2025. Pre-1996 items were included if they established contextual history.
4. Document types, peer-reviewed research, official publications, grey literature from recognised bodies.

Sources failing any of these criteria were excluded from the used body of research.
All sources are publicly available; no personal data processed.

3.1 Comparative Regulatory-Governance

To explain why two advanced economies arrive at opposite GMO regulatory frameworks, this paper takes a comparative approach.

According to peer-reviewed studies, the European Union is a consensus-driven system where decision-making is shared between EU-level bodies and individual Member States.
On the other hand, the United States follows a coordinated organisation model: three federal agencies share both assessment and management, with limited scope for sub-federal vetoes (OSTP 1986; Héritier et al. 2001; European Commission 2002).

This difference builds the foundation for research question 1, *"How are GMO regulations applied in practice in the EU and the U.S.?"*

3.2 Risk-Governance Model

The analysis of approval procedures is mapped onto Renn's tripartite model, which divides the regulatory framework into three distinct parts; assessment, management and communication (2010).

This analysis method seeks to answer research question 2, *"What are the practical consequences of these differences in application, risk assessment and approval in regard to field trials, research and crop development?"*

Table 1. Application of Renn's risk-governance phases to EU and US GMO approval.

Phase	EU	US
Assessment	EFSA scientific risk opinion	USDA, EPA, FDA assessments
Management	PAFF vote, Council scrutiny, opt-out option	Single Federal Register decision
Communication	Public-consultation portal, EFSA Q&A	Federal docket comments, stakeholder hearings

3.3 Innovation and Diffusion in Ag-Biotech

Because the maize and soybean cases are ultimately about adoption, this thesis draws on two complementary strands of theory. Rogers' Diffusion of Innovation (DOI) model (2003) and Agricultural Innovation System (AIS) literature (Klerkx & Gildemacher 2012).

Rogers provides a framework that links adaptation to observable factors that results in concrete adoption outcomes.

1. Compatibility: Does the GMO fit existing farming practices, cultural food preferences, and regulatory norms?
2. Trialability: Can farmers/developers run small, low-risk field trials before committing?
3. Relative advantage: In what way is this innovation better than the alternatives? E.g. yield boosts, reduced pesticide costs, nutrition traits?
4. Observability: Are its benefits noticeable? Neighbouring farmers can see caterpillar-free Bt cotton or policymakers can read about increased productivity?
5. Complexity: The simpler, more transparent and harmonised application, approval and implementation, the faster a GMO trait moves from lab to widespread use. Whereas a fragmented, politicised regulatory morass stifle investment and stalls adoption.

(Rogers 2003)

Agricultural innovation system analyse how brokers, i.e. networks of actors (individuals, organizations, and enterprises) together with supporting institutions and policies, in the agricultural sector affect the factors that Rogers looks at.

Highlighting that in systems where these connectors reinforce or hinder the spread of innovation have vastly different outcomes.
Together DOI and AIS provide an explanatory framework for why adoption diverges between the EU and the U.S.

Which answers research question 3, *"How have these differences manifested in maize and soybean as case studies?"*

4. Results

4.1 Adoption patterns

This body of research makes the consequences of regulatory differences clear. They are less about analysing policy and more about illustrating the real-world impact of the different frameworks between the U.S. and the EU.

The USDA Economic Research Service (2025b) reports that an excess of 90 percent of all American maize is genetically engineered, while GE maize in the EU is limited to less than 1 percent. Observing adaptation patterns of GE-maize between the EU and the U.S. we can observe that between 2013 and 2023 U.S. GE-maize adoption rose from 90 percent to 93 percent, (starting with 4,4 percent adaptation in 1996). The EU's percentage has been decreasing to less than 1 percent overall with relative adoption in Spain and Portugal decreasing from a high of 31 percent to 15 percent in 2023 (Fig. 1).

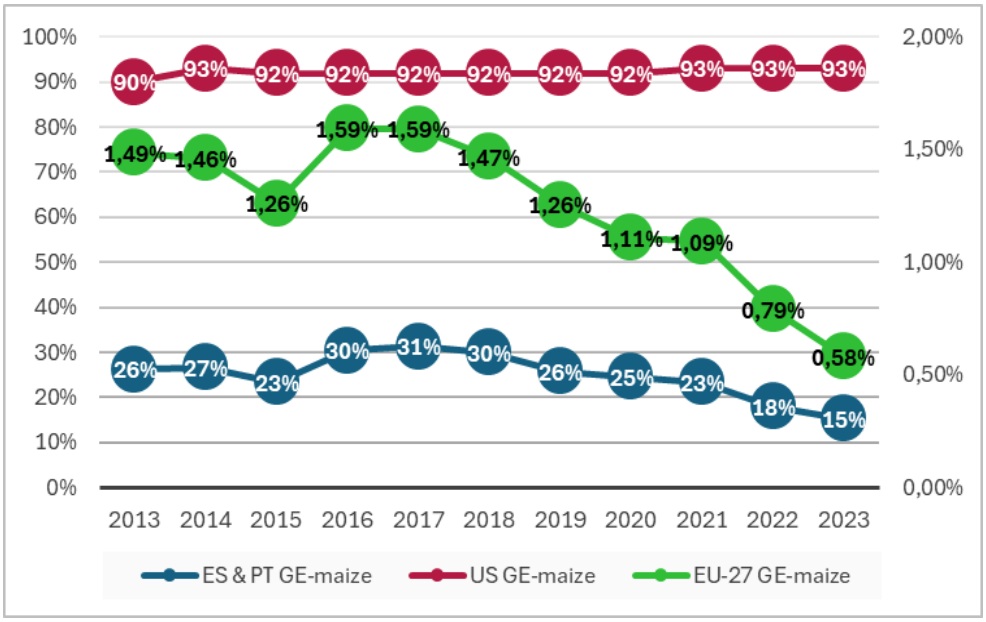

Fig. 1. Adoption of GE-maize (% of total maize area), EU-27, EU-Spain & Portugal vs United States, 2013-2023.

Source: Nicolia et al. 2014; E.F.S.A. et al. 2020, 2021, 2022, 2023, 2024; Bayer Agriculture BV 2024; USDA - Economic Research Service 2025b

These decreasing percentages could be a result of overall decreasing maize area across the EU. However, during the last ten years the overall area has remained relatively consistent (Fig 2).

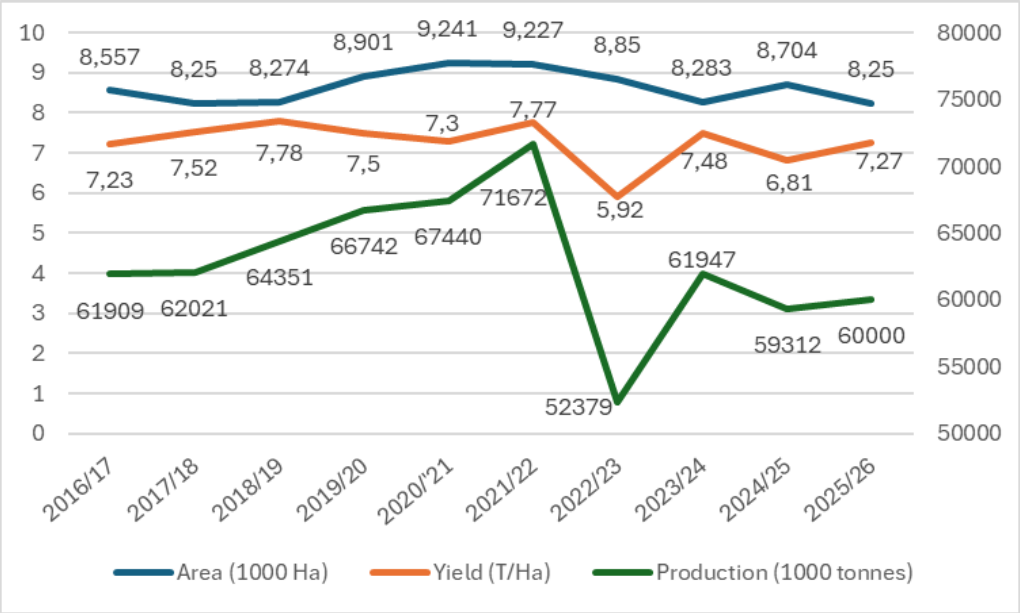

Fig. 2. European Union Corn Area, Yield and Production

Source: USDA - Foreign Agricultural Service 2025a

Brookes (2019) offers a two-decade summary of farm-level experience with Bt maize in both Spain and Portugal. The paper shows that growers who adopt the trait enjoy consistently higher yields and stronger profitability while using noticeably less insecticide, fuel and irrigation water. A composite Environmental-Impact Quotient confirms that the overall toxic load on fields falls, and the grain itself tends to be cleaner via lower levels of mycotoxin as insect damage is kept in check.

Importantly, these agronomic and environmental gains are stable across years and replicated in two neighbouring Mediterranean production zones, which strengthens the external validity of the findings.

The study therefore illustrates how a single genetically engineered event can deliver simultaneous economic and sustainability benefits under real-world conditions. This is further supported by a similar rapport from the European Commission's Joint Research Center (Kathage et al. 2016)

GE maize, while grown in Spain and Portugal, has been banned elsewhere in the EU (Laaninen 2015b). This illustrates that the opt-out clause is used politically rather than risk-based. Making MON 810 a case of divergence, one identical product is a staple in one jurisdiction and politically contentious in another.

A similar divergence is evident for herbicide-tolerant soy, with adaptation of soybean in the U.S. which has risen since 2013, reaching 96 percent, while remaining prohibited for EU cultivation (Fig. 3) (USDA - Economic Research Service 2025b).

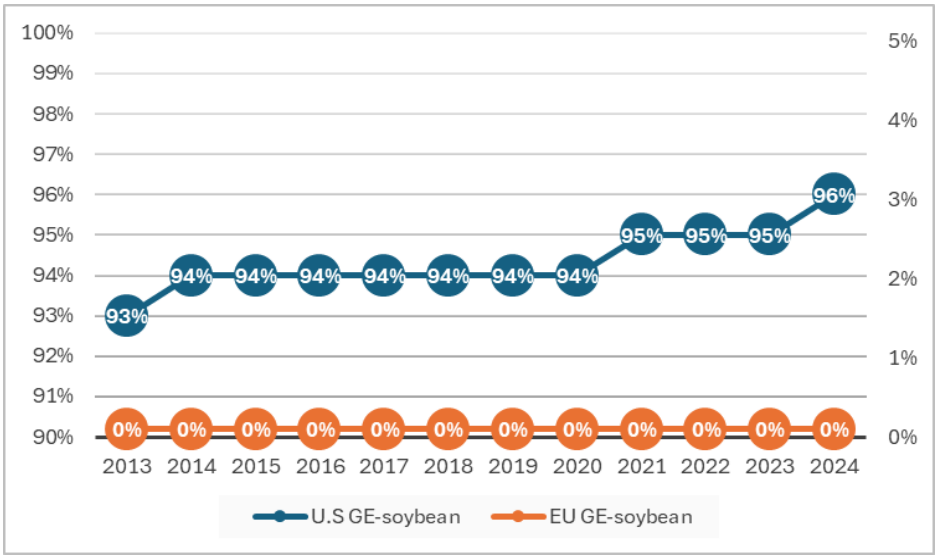

Fig. 3. Adoption of glyphosate-tolerant soybeans (% of soybean area), EU-27 vs United States, 2013-2024.

Source: European Commission 2025; USDA - Economic Research Service 2025b

4.2 Trade exposure to GE soy protein

A report from the USDA's Foreign Agricultural Service (2024) shows that the EU imports between 30 and 40 million tonnes of soybeans and soymeal annually for animal feed, most of which is GE. Of these, 11 million tonnes annually dominates the EU's protein imports and according to a report from the European Commission's Directorate-General for Agriculture and Rural Development (2024) that outlines the EU's dependency on foreign soy imports classifies the feed sector as having a *"high dependency on imported high-protein feed"*.

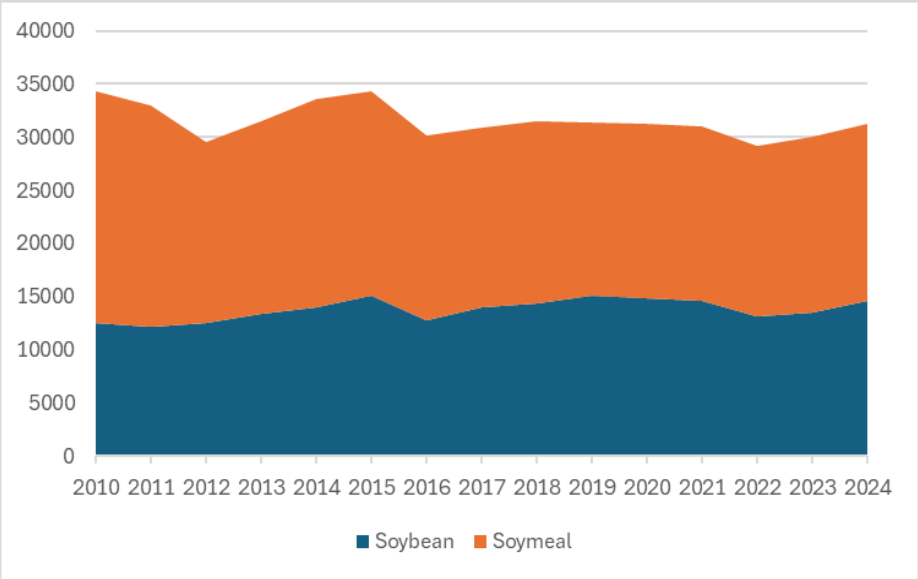

Fig. 4. EU-27 imports of soybeans and soymeal, 2010-2024 (1000 tonnes).

Source: USDA Foreign Agricultural Service 2025a; b

A briefing from the European Parliament from 2015 (Laaninen 2015a) stated that at the time of writing there were 68 GE varieties of crops within the EU that were approved for use in food and feed, many of which are soy.

Stein and Rodríguez-Cerezo (2010) shows evidence of so called asynchronous approval, where a new GE soy strain planted in the U.S. that have not yet been approved in the EU, because of delays, might lead to a shipment being rejected due to low-level presence of unapproved GE material. The article further goes on to say that such delays or mismatched timings have led to trade disruptions.

The soy-import figures show that an exceedingly high share of the protein entering the EU market, about 94 percent, is genetically engineered.

Table 2. Share of imported protein derived from GM soy.

Year	Soy protein share imported (%)
2024	94 %

Source: European Commission, Directorate-General for Agriculture and Rural Development 2024

This underpins later analysis of policy consistency (the EU bans domestic GE cultivation yet relies on imported GE feed) and of the economic risks created by asynchronous approvals (European Commission, Directorate-General for Agriculture and Rural Development 2024).

4.3 Approval Procedures and Compliance Costs

One of the most tangible consequences of the differing regulatory frameworks is the cost and time associated with applying and gaining approval for GE crops. This body of research accentuates how excessive process-based reviews, such as in the EU, result in a higher regulatory burden, longer delays, and fewer commercialized traits.

A key study by Kalaitzandonakes et al. (2007) estimates the cost of new applications of GE crops, with a significant portion of the costs attributed to uncertainty and the need to meet varying international regulatory demands. The authors argue that these high costs are often affordable only to large multinational companies, effectively pricing out public institutions and smaller private developers from the market.

Philips and Williams (2023) further demonstrate that these costs are not fixed but depend heavily on factors such as regulatory scope, risk classification, and data requirements, which can vary widely between regions.

Beyond development and approval processes, additional costs arise from post-approval compliance, such as coexistence measures required to manage potential cross-contamination between GE and conventional crops (Ramessar et al. 2010)

A similar report by Phillips McDougall (2011), commissioned by Crop Life International, looked at the average time to develop and commercialize a new GE crop, with a notable amount spent solely on regulatory approval processes. These

findings align with subsequent studies, such as Smart et al. (2016), which showed an apparent increase in EU authorization times between the early 2000s and 2015.

Morris and Spillane (2008, 2010) show that such delays are not solely bureaucratic in nature. They trace many of these delays to the political deadlock in the EU approval processes, which might cause scientifically approved crops to either be outright denied or otherwise be put in limbo between approval and rejection. This is further supported by Mampuys and Poort (2019) in their Directive (EU) 2015/412 analysis.

Tabel 3. Mean days of major regulatory stages for genetically engineered-crop approvals in the European Union (1996 – 2015) and the United States (1998 – 2015)

Regulatory stage	European Union mean days *n = 58-68*	United States mean days *n = 51-53*
Initial application / field-trial step	**263** (Member-State validation)	**1 614** (field-trial step)
Scientific risk assessment / petition review	**929** (EFSA opinion)	**889** (USDA/EPA/FDA petition review)
Risk management / political decision	**594** (Commission & PAFF/Appeal vote)	**N/A** (no separate political layer)
Entire recorded process*	1 **763**	**2 467**

**Economic clock, ignoring technical stoppages such as EFSA asking applicants for more information while stopping the clock from ticking. Possibly adding years until EFSA publishes its opinion*

Source: Smart et al. 2016

The authors emphasize that a direct comparison of the total processing time in the US and the EU would be misleading: *"We deliberately avoid any statistical comparison of the two region's total approval time".*

Further adding *"It is tempting to make a direct comparison of the approval length between the US and the EU. However, a direct comparison is insensible."* The reasoning being that *"the approval system of the US starts with a 'scientific' step characterized by field trials and ends with a 'bureaucratic' step,"* while *"that of the EU starts when a developer applies to its Member State for approval ... followed by a 'risk assessment' step ... ending in a political decision-making process."*

Furthermore, they point out *that "applications in the US almost always include field trials as applications include cultivation, while the majority of the applications for approval in the EU are for import and processing and not for cultivation."*

Therefore, they conclude, a direct statistical comparison would be *"theoretically flawed,"* and the analysis focuses instead on the trends within each stage (Smart et al. 2016).

4.4 Innovation and Field Trial Impacts

A survey of GMO field trials in Europe, conducted as reported by CORDIS (European Commission 2006), shows that field trials have fallen by a staggering amount since 1998. Both researchers and companies cited regulatory uncertainties and an unfavourable legal environment as reasons for cancelling GM trials.

The study further notes that large multinational corporations conduct a clear majority of field trials, which supports Kalaitzandonakes et al. (2007). Thomaz Zimny (2023) analyses the current field trial framework and finds it unsuitable for plant breeding innovation. Even as the EU considers easing final market approval for certain gene-edited crops, Zimny argues that if the current rules remain unchanged, breeders will still encounter significant obstacles in testing new varieties.

When comparing EU field trial regulations to those of other countries, the paper concludes that EU researchers face a competitive disadvantage due to these constraints.

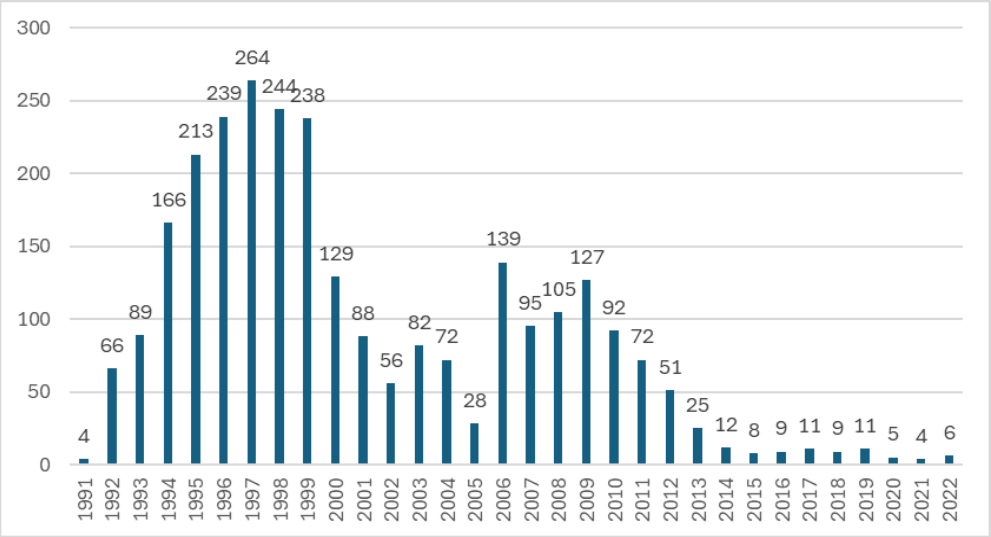

Fig. 5. Total amount of Summary Notifications (SNIFs) to EU Member States (1991–2022)

Source: Eriksson 2020; Ichim 2024

Wesseler et al. (2019) present the concept of forgone benefits resulting from the delayed or obstructed approval of GM crops. This concept signifies the loss of advantages, including yield gains, a decrease in pesticide usage, and the opportunity costs associated with stringent regulations.

This allows for an analysis of the additional costs incurred by such regulations and the repercussions regarding lost innovation and sustainability enhancements.

Areal et al. (2013) examined maize cultivation in Spain, the EU's primary adopter of GM maize, and found a difference in yield and reduced mycotoxin contamination compared to conventional maize, which benefits Spanish farmers.

This paper serves as a positive example of innovation where regulation facilitated adoption.

4.5 Risk Assessment Approaches and Safety Evaluation

Nicolia et al. (2014) reviewed scientific publications on the safety of GE crops from 2002 to 2012. The authors concluded that scientific research did not identify any significant hazards associated with using GE crops during this period. This publication serves as the foundation for the scientific consensus regarding the safety of genetically engineered crops.

It raises questions about assessing risk and suggests that the EU’s stringent regulations are not based on scientific findings.

A U.S. report (Committee on Genetically Engineered Crops: Past Experience and Future Prospects et al. 2016) examined decades of data on GE crops. It found no verifiable evidence supporting the claim that GE crops are inherently riskier than conventional crops and noted that the substantial equivalence assessed by U.S. agencies is broadly regarded as safe. It further recommends reforms to align more closely with the scientific consensus towards trait-based regulatory systems.

An article in the "Critical Reviews in Biotechnology" journal (Panchin & Tuzhikov 2017) reviewed a substantial number of published articles from the last ten years and argues that the damage from a single article showing a mild negative difference between GM and non-GM crops can be significant.

One article can galvanise public debate and cause lasting agitation within public and media perception. The authors urge policymakers to consider the full body of studies rather than focusing on single articles until independent studies have confirmed those articles.

4.6 Public Perception and Political Responses

An article published by the International Service for the Acquisition of Agri-biotech Applications (2019) cites a Eurobarometer survey regarding EU countries' concerns about GMOs. The article reveals a sharp decrease from a similar survey conducted ten years ago, illustrating that public perception has stabilised since the 2000s.

Mampuys and Poort (2019) analyse the opt-out Directive (EU) 2015/412, which authorises Member States to ban the cultivation of GM crops that have already been cleared at EU level on non-risk grounds, such as socio-economic factors or the protection of cultural landscapes. They illustrate the advantages for opponents of GM crops through the low-effort *"stage 1"* notification, which allows short opt-out requests without the need for risk data or socio-economic arguments. Anti-GMO governments can maintain the status quo with virtually no political cost.

In contrast, proponents face additional layers of complexity and delays without achieving faster approvals. The authors also contend that the European Commission underestimated the extent to which Member States continue to challenge the underlying safety assessment.

This blind spot further undermines the directive's effectiveness. Smart et al. (2015), published in the "German Journal of Agricultural Economics", examens the voting behaviours of the EU's approval committees. They revealed that representatives from Member States consistently fail to reach qualified majorities, either for approval or rejection, resulting in a so-called comitology gridlock.

The study indicates that national votes often correlate with domestic public opinions or political agendas rather than scientific opinion from the EFSA. This article presents clear evidence that national politics and public perception overshadow scientific evidence.

Kuntz et al. (2013) critique the French government's 2012 emergency ban on the cultivation of EU-approved Bt maize MON 810. They demonstrate that the *"new risk data"* invoked by Paris had already been assessed and rejected by EFSA, rendering the prohibition a matter of domestic politics rather than evidence-based risk assessment and serving as a clear signal to GMO-sceptic voters.

The authors further highlight how allowing such politically driven opt-outs undermines the EU's claim to a harmonised, science-based regulatory framework and sets a concerning precedent for other Member States.

5. Discussion

5.1 Key Concepts

Risk is distinguished from hazard: a hazard is an intrinsic property, such as a Bt toxin's ability to kill Lepidoptera, whereas risk combines hazard with likelihood of exposure. This distinction serves as the foundation of both EFSA and EPA's safety assessments (EFSA 2016).

5.2 Revisiting the research questions

This chapter interprets the empirical findings presented earlier through two theoretical lenses: Renn's risk-governance framework and Rogers' innovation diffusion model.

The purpose of this section is to address the research questions outlined in the subject matter and scope. The concluding sections reflect on methodological limitations and outline priorities for future research.

5.2.1 Research question 1.

How are GMO regulations applied in practice in the EU and the U.S.?

As mentioned in the introduction, the regulatory frameworks of the EU and U.S. differ in their approach: the EU functions under a single horizontal legal act, while the United States allocates authority among APHIS, EPA, and FDA, interconnected by the concept of substantial equivalence (OSTP 1986; European Parliament, Council of the European Union 2001).
In theory, this suggests differences at the risk assessment stage.

However, in practice, this is not the most significant distinction between the two systems; rather, the risk management stage is where the differences become most apparent.
The data reveal nearly identical scientific timelines; the crucial gap emerges during risk management, where the EU includes a political decision layer absent in the U.S. system (Table 3).

Renn's risk-governance framework (2010) outlines decision-making as consisting of four interconnected phases: pre-assessment, risk appraisal, risk characterisation/evaluation, and risk management, all supported by ongoing communication with stakeholders (Table 1).
He also comments on the separation between risk assessment and risk management:

> There should be a functional separation of risk assessment and risk management in order to ensure the scientific integrity of the risk assessment, avoid confusion over the functions to be performed by risk assessors and risk managers, and reduce any conflict of interest. However, it is recognised that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application (Dreyer & Renn 2009:208)

As highlighted in the introduction, the EU outlines distinct phases for appraisal and management to uphold the scientific integrity of evaluations.

However, this distinction has created three transition points between scientific appraisal and decision-making, with each transition acting as a potential veto point where non-scientific interests might disrupt the process. Although the risk management phase is separate, it remains vulnerable to political influences.

In contrast, the United States integrates both functions within the same governmental agencies. Scientific data flows directly from field trials into statutory reviews and approval. No separate political chamber revisits the science; only judicial review remains an external check (FDA et al. 2020).

The two systems within Renn's model are positioned at opposite ends of the separation spectrum. The framework predicts, and the data confirms, that the EU will face extended timelines and a higher frequency of stalemates specifically during the risk management phase (Smart et al. 2016).

The PAFF committee achieved a qualified-majority vote on a genetically modified organism file only once; in all other instances, matters escalated to the Commission, occasionally resulting in no final decision for several years (Smart et al. 2015). By dissociating scientific appraisal from political decision-making, the comitology system establishes a congested arena with numerous stakeholders and value conflicts, making stalemate nearly unavoidable whenever Member States hold conflicting perspectives on biotechnology.

5.2.2 Research question 2.

What are the practical consequences of these differences in application, risk assessment and approval in regard to field trials, research and crop development?

Renn (2010) emphasises that keeping risk assessment distinct from risk management helps protect scientific integrity. Nevertheless, critics caution that each additional transfer introduces new points where coordination breakdowns or conflicting values may delay or halt decisions (Smart et al. 2015).

The results section has already demonstrated that the EU introduces a political layer in the regulatory process, adding an average of approximately 594 days

(Table 3), while this stage is absent in the U.S.
Research question 2 will be addressed by examining three ripple effects stemming from this separation of risk assessment and risk management.

Field-trial activity

As noted in the results section, the number of applications for field trials in the European Union has declined from a peak of 139 in 2006 to a low of just six in 2022 (Fischer et al. 2025). This contrasts with the United States, where field trials still total around 1500 annually (United States Government Accountability Office 2008).

A survey of private companies and research institutions indicates that this drop can be attributed to an *"unclear legal situation, low public acceptance of GM products, and an uncertain market situation"* (Mitchell 2003).
It can be interpreted that the EU's multiple veto points present a high risk for developers, as any trial can be politically halted after the scientific safety assessment of their products has been completed. This results in developers applying sparingly for trials within the EU.

Relocation of private research and development

Examining the R&D landscape shows that in the mid-1990s, Europe accounted for one-third of global agricultural R&D investments. However, by 2013, this percentage had fallen below ten percent (Phillips McDougall 2013 cited in Smyth et al. 2021).

An article in Transgenic Research attributes this decline to the EU's regulatory framework, which has *"driven billions of euros of investment to jurisdictions with functioning regulatory systems"*. The article also emphasises that EU Directive 2001/18 and a politically motivated approval process create uncertainty and delays, despite clear positive risk assessments from EFSA. Consequently, these challenges hinder R&D progress and innovations in plant breeding, leading many developers to consider relocating their development centres outside the EU (Smyth et al. 2021).

Thinner product pipeline and asynchronous trade

With an increasing number of trials failing to reach the variety testing stage, the commercial pipeline in the EU is becoming more limited. Currently, only one GE crop is authorised for cultivation in the EU (European Commission 2025).
In stark contrast, the U.S. has deregulated 128 GE varieties across 20 crops as of 2024 (USDA - Animal and Plant Health Inspection Service 2025a).

This disparity forces the EU to import over 30 million tonnes of soybeans or soymeal annually, with the majority being genetically engineered (European Commission, Directorate-General for Agriculture and Rural Development 2024; USDA - Foreign Agricultural Service 2025c; b).

In summary, risk assessment and risk management are interconnected, evident in U.S. field testing and trait commercialisation, allowing for unhindered progress. However, when they are overly divided and multiple veto points arise, they hinder field trials, necessitate the relocation of research and development, and restrict domestic crop advancement, ultimately heightening reliance on imports.

5.2.3 Research question 3.

How have these differences manifested in maize and soybean as case studies?

This case study was designed to include genetically engineered crops: one major feed crop (maize) and one principal oil-protein crop (soybean), both critical to EU import dependency and both have extensive histories in the U.S. and minimal cultivation within the EU.

This case study employs Rogers' Diffusion of Innovation as a framework for analysing the differing records, alongside the Agricultural Innovation System, to clarify why innovation brokers in the U.S. appear to reinforce Rogers' attributes, whereas the lack of similar networks in the EU undermines them (Rogers 2003; Klerkx & Gildemacher 2012).

Trialability and regulatory complexity

The number of Summary Notification Information Format (SNIF), that is application sent into the EU, has dramatically dropped from a relative high before the implementation of GMO regulations in 2001 to comparatively negligible in present day (Fig. 5).

Each field trial triggers a public consultation, multiple detailed dossiers and an EFSA risk assessment, and remains vulnerable to late-stage political vetoes at Member-State or Council level.

These factors create high procedural complexity and low trialability for developers (European Parliament, Council of the European Union 2001; European Commission 2009, 2013).

By contrast, APHIS issues approximately 1500 field trial permits and notifications yearly. The majority of trials are approved through a streamlined notification process designed to facilitate the conduct of small plot experiments by firms and land-grant universities at minimal regulatory costs.

This process results in enhanced trialability and a reduced perception of complexity (USDA—Animal and Plant Health Inspection Service 2025b).

Relative advantage and compatibility

In the United States, GE maize constitutes over 90 percent of the total maize area. Studies demonstrates consistent increases in yield as well as a reduction in insecticide expenditures for growers, leading to a distinctly perceived relative advantage that is consistent with pest management programmes, i.e., high compatibility.

Similarly, soybean is associated with a 96 percent adoption rate in the United States in 2024 (Committee on Genetically Engineered Crops: Past Experience and Future Prospects et al. 2016; USDA - Economic Research Service 2025b).

In the EU, MON 810 is confined to 15 percent of Spanish and Portuguese adaptation and less than 1 percent of the total European area (Nicolia et al. 2014; EFSA et al. 2020, 2021, 2022, 2023, 2024; Bayer Agriculture BV 2024).
With such a small footprint, it limits those who can observe the benefits (or completely remove them, in the case of soybeans,) this combined with the political barriers and social conventions, undermines consumer compatibility.

Observability and the role of innovation brokers

The Agricultural Innovation System underlines that innovation brokers translate trial data into relevant knowledge for farmers and developers and coordinate joint learning across the entire actor network (Klerkx & Gildemacher 2012).

The U.S. has an extensive network, organising field days to enhance the exposure of farmers and developers to new innovations (Purdue University 2025). Such brokers boost observability and expedite peer-to-peer diffusion. The EU lacks any continent-wide equivalent. Although there is some visibility in Spain and Portugal, the opt-out option for Member States prevents the showcasing of research plots for those Member States that invoke this option, further diminishing Rogers' observability and trialability scores.

These contrasts across maize and soybean demonstrate that the United States surpasses the EU in all five of Rogers' attributes, except for a lower compatibility with specific EU consumer values, the AIS clarifies why.
With an established broker network and integrated regulatory pathways, the attributes are reinforced. The EU's fragmented network and politicised risk management seemingly undermine them.

The results indicate that GE maize and soybeans have become nearly ubiquitous in the U.S. agricultural environment, whereas they remain niche or entirely absent in the EU. These differences do not appear to be rooted in biological or environmental performance but in how the regulatory framework shapes trialability, complexity, and observability. Furthermore, the presence or absence of innovation brokers amplifies those effects.

These findings complete the explanatory chain from institutional design through delays and R&D relocation to specific adoption patterns in these two major crops.

5.3 Consistency and policy contradictions

Paradoxically, the EU is both a major consumer of imported GE products and prohibits their cultivation (except for MON 810). This inconsistency raises questions about policy coherence, e.g., consumers being shielded from GE cultivation while indirectly supporting GE-based systems. Furthermore, the EU promotes these systems externally while denying its farmers the benefit of the innovations derived from them.

Furthermore, the EU's understanding of the precautionary principle mandates that it be non-discriminatory. It should not arbitrarily apply different treatments based on factors like geographical origin or the nature of the production process. In practice, this principle is most vigorously enforced to cultivate GE crops within the EU, while identical genetic engineering events and subsequent commodities receive authorisation as imports.

Thus, the EU’s application of the precautionary principle is more selective than the all-encompassing framework it intended to represent. It is strict for local farming but more relaxed for trade, motivated by technique-based processes considered devoid of domestic and global risks based on scientific assessment. This underscores the larger argument that institutional structure, rather than scientific ambiguity, is the primary reason for the disparity in adoption between the EU and the U.S. (Morris & Spillane, 2010).

5.4 Limitations

This thesis only analyses maize and soybeans for its case study; this means that the results may not be generalisable to all crops. Additionally, the thesis is built on publicly available documents without access to primary interviews, surveys, or field studies, which can lead to publication bias. As stated earlier, proving direct causality between a given regulatory framework and a specific outcome is

difficult due to several contributing factors, including public perception, funding landscapes, and market forces.

This comparison is restricted to the European Union and the United States. It does not encompass other significant contributors, such as Brazil, Canada, and Argentina, whose regulations are frequently perceived as intermediate, thereby limiting global generalizability.

A small but important note is that most of the referenced literature is in English, which means that national reports or background material in other languages may have been overlooked, potentially distorting the picture of the EU debate.

Farms in the United States are, on average, nearly ten times larger than their European counterparts, even though there are over four times as many farms in the EU (USDA - Economic Research Service 2025c; European Commission 2022b; Lacy 2025). American farming has therefore become highly pragmatic by necessity, with economic pressures and the need to preserve soil quality making GE crops an attractive option. In contrast, in 2020, more than 60 percent of EU farms operated on less than 4.9 hectares (European Commission 2022b). This can skew the statistics when comparing the total area of adaptation; it would take about ten typical EU farms to match the land area of one average U.S. farm adopting GE seed.

5.5 Future research

This thesis emphasises the influence of EU and U.S. regulations on the innovation speed of genetically engineered crops.

However, it also identifies several areas where further research is needed, particularly in examining the effects of the proposed EU reform on new genomic techniques, especially concerning targeted mutagenesis.
Implementing a model-based approach that correlates approval timelines with R&D investments and cultivated areas could offer early insights into the reform's potential impact.

Moreover, incorporating a broader variety of crops than those included in this study would improve its generalizability. Conducting the analysis again for tomatoes, potatoes, or apples enables us to verify if the identified trends are also applicable to vegetatively propagated or high-value speciality crops.

Additionally, a thorough comparison between Member States, like Spain, which allows commercial cultivation of MON 810 maize, and France, which

forbids it, could clarify the impact of national implementation on the practical enforcement of EU legislation.

Conducting in-depth interviews with farmers, biotech companies, and authorities, along with surveys measuring their perceived barriers and drivers, could yield a more nuanced picture of how regulations are translated into innovation and investment decisions.

5.6 Conclusion

The regulatory framework is crucial in determining the results of adoption processes. Its influence is felt not only through the direct approval or denial of new technologies and practices but also through elements like associated costs, the intricacy of the regulatory landscape, and the timing of decisions.
The study's findings support the idea that within the EU framework, political vetoes frequently outweigh scientific consensus, this dynamic leads to significant material impacts that go beyond regulatory outcomes; it affects innovation, shapes trade relationships, and ultimately influences agricultural income.

By grasping these implications, stakeholders can more effectively navigate the complexities of the regulatory environment to enhance both the economic and scientific prospects of agricultural innovations. The research shows that institutional design, not scientific uncertainty, predominantly shapes the future of GE crops.

In the United States, a product-focused, integrated-agency system channels scientific data directly into regulatory decisions, facilitating rapid field experimentation (around 1,500 permits each year) and significant commercial uptake of GE maize (93 percent) and soybean (96 percent). Conversely, the European Union’s process-driven structure adds three sequential political veto points following the EFSA’s scientific opinion, resulting in delays of approximately 600 days and a decline in field-trial notifications to just six in 2022.

Procedural issues are leading to real consequences. Private R&D have moved out of the EU, resulting in only one approved genetically engineered (GE) crop (MON 810), while the U.S. has 128 fully deregulated events. This creates a gap in adoption that the EU compensates for through trade, importing over 30 million tonnes of primarily GE soy feed annually.
This highlights a contradiction in EU policy: it limits domestic GE crop cultivation but still depends on foreign GE production.

Adjusting risk assessments to match product features, simplifying field-trial approvals, and coordinating import and cultivation approvals would lower regulatory confusion, boost local breeding efforts, and improve trust between policy and real-world applications.

The evidence shows that the EU could better achieve its goals of safety and consistency by changing from a one-size-fits-all process to a more tailored, trait-based system.

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☒ YES, I, John Allmark, have read and agree to the agreement for publication and the personal data processing that takes place in connection with this.