New Genomic Techniques in Europe: Perspectives on the European Commission's Policy Initiative Concerning the Regulation of NGTs in the EU

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ABSTRACT

The European Union has long been known for its strict rules on Genetically Modified Organisms (GMOs). With an extensive regulatory framework in place that covers authorisation procedures, traceability rules, labelling requirements and other legal obligations, the EU arguably has one of the most stringent GMO regimes in the world. In recent years, this scientific field has progressed extensively, which has led to the rise of New Genomic Techniques. These technologies allow for increasingly precise genetic changes – in some cases without the need to introduce foreign DNA – and have opened up a new debate on the regulation of these technologies in the EU. In 2018 the Court of Justice of the European Union ruled that certain New Genomic Techniques were to fall under the scope of the EU's regulatory framework for Genetically Modified Organisms (GMOs). Since then, the European Commission has started a policy initiative to pursue new regulations for NGTs such as cisgenesis and directed mutagenesis, which is the focus of this study. This paper focuses on different perceptions of the European Commission's main motivations for pursuing regulatory change through documentary analysis and a number of interviews with organisations and individuals in this field. By combining these research methods with thematic analysis and a theoretical framework based on private and public interest theories of regulation, this paper identifies several overarching themes which offer insights into Commission's actions in this field. The findings indicate that there are several conflicting perspectives on the Commission's policy initiative, which each support different theoretical perceptions of these regulatory developments. This paper, therefore, provides preliminary insights into the perspectives on the drivers behind this policy initiative and paves the way for further research into this rapidly developing field.

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LIST OF ABBREVIATIONS

- CJEU = Court of Justice of the European Union
- DNA = Deoxyribonucleic Acid
- EFSA = European Food Safety Authority
- EGD = European Green Deal
- ESSB = Erasmus School of Social and Behavioural Studies
- EU = European Union
- F2F Strategy = Farm to Form Strategy
- GDPR = European General Data Protection Regulation
- GM = Genetically Modified
- GMO = Genetically Modified Organism
- IIA = Inception Impact Assessment
- NGO = Non-Governmental Organisation
- NGTs = New Genomic Techniques
- UNSDGs = United Nations Sustainable Development Goals
- USA = United States of America
- WTO = World Trade Organisation

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1. INTRODUCTION

1.1. Background & Empirical Puzzle

While humankind has engaged in the genetic modification of crops for millennia through processes such as selection and crossbreeding, the technological advancements of the past century have opened up a whole new frontier for innovation (Chassy, 2007). New genetic technologies have advanced rapidly over the past few decades and provide increasingly precise tools for the modification of plant species (Davison & Ammann, 2017). Desirable characteristics can be pre-programmed into the DNA of target plants, such as pest resistance, increased crop yields, biofortification, and herbicide tolerance (FDA, 2020a) and some techniques even provide the opportunity to produce changes within the genome without the introduction of foreign DNA (Selfa et al., 2021). According to the proponents of these techniques, such genetic alterations and the resulting traits could produce wide-ranging benefits for the agricultural sector and society as a whole (McNamara, 2022). For this reason, Genetically Modified Organisms (GMOs) and New Genomic Techniques (NGTs) have been hailed by some as an important tool in the fight against food shortages, crop damage, and falling crop yields (Bawa & Anilakumar, 2013; McNamara, 2022). In contrast, genetically modified plant species and their introduction to the natural environment have also been met with fierce resistance from different groups and consumers due to the possible risks associated with Genetically Modified (GM) crops (Bawa & Anilakumar, 2013). The two sides of the debate, therefore, have contrasting views on the possible uses and safety of GMOs and NGTs.

These discussions have also led to diverging rules and policies around the world pertaining to the regulation of genetically modified plant species (Lau, 2015). The European Union (EU), for instance, is known for its stringent regulation of GMOs (Lau, 2015), which includes a multi-tiered system that focuses on traceability, labelling, environmental protection, the preservation of human health, harmonised risk assessments and authorisation procedures for GMOs across the EU (European Commission, 2022c). The EU's GMO legislation is primarily based on six regulations and directives from the early 2000s, which range from rules on the traceability of GMOs to frameworks outlining the procedure and conditions for the release of GMOs into the environment (European Commission, 2022c). Additionally, the Court of Justice of the European Union (CJEU) ruled in 2018 that the aforementioned legislation also applied to plant species whose genes have been edited using certain New Genomic Techniques (NGTs), such as directed mutagenesis and cisgenesis (CJEU, 2018). This ruling expanded the scope of the EU's GMO legislation to include organisms in which only minor genetic

alterations had taken place - sometimes even within the same genome - (Rehbinder, 2018), which highlights the stringency of the existing EU legislation. Furthermore, the strictness of the EU's regulation of GMOs is also visible in EU Directive 2015/412, which gives member states the right to temporarily ban or limit the cultivation and use of GMOs in their territories under certain conditions (Directive 2015/412, 2015).

Strikingly, while the EU largely depends on GM crops for animal feed (Castellari et al., 2018), only two EU member states grow GM crops commercially: Portugal and Spain. In 2020, these two countries grew 4,215.6 and 98,151.6 hectares of land with GM crops respectively (REA, 2021). Comparatively, the United States of America (USA), the world's largest producer of GM crops, cultivated 71,500,000 hectares of land with genetically modified crops in 2019, whereas Brazil used approximately 52,800,000 hectares (Shahbandeh, 2022). Hence, the amount of land devoted to the cultivation of GM crops in the EU arguably pales in comparison to other cultivators of GMOs. The differences between the EU and other countries are also visible in the extent to which GM crops are used in the agricultural sector. In the USA, 92% of the corn grown in 2018 was genetically modified (FDA, 2020b) compared to 35% in Spain in the same year (Ministerie van LNV, 2019). Furthermore, the number of EU member states involved in the cultivation of these has continued to decline in the past few years as other EU member states, such as Czechia, Slovakia and Romania, have halted the cultivation of GM crops (Ichim, 2021).

However, with the advent of New Genomic Techniques (NGTs) and the 2018 CJEU judgment, the European Commission has arguably started to change its regulatory stance on NGTs. As mentioned above, the CJEU ruling in 2018 confirmed that certain NGTs fall under the GMO legislation adopted by the EU in the early 2000s (CJEU, 2018). Nevertheless, the Commission has recently announced its intention to review the regulation of NGTs under the existing GMO legislation by arguing that the current legislative framework is unfit for the regulation of NGTs (Fortuna & Foote, 2021). Hence, in 2021, the Commission started a new policy initiative to review the existing regulations with the aim of potentially revising the regulatory status of NGTs under the current legislative framework for GMOs (European Commission, 2022d).

For now, the provisional key points outlined by the Commission focus on the introduction of plant species created using NGTs, such as targeted (or directed) mutagenesis and cisgenesis (European Commission, 2021d). Furthermore, the Commission's proposal will aim to clarify the legal rules pertaining to the regulation of GMOs aand NGTs cross the internal market of the EU (European Commission, 2021d). While the Commission has not yet adopted

a full proposal concerning the regulation of NGTs, its recent policy initiative to consider an adaptation of the GMO legislation for NGTs already arguably marks a noticeable change in its approach towards GMOs and NGTs and their introduction to the internal market by opening up the possibility of creating a new regulatory framework for NGTs in the EU. This, therefore, represents the empirical puzzle underlying this study.

1.2. Societal Relevance

Regarding the societal relevance of this paper, it is important to note that GMOs have been at the centre of widespread debate across the world (Maghari & Ardekani, 2011). Over the years, farmers, citizens, businesses, and governments have voiced different opinions on the use and cultivation of GMOs, and the introduction of genetically modified plant species has elicited strong reactions from both sides of the debate (Bawa & Anilakumar, 2013). As mentioned above, concerns regarding the potential environmental and health risks associated with GMOs also permeate these debates (Bawa & Anilakumar, 2013). Regulations concerning GMOs and NGTs at the EU-level arguably also have very tangible consequences for the European agricultural and biotechnology sectors and can also affect consumers and the range and type of agricultural products available to them. Furthermore, the societal relevance of this thesis also lies in the fact that it aims to study a possible future shift in the regulation of GMOs produced with NGTs in the EU that could potentially transform the role of biotechnology in EU member states. Regulatory changes in this policy area may also affect different levels of society, which thereby highlights the societal relevance of this thesis. Lastly, given that different actors in this debate have pointed out various advantages and disadvantages that may be associated with the use of GMOs and NGTs (Gaille, 2017), it is arguably important to study the development of the regulation of these technologies at the European level as well as the different perspectives on this development considering the potential impact of such decisions on agriculture and international trade.

1.3. Academic Relevance

Similarly, this thesis is also academically relevant as it aims to study a recent phenomenon that has not yet been studied in great detail, which thereby fulfils the requirements of academically relevant research as established in the existing literature on academic research (Lehnert et al., 2007, p.23-25). While past research has primarily delved into the techniques used to produce GMOs and the legislation introduced by the EU in the early 2000s (Lee, 2008; Tiberghien, 2009), this thesis aims to study the most recent developments, which is why this paper arguably represents an original addition to the existing literature on the regulation of

GMOs and NGTs in Europe. Furthermore, as the biotechnological field continues to evolve rapidly, as evidenced by the introduction of NGTs, further research is needed into the regulation of GMOs, NGTs and the policies introduced by different actors, such as the EU and its institutions. The findings of this study could also have some explanatory leverage in other policy areas of European policymaking, which further highlights the academic relevance of this thesis. The results may also offer valuable preliminary insights when studying the development of GMO and biotechnology regulation in other regions, countries, and trading blocs. Furthermore, this thesis is also academically relevant due to the fact that it focuses on different perspectives on the Commission's new policy initiative through a theoretical lens, which allows this thesis to build on the different theories in the field of regulation and evaluate their applicability to regulatory developments in the EU. Additionally, while the Commission has yet to present a final proposal on the regulation of NGTs in the EU, this paper represents an original academic contribution by studying perspectives on the Commission's policy initiative and the process leading up to the final proposal through thematic and theoretical analysis.

1.4. Research Question & Methods

Hence, based on the empirical puzzle as well as the societal and academic relevance of this paper outlined above, this thesis will focus on the following research question: **when looking at the perspectives of different actors in this field, does Public Interest Theory or Private Interest Theory best explain the European Commission's policy initiative to review the regulation of New Genomic Techniques under the existing GMO legislation?**

To answer the proposed research question, this thesis makes use of existing theoretical frameworks, such as the Public Interest and Private Interest Theories of regulation, which offer contrasting perspectives on what may cause regulation to arise and change. Different theoretical expectations have been devised on the basis of these theories, which will form the basis for further analysis in this paper. Moreover, this paper combines documentary analysis with seven interviews to determine which theory corresponds best to the case outlined above. It is also important to note that the scope of this paper is limited to studying genetically modified plant species in the EU. While the genetic modification of animal species is arguably an intriguing topic that also warrants further research, the EU currently does not have any genetically modified animals or animal products approved for use in the EU's internal market (EFSA, 2022), which justifies the limited scope of this paper. Furthermore, while there are many different types of NGTs, this thesis focuses specifically on the NGTs addressed in the

Commission's policy initiative, namely cisgenesis and directed mutagenesis (European Commission, 2022d).

1.5. Structure

For the purpose of clarity, this paper has been divided into different sections. Following the introduction outlined above, this thesis first presents an overview of the existing literature and background information relevant to this research project. Next, this paper outlines different theories from the existing literature, followed by a number of contrasting hypotheses, which will form the basis of this paper's analysis. This is followed by the methodology section, in which the research design is explained in detail, and a results section. After this, the results are analysed in the discussion section, which is then followed by a brief conclusion outlining the key points covered in this thesis.

2. BACKGROUND/LITERATURE REVIEW

Before delving into the guiding theoretical frameworks and analysis, it is first important to outline the existing literature on this topic. Thus, this next section will provide background information on the key concepts introduced above and the state of the existing academic literature, which will provide further evidence for the research gap this paper aims to tackle.

2.1. Defining GMOs

While many different definitions of GMOs exist, the most relevant definition, in this case, can be found in the existing EU legislation, which defines GMOs as "organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination" (Plan & Van den Eede, 2010, p.3). This definition clearly distinguishes between the genetic modification technologies that were introduced in the past few decades and the agricultural techniques that have existed for millennia, such as selection and crossbreeding. However, before outlining the different techniques used in this field, it is important to outline the history of GMOs and the types of GM crops produced in recent years, which is what the next section of this literature review will address.

2.2. A Brief History of GMOs

2.2.1. Early Origins

As mentioned briefly above, humans have engaged in the manipulation of genetic material for millennia, even if they were sometimes unaware of this (Fedoroff, 2010). Traditional agricultural techniques, such as crossbreeding certain plant species and selecting organisms based on their characteristics, essentially also represent a form of genetic modification (Uzogara, 2000). Hence, many of the agricultural products consumed around the

world looked very different prior to their domestication by humans (Fedoroff, 2010). For example, the corn grown commercially around the world looks almost nothing like teosinte, its closest wild relative, even though the two species share a common ancestor and only have a few different genes (Fedoroff, 2010). Another famous example is the modern banana. While many are now used to the widely available (almost) seedless variety, most people are unaware of the fact that, in the past, bananas were typically packed with tough round seeds that made eating the fruit a tricky affair (Hunt & Premathilake, 2018). Thus, over the years, banana varieties were selectively bred until the modern plant produced sterile seedless bananas (Hunt & Premathilake, 2018). Other plant species have undergone similar metamorphoses, such as tomatoes, tubers, and grains, using a multi-generational selection process through which human beings were able to produce new varieties that better suited their demands (Fedoroff, 2010).

The first insights into what may be causing these changes were provided by Gregor Mendel, an Austrian monk whose work on inherited traits in 1865 paved the way for further biotechnological innovation and the foundation of the field of genetics (Edelson, 1999). As the field progressed, new innovations ultimately led to the creation of the first modern GMO in 1973 by Herbert Boyer and Stanley Cohen using genetic engineering technologies (Science History Institute, 2016). Boyer and Cohen used the DNA of other organisms to create a type of bacteria with antibiotic resistance (Science History Institute, 2016). Hence, the topic of GMOs has, in recent years, moved past the traditional techniques of selective breeding and now commonly refers to the highly complex techniques developed in the past few decades.

2.2.2. Recent Developments

These genetic modification techniques have been used to produce several GM crops, such as the MON810 corn approved for use in the EU. MON810 is a Bt-corn, which has been genetically modified to include genes from *Bacillus thuringiensis*, a type of bacteria commonly found in soil (Byrne, 2014). These ‘Bt’ genes allow the corn plant to naturally produce proteins that can kill crop pests, such as European corn borers (Byrne, 2014), which are known for their deleterious effect on corn yields (OMAFRA, 1998). Other examples include genetically modified cotton, which produces higher yields, GM crops that are resistant to certain types of insecticide and herbicide (Byrne, 2014) and plants that have been modified to produce certain traits, such as longer shelf lives (Rangel, 2015).

2.3. Genetic Modification & Editing Techniques and NGTs

When looking at the techniques used to produce GM crops, a contrast can be made between more traditional techniques and new technologies that may fall under the umbrella term 'New Genomic Techniques', which are described below.

2.3.1. Traditional Techniques

In the more traditional category, techniques such as mutagenesis and protoplast fusion are commonly discussed in the academic literature (Institute of Medicine (U.S.), 2004). While the term mutagenesis has been widely used to refer to both traditional and newer techniques in the field of biotechnology, mutagenesis in the traditional sense refers to the use of certain chemicals or ionising radiation to promote random mutations in the genome of selected species (Institute of Medicine (U.S.), 2004, p.27). Plants are then grown to maturity, after which the cultivator checks the resulting plants for the desired traits (Institute of Medicine (U.S.), 2004). Mutagenesis has been used in many contexts since the 1950s and is, therefore, often seen as a more traditional method of genetic modification (Oladosu et al., 2016). Protoplast fusion, on the other hand, requires the fusion of two protoplasts (plant cells without cell walls), which allows for the creation of hybrids with genetic material from both 'parent' cells (Institute of Medicine (U.S.), 2004).

Other 'traditional' methods of genetic modification include techniques that are also commonly known as genetic engineering. These methods include, for example, the use of vectors (viruses or other microbes) to change specific parts of the targeted genome and DNA 'bombardment' using microprojectiles (Institute of Medicine (U.S.), 2004). Vector-based techniques typically use a soil bacterium known as *Agrobacterium tumefaciens*, whose natural cycle of life lends itself to the intentional genetic modification of plants (Powell, 2015; Royal Society, 2016). This specific type of bacteria reproduces by copying some of its own genes and implanting them into a target plant cell (Powell, 2015). Thus, by controlling the type of genes this bacterium changes in its cell host, the cultivator can attempt to produce specific traits in the target species. Hence, this GM technique is reportedly one of the most widely used techniques in this field (Institute of Medicine (U.S.), 2004). In contrast, microprojectile bombardment is a much less specific method of genetic modification and requires the use of microscopic pieces of metal that have been coated with specific genes, which are then shot at the target cells (Royal Society, 2016).

2.3.2. New Genomic Techniques

However, in recent years new technologies have been created that allow for complex and specific changes to be made to the target species' genome, which are referred to as gene editing techniques or New Genomic Techniques by the Commission. (Kawall et al., 2020) According to a study commissioned by the Commission, NGTs can be defined as "techniques that are capable of altering the genetic material of an organism and that have emerged or have been […] developed since 2001" (European Commission, 2021, p.6). These tools include gene editing techniques commonly known as directed mutagenesis, such as CRISPR-Cas9 [1] (Kawall et al., 2020). The CRISPR-Cas9 technology combines the enzyme Cas9 with a strand of guide RNA, which allows scientists to alter specific parts of the DNA sequence by altering, removing or inserting genetic information, which ensures that the inserted genes only bind to the desired location (El-Mounadi et al., 2020). Furthermore, in contrast to conventional mutagenesis, directed mutagenesis allows for more precise alterations when compared to more traditional forms of mutagenesis (Walker, 2016) and is currently considered to be the most precise technique available (YourGenome, 2022). It is also important to note that directed mutagenesis also allows for changes within the genome that do not require the use of foreign DNA (Selfa et al., 2021). Hence, directed mutagenesis, which is also sometimes referred to as targeted mutagenesis, allows "mutations [to be] induced in selected target locations of the genome without insertion of genetic material" (European Commission, 2021b, p.1).

Another NGT that has generated significant interest is cisgenesis, which is a technique in which "genetic material […] is inserted into a recipient organism from a donor organism with which the recipient is sexually compatible (crossable) in nature, e.g., [introducing] a gene from a wild potato into a domesticated potato" (European Commission, 2021b, p.1). Consequently, some argue that despite the use of technologically advanced techniques, the resulting plant species could also have been created using more conventional and traditional agricultural breeding methods (Laaninen, 2019).

Thus, biotechnological innovation has created increasingly precise methods of genetic modification, which, as outlined above, have reignited the discussion on GMOs in the EU. Given these recent developments, the next section of this literature review will focus on the current regulation of GMOs in the EU.

[1] While there are many other techniques, it is beyond the scope of this paper to describe these technologies in detail.

2.4. GMO Legislation in the European Union

2.4.1. Early Beginnings

Until the middle of the 1980s, the EU's GMO regulations were noticeably less stringent than those of other countries at the time, such as the USA (Lynch & Vogel, 2001). However, as the USA began exporting genetically modified soybeans, the Commission faced heavy resistance from various food retailers and interest groups, who demanded the separation of GM soybeans from non-GM soybeans with appropriate labelling (Lynch & Vogel, 2001). This ultimately contributed to the creation of a new regulatory framework specifically designed for GMOs in the EU's internal market (Lynch & Vogel, 2001). While the EU had approved certain GM crops in the 1990s, a de facto EU-wide moratorium was imposed on GMO authorisations until the new regulatory framework was in place (Gonzalez, 2007). This ultimately led to a trade dispute at the World Trade Organisation (WTO) when Argentina, the USA, and Canada filed a complaint against the EU for its de facto import ban on GM crops (Gonzalez, 2007). Although the WTO eventually ruled in favour of the complainants (Gonzalez, 2007), the EU's GMO regulation is still regarded as one of the strictest regulatory frameworks in the world (Woźniak et al., 2021). The next section of this thesis will, therefore, delve into the existing legal instruments in the EU that regulate GMOs.

2.4.2. The European GMO Legislation

Aside from supplementary rules and recommendations, the EU's regulatory framework on GMOs consists of the following legal instruments: Directive 2001/18/EC, Regulation 1829/2003, Directive 2015/412, Regulation 1830/2003, Regulation 1946/2003, and Directive 2009/41/EC (European Commission, 2022c). EU Directive 2001/18/EC (henceforth: the 2001 GMO Directive) regulates the deliberate and experimental release of GMOs into the environment (Directive 2001/18/EC, 2001) and is primarily based on the notion of preserving human and environmental health and the precautionary principle (EUR-Lex, 2017). The precautionary principle is a concept used in the field of international environmental law, which can be defined as "an approach to risk management, where, if it is possible that a given policy or action might cause harm to the public or the environment and if there is still no scientific agreement on the issue, the policy or action in question should not be carried out" (EUR-Lex, 2022).

The 2001 GMO Directive also specifically places certain genetic modification techniques under the scope of the directive, such as protoplast fusion involving distinct plant species and vector-based modification techniques, and outlines a methodology for GMO risk

assessments (Directive 2001/18/EC, 2001). However, not all genetic modification techniques are regulated in the EU. Notably, radiation-induced mutagenesis is explicitly excluded from this directive due to the fact that this method emulates processes in the natural environment of the target species, albeit with a form of human intervention, and "has a long history of safe use" (Laaninen, 2019, p.2). Protoplast fusion involving cells from the same species is also exempted from the regulations in the directive (Directive 2001/18/EC, 2001). Furthermore, the 2001 GMO Directive also includes a monitoring requirement for GMOs released into the environment and a safeguard mechanism that allows for the termination or suspension of released GMOs if new information arises concerning their safety (EUR-Lex, 2017). Furthermore, product labels must indicate that the product is a GMO or contains GM ingredients (EUR-Lex, 2017).

Building on the 2001 GMO Directive, Regulation 1829/2003 outlines the authorisation procedure for new GMOs (EUR-Lex, 2015b). This regulation specifies that applications must be submitted to the European Food Safety Authority (EFSA) for all uses of the GMO, including cultivation, use in animal feed, and human consumption (Regulation 1829/2003, 2003). Under this regulation, the Commission is tasked with managing the risks of GMOs and is expected to issue a recommendation concerning new GMO applications to the Standing Committee on Food Chain and Animal Health (Regulation 1829/2003, 2003). Furthermore, the regulation also stipulates that GMOs, whether intended for animal or human consumption, must clearly be labelled as such, with the exception of products with a GMO content of less than 0.9% if the inclusion of GMOs in the product cannot be avoided (Regulation 1829/2003, 2003).

In contrast, Directive 2015/412, which is an amendment to the 2001 GMO Directive introduced and adopted in 2015 (EUR-Lex, 2018), gives member states the right to restrict or ban the cultivation of GMOs in (parts of) their national territories provided that the decision is non-discriminatory and proportional (Directive 2015/412, 2015). The directive outlines various reasons that can be cited as a justification for the decision to ban or restrict GMOs, such as possible socio-economic impacts, certain policy objectives, and urban design issues (Directive 2015/412, 2015). The directive also specifies that member states that do cultivate GMOs must attempt to avoid cross-border contamination of GMOs in case a neighbouring member state bans or restricts GMOs (Directive 2015/412, 2015). As of 2022, 19 out of 27 member states in the EU have banned or restricted GMOs in (part of) their national territories (European Commission, 2022e). This directive is also known as the 'Opt-Out Directive'.

Furthermore, Regulation 1830/2003 focuses specifically on traceability, which refers to "the ability to trace GMOs and products produced from GMOs at all stages of their placing

in the market through the production and distribution chain" (Regulation 1830/2003, 2003). Under this regulation, sellers of GMO products have an obligation to notify buyers about the GMO contents of products, provide a 'declaration of use', and list the unique identifies of each GMO used in the product (Regulation 1830/2003, 2003). The seller also must also clearly identify GMO ingredients on the ingredient list of products. In terms of labelling, this regulation adds a specific product packaging requirement that communicates to the buyer that the product contains GMOs by using the phrase "[t]his product contains genetically modified organisms" (Regulation 1830/2003, 2003). Nevertheless, this regulation maintains the exceptions introduced by Regulation 1829/2003 and requires EU member states to check whether the labelling rules are being followed (EUR-Lex, 2016).

Moreover, Regulation 1946/2003 establishes rules for the export of GMOs and GM products to countries outside the EU (EUR-Lex, 2015a). These rules include notification and information requirements when exporting GMOs and allow for the implementation of the provisions of the 2000 Cartagena Protocol on Biosafety (EUR-Lex, 2015a). Lastly, Directive 2009/41/EC outlines the rules pertaining to the 'contained use' of GMOs (i.e., in laboratories or test facilities), such as mandatory contingency plans in the event of a dangerous incident or accidental release into the environment (Regulation 1946/2003, 2003). This directive also specifies different risk classes as well as consent and authorisation mechanisms and requires member states to inform citizens who may be affected by an accident involving GMOs (Regulation 1946/2003, 2003).

While this section is by no means an exhaustive review of all rules, directives, regulations, and provisions that apply to GMOs, these legal instruments give an overview of the EU's current regulatory framework.

2.5. The CJEU Case & NGTs in Europe

As mentioned above, the introduction of NGTs in the field of biotechnology has led to renewed discussions surrounding GMOs and the techniques that are regulated by the EU. While the 2001 GMO Directive explicitly excludes genetic modification techniques such as mutagenesis that have a long track record of safe use, mutagenesis was left undefined in the directive, which led to uncertainty concerning the status of NGTs since many of these new techniques also fall under the umbrella term 'mutagenesis' (Dederer & Hamburger, 2022). Nevertheless, in 2015 a number of French associations brought a case before the French Council of State, which then asked the CJEU to issue a preliminary ruling (CJEU, 2018). The nine French associations argued that mutagenesis techniques have progressed since the 2001

GMO Directive and allow for changes in the genome without introducing external DNA that cannot occur in a natural environment, such as herbicide resistance in plants (CJEU, 2018). In contrast, others have argued that these NGTs allow for genetic changes to be made that can occur naturally and can be so minimal that the resulting organism is practically indistinguishable from organisms that have mutated naturally (Rincon, 2018).

In its preliminary ruling, the CJEU held that the 2001 GMO Directive does, in fact, apply to mutagenesis techniques and NGTs that produce genetic changes that do not happen in nature, such as through directed mutagenesis, even if these techniques do not involve the introduction of foreign DNA (CJEU, 2018). However, the CJEU also specified that the exemption outlined in the directive for mutagenesis techniques that have been safely used for decades still holds, such as mutagenesis induced by radiation or chemicals (CJEU, 2018). Using the precautionary principle, the Court also held that the directive applies to new technologies developed since the introduction of the 2001 GMO Directive since NGTs may produce similar risks as technologies that existed at the time of the directive's adoption (CJEU, 2018). Thus, the CJEU's judgment confirmed that even NGTs that allow for genetic changes that do not require the introduction of foreign DNA fall under the GMO legislation outlined above. The CJEU's ruling, therefore, represented a significant setback for the biotechnology sector (Michalopoulos, 2018).

2.6. The European Commission's Initiative & GMOs

After the 2018 CJEU ruling on the 2001 GMO Directive, the Council of the European Union asked the Commission in 2019 to look into NGTs and the applicability of the existing regulatory framework (European Commission, 2021d). This study was eventually released in 2021 and contained several conclusions that elicited a wide variety of responses (Fortuna & Foote, 2021). The study's conclusions indicated that the current legislation on GMOs was unfit for the regulation of NGTs and cited several benefits associated with NGTs, such as the possibility of creating a "more resilient and sustainable agri-food system" (European Commission, 2021a, p.2). Thus, based on these conclusions, the Commission has started preparing a new proposal that would apply to NGTs considering the outcomes of the Commission's study (European Commission, 2021d). As indicated in the EU's Inception Impact Assessment, which gives an indication of the policy options that could be included in a future proposal, the Commission is contemplating adapting the risk assessments, approval rules, as well as the traceability and labelling requirements for crops produced with NGTs (European Commission, 2021d). These new regulations would be "proportionate to the risk involved" that

would enable "the placing on the market of plants produced by targeted mutagenesis or cisgenesis [i.e., NGTs] provided they are safe for health and for the environment" (European Commission, 2021b, p.6). As part of this initiative, the Commission requested feedback from stakeholders from September to October 2021 and opened a public consultation process in April 2022 (European Commission, 2022d). After completing this process, the Commission aims to adopt a definitive proposal in the first half of 2023 (European Commission, 2022d).

The Commission's initiative has been criticised by those opposing GMOs, who argue that the initiative essentially provides for the deregulation of GMOs produced through NGTs in the EU's internal market (Foote, 2021). Others have praised the initiative for its capacity to facilitate further innovation in the biotechnology industry (ALLEA, 2020; Fortuna & Foote, 2021). Despite these differing perceptions of the Commission's initiative, these policy options arguably represent a shift in the EU's regulation of GMOs by opening up the possibility of creating a new regulatory framework for NGTs in the EU.

2.7. GMOs, NGTs and the European Union: The Existing Literature

As outlined above, the topic of GMOs has been discussed extensively in the existing academic literature. The academic literature on the general topic of this paper is well-established and has been studied from different perspectives by researchers from a wide range of disciplines. Some authors have, for example, focused on the technical and scientific aspects of GMOs and NGTs (Eckerstorfer, Dolezel, et al., 2019), while others have researched the different perspectives on GMOs in Europe and other regions of the world (Napier et al., 2004; Wunderlich & Gatto, 2015). Similarly, the issues associated with the traceability criterion for NGTs in the EU's GMO legislation outlined above have been researched extensively (Broothaerts et al., 2021; Zimny & Sowa, 2021).

Furthermore, there is also an established body of academic research on the regulation of GMOs at the EU-level from the early 2000s. These studies have focused mainly on the regulatory differences between the USA and the EU as well as other non-EU countries (Eckerstorfer, Engelhard, et al., 2019; Lynch & Vogel, 2001). Other studies have looked into specific aspects of the EU's GMO legislation and the debates, legislative processes, and developments leading up to the adoption of the existing regulatory framework (Christoforou, 2004; Dąbrowska, 2007; Grossman & Endres, 2000; Lee, 2008).

More recently, given the growing interest in NGTs and the CJEU's decision on the applicability of the EU's GMO legislation to NGTs, an increasing number of studies have focused on the subject of NGTs (Purnhagen & Wesseler, 2021; Van Der Meer et al., 2021).

However, considering the fact that the Commission only very recently published its study and started its initiative regarding the potential introduction of new regulations for NGTs in late 2021, a new academic gap is emerging in this field that warrants further research. The bulk of the existing literature on NGTs was published or written before the Commission's study and initiative and focuses primarily on the scientific background of NGTs, the applicability of the existing legislation, the future of GMOs produced with NGTs, and the potential applications of these novel technologies (Broothaerts et al., 2021; Ribarits et al., 2020; Van Der Meer et al., 2021). Other academic works include critiques of the EU's current GMO legislation, articles advocating for regulatory change, and academic opinion pieces on the need for change in this policy area (Kawall et al., 2020; Sprink et al., 2016; van der Berg et al., 2021). Thus, there is a notable lack of academic research on the EU's initiative, which provides a further academic justification for this research. This thesis will, therefore, focus on delivering initial exploratory research on this topic to pave the way for future research. In doing so, this thesis will make use of existing theoretical frameworks to analyse perceptions of the Commission's policy initiative, which is what the next section of this thesis will focus on.

3. THEORETICAL BACKGROUND

Given that this study focuses on the Commission's initiative to potentially introduce new regulations for NGTs, it is important to outline the existing theoretical frameworks that can provide explanatory leverage in this case. Hence, this section will focus on different theories in the field of regulation as the guiding theoretical framework for this thesis.

3.1. What is Regulation?

Before outlining the existing theories in this field, it is first important to explain what is meant by regulation. As a concept in the academic literature, regulation has been the subject of widespread debate. The absence of a common definition of regulation has led some to claim that the term has simply "acquired a bewildering variety of meanings" (Ogus, 2004, p.1). Some academics and organisations make use of broad definitions that see regulations as "an official rule" (Legal Information Institute, 2022). Similarly, regulation can also be defined as "government intervention in the private domain or a legal rule that implements such an intervention" (Orbach, 2016). However, to improve the clarity of this section, this paper uses a relatively broad conceptualisation of regulation by defining the term as "a form of governance designed to address complex social, environmental, and economic problems that relies heavily on rules, enforced against market actors, and administrative authorities" (Bignami, 2016, p.4).

It is also important to note that regulation in the context of this section has a different meaning than the term 'regulation' as used in some of the legal frameworks outlined above. Within the EU, "regulations are legal acts that apply automatically and uniformly to all EU countries as soon as they enter into force" (European Commission, 2022f), which is different from regulation in the economic, social or academic sense of the term. Hence, this section will primarily focus on the general definition outlined above.

3.2. Motivations for Regulation

In the existing literature on regulation, a number of key motivations for the introduction and development of regulations can be observed. Notably, Baldwin & Cave (1999) outline twelve distinct justifications for the introduction of (new) regulatory frameworks, including monopolies, externalities, continued service delivery, resource scarcity, asymmetric bargaining power between societal actors, long-term planning, anti-competitive behaviour, windfall profits, information asymmetry, greater coordination, public goods provision, and social policy.

The first justification focuses on the use of regulations to solve market failures due to the existence of a (natural) monopoly (Baldwin & Cave, 1999; Den Hertog, 2012). In this situation, regulation may be necessary due to the fact that there is one seller dominating the market or the product in question lends itself to the creation of a monopoly (Pera, 1989). This creates a situation in which there is a complete lack of competition on the market, which leads to undesirable effects (Den Hertog, 2012). Hence, regulations may be introduced in the form of price caps or competition laws (Baldwin & Cave, 1999). In contrast, the second justification focuses on the need to address externalities (Litan, 2018). Externalities arise when consumers or members of society that do not participate in a certain transaction or activity are still affected by them (Litan, 2018). For example, pollution caused by the production activities of a factory represents a negative externality to society, which thereby provides a reason to regulate this activity (Caplan, 2018).

Furthermore, continued service delivery represents another important justification for the introduction or development of regulations (Baldwin & Cave, 1999). In situations where a certain key service needs to be provided in a market that does not inherently guarantee the continued provision of that particular service, a regulatory agency can intervene and ensure continued service delivery. (Baldwin & Cave, 1999) This may, for example, be the case in the water and sanitation sector, where equitable service provision is desirable but not necessarily profitable (Castalia, 2005). In this case, regulation may be used to allow for the continued provision of key services at an acceptable standard (Castalia, 2005).

Resource scarcity represents another possible motivation for regulation (Orbach, 2016). Where resources such as minerals or natural gas are scarce, intervention may be necessary to ensure the most desirable or acceptable allocation of resources in society (Baldwin & Cave, 1999). Moreover, asymmetries in the bargaining power associated with certain societal actors may form another justification for regulation (Baldwin & Cave, 1999). In situations certain actors, such as employees or consumers, do not have strong bargaining positions, regulatory agencies may introduce regulations to protect the interests of the weaker parties, such as safety standards in the workplace (Baldwin & Cave, 1999). Similarly, information asymmetry between societal actors is also an important justification for regulation (Litan, 2018). Without regulations in place, there may be little to no incentive to inform consumers and other societal actors of the possible effects of a product or service, which may be positive or negative (Baldwin & Cave, 1999). For example, tobacco companies provided little to no information about the harmful effects of smoking until regulatory agencies made this a labelling requirement on tobacco products (Baldwin & Cave, 1999). Hence, regulations can be a powerful tool to reduce information asymmetry in society and give consumers the information they need to make an informed choice (Baldwin & Cave, 1999).

Anti-competitive behaviour by companies may also represent another justification for the introduction of regulations (Baldwin & Cave, 1999). Firms may engage in such behaviour to rid the market of competitors through, for example, anti-competitive pricing strategies and enhance their market share, which is why regulations may be needed (Baldwin & Cave, 1999). In contrast, the windfall profits justification is more redistributive in nature. According to this justification, regulations may be needed to redistribute windfall revenues so that other societal actors can also benefit from such immense profits (Baldwin & Cave, 1999). Moreover, regulations may also be motivated by a desire to protect future generations and their interests, such as the preservation of the natural environment (Baldwin & Cave, 1999). Hence, long-term planning represents another justification for the introduction of new regulations, as such rules can provide the basis for greater coordination in pursuit of long-term objectives (Baldwin & Cave, 1999).

Additionally, coordination in a market can also be improved through regulation. According to the proponents of this justification, greater coordination can be achieved through regulation in the form of processes of standardisation and centralisation (Baldwin & Cave, 1999). A possible example of this is the use of public channels to facilitate communication or creating a single agency that is charged with setting and upholding standards (Baldwin & Cave, 1999). Another motivation for regulation can be found in the realm of public goods, which is

an important school of thought in the field of governance (Drahos, 2004). This argument postulates that regulation may be necessary to prevent freeriding during the provision of public goods and limit moral hazard (Baldwin & Cave, 1999; Drahos, 2004). The last justification concerns itself with social policy. This entails the distribution of resources "according to the public interest" and the prevention of "undesirable behaviour and results" through regulation, even if this means valuing some preferences over others (Baldwin & Cave, 1999, p.17).

When looking at the GMO legislation currently in place in the EU, one could argue that the primary motivations underpinning the existing regulatory framework include a desire to limit information asymmetry through traceability and labelling rules and control negative externalities that may be caused by the introduction of GMOs, such as possible environmental risks and cross-pollination. The strict authorisation procedure for GMOs, as well as other constraints regarding the introduction and cultivation of GMOs based on the precautionary principle, can also be argued to be motivated by longer-term planning objectives as described above, such as the wish to preserve health and the environment for future generations. Thus, these key motivations for the introduction and development of regulations, as defined by Baldwin & Cave, offer insights into the rationale behind the existing regulatory framework in the EU.

3.3. Theories of Regulation and Regulatory Change

Aside from the possible motivations for the introduction and development of regulations, a number of key theories help to explain why regulations arise and why they change over time, which is what this next section will focus on. Based on the existing literature, this thesis will focus on Public Interest Theory and Private Interest Theories, which offer conflicting theoretical perspectives on regulation.

3.3.1. Public Interest Theory

Public interest theory is one of the more traditional explanations for the introduction and development of regulatory frameworks and finds its origins in the works of the Greek philosopher Plato (Levine & Forrence, 1990). This theoretical perspective posits that regulators and regulatory agencies act in the public interest and introduce regulations to benefit the public. Hence, in this theoretical perspective, "[r]egulation's purpose is to achieve certain publicly desired results in circumstances where, for instance, the market would fail to yield these" (Baldwin & Cave, 1999, p.19). Horwitz (1989) argues that the public interest perspective also views regulation as a tool that can be wielded by regulatory agencies to protect consumers and their interests in the face of growing influence from private companies and organised interest

groups. This approach, which is also known as the normative or teleological approach in other contexts, thereby attempts to ensure the welfare of the general public (Horwitz, 1989). From the public interest perspective, regulation may even be introduced in situations where such rules produce economically inefficient outcomes if certain values are deemed to be more important or socially desirable (Daboub et al., 2012). The public interest approach to regulation is also driven by market failures, such as externalities and information asymmetry as outlined above, and imperfect markets as well as undesirable consequences associated with externalities (Croley, 1998). This perspective is also based on the notion of representative democracy and assumes that regulators are motivated by a benevolent desire to ensure that decisions conform to the public interest (Christensen, 2010). Thus, in this theoretical framework, changes in an existing regulatory framework can also be explained by shifts in perceptions of the public interest. Broader social and economic goals and ideas on what is good for society may shift over time which may eventually lead to changes in regulatory frameworks that were initially introduced to benefit or protect the general public (Adams, 2016). Existing regulations may also be adapted or removed if the technological, structural or demand parameters change (Keeler, 1984) or if the regulator realises that the existing regulation no longer provides "the most efficient way of dealing with the market failure" (Den Hertog, 2010, p.43). Regulatory failure may also lead to changes in regulation and can occur when the costs of the existing legislation outweigh the potential benefit it brings and when the legislation turns out not to be "fit for purpose" or leads to ambiguity (van der Heijden, 2022, p.7-8). Regulatory failure in this perspective also occurs when regulation fails to solve the market failure it set out to address or creates unintended consequences (van der Heijden, 2022, p.7-8).

However, it is also important to outline some of the theoretical pitfalls associated with this particular approach. Notably, public interest as an attainable goal is hard to define or quantify. Additionally, this approach is also often criticised due to the fact that regulations introduced with the aim of protecting the public interest in some cases produce effects that may, in fact, harm the public interest (Baldwin & Cave, 1999). Furthermore, the public interest perspective has also been criticised for its overly interventionist approach (Shleifer, 2005). This criticism is based on the assumptions that the market can solve market failures on its own and that conflicts that arise from such market failures can be solved through private litigation (Shleifer, 2005). Moreover, others also argue that this theory understates and underestimates the influence of private actors and the personal motivations of regulators (Baldwin & Cave, 1999).

Table 1: Public Interest Theory Overview

Main Arguments	- Regulators and regulatory agencies act in the public interest and are benevolent in nature - Based on the idea of a representative democracy
Perspective on Regulatory Change	- Regulations change if the proposals are in the public interest - Shifts in the perception of the public interest may also motivate regulatory change - Technological, structural and demand changes may motivate change - Regulatory failure can also be a motivation for change
Notable Features	- Regulation may also lead to economically inefficient outcomes if the desired effects are in the public interest
Criticisms	- Public interest is hard to define and quantify - Public interest regulations can have counterproductive consequences - May understate the power of private actors and personal motivations - Interpreted by some as overly interventionist

3.3.2. Private Interest Theory

In contrast, an alternative theory in the field of regulation is the private interest theory. This theoretical perspective first arose in the 1950s and 1960s in response to the perceived shortcomings of the more traditional public interest theory and sees regulation and regulatory changes as the product of private sector interests that 'capture' or influence regulatory agencies (Etzioni, 2009). This thereby allows companies or corporate interest groups to influence the type and scope of regulations introduced. In this context, the term 'capture' describes a situation that "occurs when a government's regulatory agency, which was created in the public interest, ends up advancing the political or commercial concerns of the very people, companies or entities it is supposed to be regulating" (MBN, 2022). Hence, as time progresses, "regulation will [eventually] come to serve the interests of the industry involved" (Den Hertog, 2012, p.51). Thus, while public interest theory assumes that regulation is driven by the public interest and the greater good, private interest theory is based on the assumption that regulation eventually becomes the product of private sector influence (Den Hertog, 2012). This theory also holds that private actors will attempt to 'capture' regulatory agencies to further their own interests, such as profit maximisation or business growth, which is based on the assumption of the rational

self-interested nature of societal actors (Baldwin & Cave, 1999). The introduction of regulations or regulatory change may then, despite the power struggle between different actors in the background, be framed as an attempt to further the public interest (Chu & Major Pau, 2020).

According to Etzioni (2009), there are six ways in which private interests may 'capture' regulatory agencies and influence regulation. Firstly, private actors may attempt to influence the regulatory process through lobbying before or during the legislative drafting process and thereby influence the text of the legislative proposal (Etzioni, 2009). Secondly, private interests may succeed in capturing or influencing a regulatory agency after a legislative framework has already been adopted (Etzioni, 2009). In this scenario, firms or interest groups will attempt to reduce the stringency of the existing rules or weaken the regulations that are already in place that negatively affect the interests of the societal actors involved (Etzioni, 2009). This could be seen, for example, in the case of Enron Corporation, which was allegedly involved in a financial manipulation scandal in the early 2000s (Wokukwu, 2014). After the alleged financial malpractices of this corporation came to light, the United States Congress introduced a bill which required new stringent accounting regulations, thereby imposing new constraints on businesses (Etzioni, 2009; Wokukwu, 2014). As the public outcry surrounding the scandal began to fade, businesses and corporate interest groups reportedly started lobbying to weaken these accounting regulations, which eventually led to reduced regulations (Etzioni, 2009; Wokukwu, 2014), which goes to show how this may work in practice.

Thirdly, 'regulatory capture' can lead to the reduced enforcement of existing regulations (Etzioni, 2009). Societal actors representing private interests may lobby regulators and regulatory agencies to, for example, reduce the fines associated with a certain legal transgression or create exceptions in specific cases that benefit the lobbyists (Etzioni, 2009). Fourthly, when private interests are able to influence regulators, they may try to repeal or reverse regulations that are diametrically opposed to their own interests (Etzioni, 2009). Thus, this scenario assumes that private actors may eventually successfully dismantle entire regulatory frameworks if this suits their interests (Etzioni, 2009). Fifthly, a more complex form of the private interest theory is the switching of jurisdictions through regulatory manipulation. In this scenario, private interests will seek other ways to influence regulations if they are unable to weaken or revoke existing rules (Etzioni, 2009). This can be achieved by switching jurisdictions or framing business activities in such a way that regulations at a different level of government apply to the company or legal entity (Etzioni, 2009). This may be particularly beneficial when regulations are weaker or underenforced in another jurisdiction (Etzioni, 2009).

Lastly, regulatory capture may lead to changing price caps and rate regulations (Etzioni, 2009). While this is arguably a more abstract manifestation of private interest theory, the example of train fare regulations offers insights into how this may work in practice. When regulation is used to limit the maximum prices of train fares to ensure the affordability of public transportation, regulation can be said to be in the public interest. However, once regulators start to be influenced by private interests, regulations may be wielded to serve private interests by ensuring the profitability of the companies' business activities, such as through drastically increased regulated fares (Etzioni, 2009).

However, as in the case of the public interest theory, this theoretical perspective also has a number of criticisms and shortcomings. Notably, the private interest theory has been criticised for being unable to explain why private interests are able to capture regulators or regulatory agencies and why consumers are unable to prevent this from happening (Den Hertog, 2012). Furthermore, this theory has also received criticism for being very similar to the public interest theory due to the fact that both theories assume that regulation is initially in the public interest when it is first introduced (Den Hertog, 2012).

Table 2: Private Interest Theory Overview

Main Arguments	- Regulators and regulatory agencies may act in the interest of private actors - Regulation serves the interests it regulates - Private actors will attempt to 'capture' regulators and regulatory agencies
Perspective on Regulatory Change	- Regulatory change can be explained through the influence of private interests
Manifestations of Private Interest Theory (Etzioni, 2009)	- Lobbying before the introduction of regulations - Lobbying after the introduction of regulations - Reduced enforcement of rules - Repealing existing regulations - Jurisdiction switching - Changing price caps and rate regulations that benefit private interests
Criticisms	- The theory is unable to explain why regulatory capture occurs - The theory also fails to explain why other actors are unable to prevent regulatory capture - Explanation of the origin of legislation is similar to the public interest theory

3.4. Theoretical Expectations

The two theoretical frameworks outlined above offer conflicting perspectives on the regulatory process and how regulatory change may come about. This, therefore, leads to the following alternative expectations:

> **Expectation 1:** When looking at the perspectives of different actors in this field, the European Commission's initiative concerning the potential introduction of a revised regulatory framework for NGTs can be explained by Public Interest Theory

> **Expectation 2:** When looking at the perspectives of different actors in this field, the European Commission's initiative concerning the potential introduction of a revised regulatory framework for NGTs can be explained by Private Interest Theory

Hence, if Expectation 1 is correct, one would expect the perceived motivations of the Commission as an initiator of regulatory change to be based on securing the public interest. In contrast, if Expectation 2 is correct, the Commission's perceived motivations would be influenced by private interests.

4. METHODOLOGY

To address the research question outlined above, this thesis uses a variety of qualitative methods that may offer insights into the selected case. The following section will, therefore, outline the selected research methods, the rationale behind the case selection, as well as the selected data collection and analysis methods. This section also discusses the limitations that are associated with the chosen research design and explains the methods used to mitigate these limitations. An overview of this paper's methodology is provided in Table 3 below.

Table 3: Methodology Overview

Research Design	Small-N Case Study Focus: The EU's GMO legislation and the European Commission's policy initiative concerning the regulatory status of NGTs under the current legislation
Method of Data Collection	Seven semi-structured interviews with organisations and individuals operating within the European Union with different views on NGTs

	Purposive sampling approach for interviews Documentary analysis of different sources (201 coded pages, 52 written sources), including reports, newspaper articles, position papers, public documents/statements, written reactions, blogs, webpages, and other written sources Snowballing sampling approach for documentary analysis Timeframe for documents: 07/2018 – 06/2022
Method of Data Analysis	Thematic coding approach applied to the transcripts of the interviews and texts The coding scheme was created inductively Transcripts and texts were coded using ATLAS.ti software

4.1. Research Design Rationale

When considering the full range of possible methods in the field of research design, the use of qualitative methods arguably allows for a better fit with the selected research question. Hence, this paper uses a small-N case study of the EU and the Commission's initiative regarding the potential introduction of a new regulatory framework for NGTs to gain insight into this process and the Commission's motivations for pursuing regulatory change. This particular case was chosen on account of the empirical puzzle that it presents and its interdisciplinary nature. This case is arguably also fascinating due to the fact that the EU's legislative framework on GMOs is considered to be one of the strictest GMO regimes in the world (Woźniak et al., 2021). This is supplemented by the contentious nature of GMOs and the differing perspectives that exist in the EU and the rest of the world concerning their potential benefits or dangers.

However, it is also important to note that the qualitative approach to research has been criticised in the academic world (Bryman, 2012). Notably, the main criticisms of qualitative research methods focus on the subjectivity of the research process and the issues associated with the replication of conducted research (Bryman, 2012). Additionally, qualitative research has also been criticised for lacking external validity, which limits the extent to which a study's findings can be generalised to the entire population of interest (Bryman, 2012). However, with regards to the issue of generalisability, some researchers have claimed that qualitative research does, in fact, allow for limited generalisations to be made based on the findings of a study,

which is an important perspective to consider (Bryman, 2012). Researchers who select qualitative research methods must also be aware of the transparency issues often associated with this type of research, such as in the analytical process or the selection of research subjects (Bryman, 2012). While this thesis will attempt to mitigate these criticisms as much as possible, it is important to acknowledge the impact of the inherent limitations of the selected research design.

4.2. Method of Data Collection

This thesis uses seven semi-structured interviews (see Table 4 below) with individuals and representatives from different organisations, such as interest groups, Non-Governmental Organisations (NGOs) and other organisations to gain insights into the Commission's motivations to pursue regulatory change and how these organisations and people perceive this policy initiative. Considering the need to provide the most accurate reflection of perspectives on this initiative, an equal number of interviews was conducted with organisations that had an overall positive view on NGTs as well as those that took a more negative stance towards this topic. Additionally, one interview was conducted with an official from the European Commission. As is usually the case in semi-structured interviews, a number of guiding themes were used alongside general questions when conducting the interviews, such as the interviewees' perspectives on GMOs/NGTs as well as their views on other organisations and groups active in this field, the interviewee's view on the Commission's motivations to pursue change in the EU's GMO legislation, the CJEU's 2018 ruling, and the possible implications of the Commission's initiative for different stakeholders. Interviewees were, whenever possible, presented with relatively neutral questions to avoid the possibility of the interview questions being perceived as leading. This helps to improve the validity and reliability of the selected research design (Alshenqeeti, 2014, p.44).

Given the specific nature of this topic, a purposive sampling method was used to select interviewees for this thesis. This non-probabilistic type of sampling allows the researcher to select interviewees "so that those sampled are relevant to the research questions that are being posed" (Bryman, 2012, p.418). Hence, in the context of this thesis, interviewees were selected and invited based on the relevance of their activities, their perspectives on GMOs and NGTs, and whether the organisation or individual was active at the EU-level or aware of the regulatory process in the EU and the Commission's initiative. Regarding the potential methodological limitations associated with this approach, it is important to note that this sampling method is

associated with external validity issues as the results of the interviews cannot be used "to generalise to a population" (Bryman, 2012, p.418).

When looking at the advantages and disadvantages associated with the use of interviews, one can clearly distinguish between advocates and opponents of this method. While some scholars who ascribe more to the quantitative research paradigm have portrayed interviews as "unreliable, impressionistic and not objective", others see interviews as "a useful way for researchers to learn more about the world of others" (Qu & Dumay, 2011, p.239). Additionally, interviews have been described as valuable due to the fact that they allow the researcher to collect data that may otherwise be inaccessible when using alternative techniques (Alshenqeeti, 2014). This is also facilitated by the fact that the researcher can explain or rephrase questions if the interviewee has trouble understanding them and has more flexibility in the data collection process (Alshenqeeti, 2014). However, interviews are also often viewed as overly time-consuming, at-risk for biases, and sometimes inconsistent (Alshenqeeti, 2014). A further limitation that should be taken into account is that the transcription of interviews can omit the non-verbal communication that is often present in interviews (Parameswaran et al., 2020). To counter this, the recorded videos were reviewed to see if any non-verbal gestures or signs were present that could be of value to this paper's analysis.

While this thesis was initially supposed to include 15 interviews with different stakeholders in this field, it is important to note that the final study only includes seven interviews due to the fact that only a limited number of interviewees agreed to participate in this research. Due to the limited availability of interviewees, an additional data collection method was necessary to ensure the methodological robustness of the paper's research design, which is why the use of interviews was supplemented with documentary analysis. Documents were selected on the basis of their relevance to the research question and topic of interest and were drawn from a wide range of sources, including publicly available information published by the Commission, position papers, written reactions, public statements, newspaper articles, blog posts, and journal articles. These documents were selected within a specified timeframe (07/2018 – 06/2022), starting from the publication of the CJEU's judgment on the status of NGTs under the current GMO legislation to ensure the relevance of the selected sources. The data gathered from these written sources were used as additional evidence for this thesis' analysis.

The use of documentary analysis alongside other methods in qualitative research has been described as a valuable tool for data triangulation, which strengthens the research findings of a paper (Bowen, 2009). Furthermore, Bowen (2009, p.29) postulates that this type of analysis

"is particularly applicable to qualitative case studies", which indicates that this method fits well with the small-N case study design of this paper. Additionally, documentary analysis has been described as cost-effective, efficient, stable, and exact, which strengthens the case for the inclusion of this data collection method. However, as with other research methods, there are a number of limitations associated with documentary analysis. Bowen (2009) notes that documents may be unable to provide sufficient detail to study the research question of interest and highlights the potential bias inherent in the selection of documents. Nevertheless, this thesis has attempted to counter these limitations by including interviews with different stakeholders as additional evidence to avoid underrepresenting certain opinions and to provide sufficient evidence to answer the research question.

The documents analysed for this thesis were selected using a snowballing approach. While this sampling approach is typically associated with interviews, documents can also be sampled using this method (Bryman, 2012). Hence, selected documents and written sources were used as a basis for finding other available sources within the timeframe identified above. The first documents were selected on the basis of their relevance to the topic and the research question presented above, after which references to other documents, key concepts and events provided the basis for the collection of additional written sources, leading to a total of 52 written sources. However, it is important to note that this sampling technique, as with other non-probabilistic methods, has inherent external validity issues, which represent an important limitation to the findings of this research (Bryman, 2012).

4.3.Method of Data Analysis

This paper uses an inductive thematic coding approach to analyse the selected data. Hence, the texts and data were analysed using the themes outlined above, which grew, evolved, and expanded as new themes emerged from the data. The interview transcripts and selected documents were coded using ATLAS.ti. Furthermore, this thesis also uses thematic analysis, as defined by Bryman (2012), to find specific themes in the texts and transcripts. The inductive coding of the texts and transcripts also allowed themes and sub-themes to be identified inductively for the topic of interest. This coding approach, combined with the thematic analysis described above, provides a systematic method of analysing the aforementioned data sources and forms the basis of this paper's data analysis. Concerning the documents selected for this paper, it is important to note that the findings presented in Section 5 reflect 201 coded pages, which are presented alongside the coded interviews.

With respect to the limitations of the selected method of data analysis, it is important to note that thematic analysis is an underdeveloped tool in qualitative research (Bryman, 2012), which may limit the internal validity of this paper. Furthermore, coding has been criticised for separating integral elements in a text and being overly subjective in nature, which is an important limitation to consider (Skjott Linneberg & Korsgaard, 2019).

4.4. Further Methodological Limitations

When looking at the selected methodology, it is also important to acknowledge the methodological limitations associated with the chosen research design. Pivotally, the selected research design suffers from external validity issues due to the methodological constraints associated with small-N case studies (Blatter & Haverland, 2012, p.69). Thus, the generalisability of this paper's findings is limited, which reduces the extent to which conclusions can be used to study other cases of GMO regulation. Furthermore, the research design of this paper does not allow for definitive casual conclusions to be made in this case, which represents another important limitation to consider. Moreover, the subjective nature of case selection in small-N research has the potential to limit the extent to which this paper's research can be replicated by other researchers (Blatter & Haverland, 2012). As mentioned above, the external validity of this paper is also reduced by the use of non-probability sampling techniques (Bryman, 2012, p.418).

There are also a number of biases inherent in social research that could be considered to be important limitations of this thesis. Cognitive biases, such as information or reporting biases, could be associated with this thesis' chosen research design and may be present in the selected data sources. Nevertheless, the effect of these biases has been countered to an extent by investigating the opinions and background of the interviewees as well as the authors of the documents and other data sources used in this thesis, which allows the positionality of the authors and the interviewees to be viewed in the appropriate context. Furthermore, this paper has also attempted to mitigate these issues by triangulating data from various sources and selecting interviewees and documents from organisations with different perspectives on GMOs and NGTs to reduce bias and improve the accuracy of the findings presented in the results section below.

Table 4: Overview of Interviewees

Type of Organisation/Interviewee	Interviewee	Views on NGTs in the EU
Representative organisation for the biotechnology and seed sector	1	Positive

Scientific organisation	2	Positive
NGO that focuses on environmental issues	3	Negative
Organic food organisation and certifier	4	Negative
Grassroots organisation with a focus on food and agriculture	5	Negative
Representative organisation for the trade of certain agricultural products	6	Neutral/Positive
Commission Official	7	Neutral/Positive

4.5. Ethical Considerations

Before the start of the interviews, the interviewees were informed of their rights as research participants and were presented with a consent form in compliance with the European General Data Protection Regulation (GDPR) and the Examination Regulation of the Erasmus School of Social and Behavioural Sciences (ESSB). Based on the individual wishes and preferences of some of the interviewees, information and direct quotations have in some cases been anonymised to protect their rights and privacy. Interviewees were also given the opportunity to ask questions at the beginning and the end of the interview.

5. RESULTS

5.1. Structure

Having thereby outlined the paper's research design, the following section presents the results of the data gathered for this thesis, including the interviews and the supplementary documents. This section is divided into subsections based on themes identified during the data collection and analysis process. Each theme outlines different perspectives on the drivers behind the Commission's policy initiative. Wherever relevant, direct quotations from the interviews and texts have been added to offer insights into the arguments and language used by the interviewees and authors.

5.2. Theme 1: Policy Goals

Starting off, one prominent theme in the interviewees' responses and the documentary analysis focuses on the EU's policy goals. Within this theme, two sub-themes can be identified based on the different perspectives identified in the interviewees and selected texts.

5.2.1. Subtheme 1: Achieving Policy Goals

Starting with the interviewees' responses, all interviewees with a positive stance on NGTs put forth the idea that the Commission's initiative is motivated by policy objectives and the drive to attain these goals. Thus, according to this perspective, a potential change in the

EU's GMO legislation may help the Commission achieve various policy objectives. More specifically, the European Green Deal (EGD) [2] and the Farm to Fork Strategy (F2F Strategy) [3] were frequently mentioned as potential policy goals or objectives that the Commission may be pursuing [#1, #2, #6]. For example, Interviewee 1 believed that "one of the main motivations is that they found out with this NGT study that these products can contribute to their policy goals, like Farm to Fork/Green Deal" [#1]. Similarly, another interviewee argued that this initiative "is also being seen as part of the European Green New Deal [sic] and the Farm to Fork Strategy, and so all of these ambitions that Europe has in terms of sustainability, I think, would be supported by this technology" [#2]. These perspectives were corroborated by the Commission official interviewed for this thesis, who also identified the United Nations Sustainable Development Goals (UNSDGs) and the need to preserve human and animal health as further goals supported by this initiative [#7]

To substantiate these arguments, interviewees often identified arguments concerning the beneficial characteristics of NGTs, such as disease, climate change, pesticide, and herbicide resistance, as well as improved sustainability, efficiency, food quality, innovation, and food security [#1, #2, #6]. Notably, Interviewee 2 mentioned that "you could create crops that require you to use less chemicals or less pesticides [or] you could create crops that are resistant to changes in climate as we see them throughout Europe" [#2]. Similarly, Interviewee 1 stated that "another advantage [of changing the EU's GMO legislation] would be that our sector can contribute more efficiently to the policy goals of the Farm to Fork Strategy – so to be able to more efficiently breed plants which can comply with the goal of having reduced pesticide use, [and greater] food security" [#1]. Interviewee 6 also mentioned that these technologies are also "cost-effective" [#6], which represents an additional advantage. Additionally, NGTs were also seen as tools that could help European farmers adapt to the adverse effects of climate change and new legal requirements imposed on them [#1, #2]. Interviewee 2 also specifically mentioned that NGTs allow for crops to be created that are "so much cleaner and actually safer than with traditional methods […] which basically makes it a very big missed opportunity if we would not consider this seriously" and noted the potential for improving food quality and efficiency using NGTs [#2]. Lastly, Interviewee 2 also noted that NGTs may also help cope

[2] The European Green Deal is "an ambitious package of measures ranging from ambitiously cutting greenhouse gas emissions, to investing in cutting-edge research and innovation, to preserving Europe's natural environment" (European Commission, 2022a).
[3] The Farm to Fork Strategy "aims to accelerate our transition to a sustainable food system" that focuses on ensuring a climate neutral/positive impact and, amongst others, reducing biodiversity loss, ensuring public health, nutrition, and greater food security. (European Commission, 2022b).

with the food supply issues that are "also emphasised now in the current geopolitical crisis" in Europe [#2], which was a perspective that was also reiterated by Interviewee 6. Thus, overall, these interviewees saw the EU's policy objectives and the role that NGTs can play in achieving those objectives as one of the Commission's major motivations.

These arguments were also present in the documentary analysis conducted for this thesis. The documents published by the Commission on the study it commissioned on NGTs, the Inception Impact Assessment (IIA), and the recently opened consultation specifically mention the beneficial characteristics of GMOs produced using NGTs, such as drought tolerance, pest resistance, reduced presence of allergens, improved food quality, and reduced chemical use (European Commission, 2021c, 2021b, 2021d, 2022g). These beneficial traits are presented in these documents as potential contributors to the achievement of the objectives of the EGD, the United Nations Sustainable Development Goals (UNSDGs), and the F2F Strategy (European Commission, 2021c, 2021d, 2022g). These underlying motivations are also discernible in the communiqué sent to members of the World Trade Organisation at the behest of the EU's Delegation, which states that the Commission "believes that new genomic techniques can contribute to the Green Deal and Farm to Fork objectives of innovation and sustainability of the food systems, as well as to a more competitive economy, which are at the centre of current priorities of the European Union" (Delegation of the European Union, 2021, p.1). Others also noted the potential for GM crops to increase crop yields, reduce emissions, decrease the use of chemicals, and produce changes in land use (Maina, 2022b). These motivations for policy change were also stated in an academic position paper in 2018, shortly after the CJEU's judgment (VIB, 2018).

Furthermore, the Commission's IIA also mentions the Biodiversity Strategies as potential policy objectives that could be attained using NGTs (European Commission, 2021d). This view is shared by others, who argue that NGTs can effectively contribute to the abovementioned policy goals (FEFAC, 2021; Maina, 2022a), and has also been reiterated in the past by Commissioners Frans Timmermans and Stella Kyriakides as well as other spokespeople for the Commission (Foote, 2021; Sacristán Sánchez, 2022; Wetzels, 2021; Zubascu, 2021). Echoing this perspective, one organisation even argued that it would be challenging for different actors to attain the EU's policy goals without these techniques in their toolbox (ELO, 2021, p.25). Additionally, with the current geopolitical crisis in Europe and increased climate change pressures, NGTs may also be seen as tools to improve the food security and agricultural resilience of the EU, which have recently returned to the top of the political agenda (Bullion, 2022; Matthews, 2022). Hence, the Commission's sustainability and

food security goals are, therefore, seen by some as major motivations for pursuing change in the EU's GMO legislation.

5.2.2. Subtheme 2: Contradicting the EU's Policy Goals

In contrast, some of the interviewees that had a more negative stance towards NGTs also identified this theme but argued that the Commission's initiative contradicted its own policy goals. Notably, one interviewee mentioned issues of climate change and biodiversity loss arising from the "typical monoculture and industrial agricultural practices" [#3] of the biotechnology sector, which would thereby contradict the objectives of the EGD and the F2F Strategy [#3]. Similarly, another interviewee stated that "the Commission wants to have 25% organic farming [in the F2F Strategy], but in organic farming, GMOs are prohibited" [#4], thereby indicating that the initiative may contradict this policy objective. Additionally, another interviewee argued that the introduction of herbicide or pesticide-tolerant crops using NGTs would not "do anything about reducing the use of pesticides" and other chemicals and would "not contribute to any sustainability goals" [#5]. This point was supplemented by the argument that the F2F Strategy "also talks about wanting to move towards agroecology, and clearly, New Genomic Techniques cannot be part of an agroecological system, so there are a lot of contradictions there" [#5]. Additionally, with regards to the objectives of the F2F Strategy, one interviewee argued that the use of NGTs "does not equal food security. […] We see it as an opportunity cost to the known sustainable food practices and techniques" [#3]. Lastly, while not directly associated with specific policy objectives, Interviewee 3 also argued that any changes to the GMO legislation that exempt NGTs or alter the rules that apply to NGTs would likely contradict the precautionary principle [#3].

Additionally, many of these interviewees also argued that the beneficial characteristics associated with NGTs did not hold true. To these interviewees, these characteristics were another example of the "unfulfilled promises" of the biotechnological sector [#3, #4]. For example, Interviewee 4 argued that the solutions offered by these technologies are "based on the promises of the industry that is putting this product on the market, but we have no idea that this would actually solve the problem in reality" [#4]. This view was shared by another interviewee, who argued that "there is no proof at this stage that NGTs are going to help with attaining sustainable food systems" [#5]. Interviewee 3 stated that these promises were just "rhetoric" and asserted that these technologies have "a track record of failed promises" [#3]. To substantiate these arguments, these research participants mentioned the example of herbicide and pesticide-tolerant GM crops from the 1990s and 2000s that reportedly led to an

increase in the use of such chemical products [#3, #4, #5]. Interestingly, one interviewee believed the Commission was pursuing change partly because NGTs appear to be "a very easy tool" that could help attain the desired changes in the agricultural system without overhauling the entire sector and identified pressures in the EU from farmers to help them adapt to new circumstances, but also noted that earlier GMOs had failed to deliver on their promises [#4].

The idea of 'unfulfilled promises' was also visible in the documents analysed for this thesis. Notably, Eurovia responded to the Commission's Inception Impact Assessment by arguing that it consisted of "undocumented assertions" and "unsubstantiated promises of the means to achieve them" (Eurovia, 2021, p.1). This organisation also used the example of transgenic plants to argue that the biotechnology sector is re-using the same sustainability arguments to promote NGTs (Eurovia, 2021). This view was shared by others, who also believe that these sustainability claims are unsubstantiated or are overly reliant on assumptions about products that are still being developed (FoEE, 2021a, 2021c; Greens/EFA, 2021b). Similarly, others have stated that "[c]laims of the contribution of NGTs to sustainability in the Commission report are theoretical at this point and not based on evidence regarding available crops" (IFOAM, 2021, p.1). This argument is also visible in the open letter sent by 51 organisations in Europe that provided a critical response to the conclusions of the Commission's study on GMOs and claimed that "the Commission relies too much on the unverifiable promises of the [biotechnology] industry" (Demeter, 2021, p.3). Instead, these organisations argue that these sustainability claims are more connected "to commercial goals" than scientific evidence (Demeter, 2021, p.3).

Eurovia's response to the initiative also claimed that the "deregulation of the new genomic techniques is the perfect recipe to sabotage both the F2F Strategy and the EU Biodiversity Strategy" (Eurovia, 2021, p.7). A similar line of argumentation was used in a joint statement signed by a number of European retailers who argued that the "deregulation of new GMOs" would be incompatible with the policy objectives of the EGD (Gamota Jr., 2021). The open letter mentioned above also mentioned claims that GM crops with herbicide tolerance would not lead to reduced herbicide, pesticide, or chemical use (Demeter, 2021), which is part of the F2F Strategy. This perspective was also advanced in a report published by the German Federal Agency for Nature Conservation (BfN), in which herbicide-tolerant crops were described as leading to increased herbicide use in the 1990s (Engelhard et al., 2021, p.9). Some even went as far as arguing that the Commission is using the F2F Strategy "as a political argument to defend its desire to revise the GMO regulations" (Krinke, 2021).

5.3. Theme 2: Narratives, Lobbying, and Corporate Influence

Another theme that was prevalent in some of the interviews and the documentary analysis was the importance of narratives, lobbying, and corporate influence. It is important to note here that this theme was not reflected in all interviews and was particularly prevalent in the arguments presented by the interviewees with a more negative stance on NGTs.

5.3.1. Subtheme 1: Narratives & Bias

Regarding the use of narratives, one interviewee stated that "it's just a bit of a shock that the Commission is playing that same agenda of the industry" and noted that their organisation "see[s] the Commission's study on potentially [introducing] new regulation for new GMOs as following the agenda of the biotech industry" [#3]. Furthermore, this same research participant argued that this industry wants "to circumvent the existing legislation" [#3]. Using a similar line of argumentation, another research participant claimed that some actors are "confusing the difference between new GMOs and GMOs – they're making it sound like they are very different things, that they don't have the same risks, that the new techniques are much more precise than the old ones and they are managing to push forward an agenda that innovation is always what we need for sustainable food systems" [#5]. In contrast, on the other side of the debate, one interviewee warned of the narratives used by anti-GMO organisations by stating that "we see some organisations that really are trying to push it in this angle [4] - organisations that are very strongly against NGTs [do] not always take the scientific facts that serious [sic] but use this kind of twist of reality to play into this public opinion" [#2].

Some of the documents analysed for this thesis also put forth the argument that the Commission is following the agenda or wishes of the biotechnology sector. For example, Eurovia argues that the language used in the Inception Impact Assessment reflects that of the biotechnology industry and its narrative on NGTs (Eurovia, 2021). Others, such as Friends of the Earth, claim that this policy initiative shows that the Commission is biased towards the biotechnology and seed sector and "looks like a wish list from the biotech industry" (FoEE, 2021a). This organisation further argues that "other voices and arguments" were "brushed aside" by Commissioner Kyriakides during the consultation process in 2021 (FoEE, 2021a). Moreover, following Commissioner Timmermans' comments on the sustainability of NGTs, the Commission was accused "of already making up their mind on their technology" (Foote, 2021). This alleged bias was also mentioned following the recent publication of the

[4] "This angle" refers to the claim that legislation is being pushed through "without creating a solid basis of support among citizens" [#2].

Commission's consultation in April 2022 (ENGA, 2022b; European Biotechnology, 2022; Eurovia, 2022; VLOG, 2022). Notably, ENGA argues that the "framing of the questionnaire primarily reflects the interests of the biotech and seed industries, and of trade partners with strong GMO industries" since the majority of questions were presented in a multiple-choice format and were framed in a particular way (ENGA, 2022b). VLOG, another NGO, shares the opinion that the consultation appears biased and claims that the structure and text of the consultation "suggest that the EU Commission's goal is extensive deregulation" (VLOG, 2022). However, on the other side of the debate, anti-GMO organisations and political parties were accused of "hijacking" the consultation on the Commission's consultation in 2021 (Heitz, 2021). These organisations reportedly prepared "pre-formulated comments" for citizens to submit, thereby helping to "flood [the] European Commission with pre-fabricated, anti-biotechnology propaganda" (Heitz, 2021).

5.3.2. Subtheme 2: Lobbying and Corporate Influence

Another sub-theme that could be identified in the interview transcripts and texts was the importance of lobbying and corporate influence and the effects this may have had on the Commission's initiative. Notably, Interviewee 3 argued that, even though the political environment of the EU is less receptive to corporate influences compared to other political structures or environments, the Commission's current initiative to review the EU's GMO legislation was "an example of corporate control" considering the "massive amount of lobbying, resources, and revolving door between the institutions and the private sector" [#3]. Another interviewee mentioned that "the lobbying that comes from the agribusiness industry is very strong, it's a bit different than what you have on other topics" and highlighted the "big financial interests" of the biotechnology sector [#4]. This argument was also presented by Interviewee 5, who noted that industrial farmers "have a strong lobby power" within the EU [#5], which may help to explain the Commission's initiative.

This theme was also prominent in the documents analysed for this paper. For example, a report by the Corporate Europe Observatory (CEO) alleged that there was a large lobby initiative underway to "derail EU rules on GMOs" (CEO, 2021, p.1). In a 22-page report published shortly before the publication of the Commission's study on NGTs, the CEO describes lobbying tactics and methods that were reportedly used to influence the Commission's position on NGTs. According to the CEO (2021), meetings were planned with selected national policy officials by certain organisations to discuss "the least difficult route to obtain deregulation" (CEO, 2021, p.4). The report further alleges that a specially created lobby

platform was used to further the interests of pro-GMO organisations and that a think-tank received funding to "pave the way to GM deregulation via climate narratives" (CEO, 2021, p.2). A researcher at CEO was also quoted as saying that the "study on new GMOs is yet another example of the corporate capture of EU decision-making" (Sánchez Nicolás, 2021). Other documents and articles also mention the existence of powerful lobby groups in this field that have attempted to change the current GMO legislation (CEO, 2022; ENGA, 2022a; Greens/EFA, 2021a, 2021b; Via Campesina, 2022). Friends of the Earth further stated in its own briefing that "top agribusiness and biotech corporations [have] spent at least €36.599.932 lobbying the European Union" on these issues and held over 182 meetings with members of the Commission (FoEE, 2021b, p.5; 2021c).

5.4. Theme 3: The Existing Legislation and its Effects

Moving on, another particularly prominent theme in the interviews was the different perceptions of the current GMO legislation, its applicability to NGTs, and its effects on different stakeholders. This theme is also divided into two subthemes with contrasting perspectives.

5.4.1. Subtheme 1: Problems with the Existing Legislation

Starting with the first subtheme, which focuses on problems with the existing legislation as a major motivation for change, several different issues were identified by the interviewees that warrant regulatory change in this field. Notably, several interviewees argued that the current GMO legislation is too strict for those seeking authorization for new GM crops, thereby creating issues for the EU's internal market. "The problem now is that the regulations are so strict that in order to get it there, you have to go through lots of tests, which makes it extremely expensive. […] It's only the very big biotechnological companies that can afford this, so it creates an imbalance" [#2]. Thus, by changing the legislation, new opportunities could be created for smaller businesses, thereby promoting greater competitiveness in the EU's internal market and "levelling the playing field between the bigger and smaller developers and producers" [#2]. This view was also shared by Interviewee 6. Other interviewees also noted that only big multinational corporations have the resources to work with the current legislation. Interviewee 1 provided an example of this by stating that the only GM crop that has received authorization in the EU for cultivation to date is MON810, which was approved in 1999 [#1]. Additionally, given the fact that 19 out of 27 member states have banned or restricted GMOs under Directive 2015/412, it was mentioned that companies are not willing to invest in crops

that do not have a market given the high regulatory costs [#1], thereby indicating that the current legislation has led to decreased innovation. Interviewee 6 also mentioned the need to change the existing legislation to enable greater innovation [#6].

These interviewees also often noted the need to change the EU's regulatory framework to keep up with legislative changes in the rest of the world [#1, #2, #6]. For example, one person argued that "it's also important not to see the EU as an isolated entity; we work in a global world where there are lots of important players […] that are [changing] or have already changed the legislation" to facilitate the use of NGTs [#2]. This interviewee also noted that this is necessary to maintain the EU's trading position compared to other countries and trading partners [#2]. Interviewee 1 also expressed the need for greater alignment and harmonisation on GMO rules, given the legislative changes that can be observed in other countries and the subsequent trade issues [#1]. Interviewee 6 also noted that the EU should not "lag behind other countries" such as India, Canada, Kenya, and the Philippines to improve the trading bloc's competitive position in the world economy [#6].

When discussing trade issues, it was also often pointed out that GMOs produced using NGTs are seen as indistinguishable from crops produced using conventional breeding methods, which has reportedly complicated imports from other countries [#1, #2, #6]. For example, Interviewee 2 mentioned the difficulties associated with complying with the traceability and labelling requirements for crops imported from outside the EU that may have been produced using NGTs. This view was also emphasised by Interviewee 1, who discussed the idea that crops produced with NGTs may end up in the EU's internal market while not being labelled as such due to detection issues. Hence, changing the legislation could, therefore, potentially facilitate trade and allow European companies to compete on an international level [#1, #2, #6]. Interviewee 6 also noted that the current legislation places a "disproportionate burden" on the seed, trade, and food industries [#6]. Additionally, two interviewees also noted the need to clarify the legal ambiguity created by the 2018 CJEU case [#2, #6], while Interviewee 6 also argued that the EU needs "a predictable regulatory landscape" [#6]. The Commission official interviewed for this thesis also noted the issues associated with legal ambiguity and the regulatory burden present in the current legislation [#7].However, this view was not shared by one of the interviewees with a negative stance on NGTs, who argued that "the goal is not to just change or to clarify any sort of legal uncertainty, it's to make it easier to produce NGT crops and put them on the market" [#5].

The documents analysed for this thesis also contained arguments that could be presented under this subtheme. Notably, the Commission's study on NGTs specifically

mentions the issue of "regulatory uncertainty" due to the lack of clarity of certain definitions following the CJEU's judgment in 2018 (European Commission, 2021b, p.54; Fortuna & Foote, 2021; Wetzels, 2021). These "legal uncertainties" are also mentioned in the IIA as issues the Commission aims to tackle (European Commission, 2021c, p.2) and cited by some as a regulatory issue that should be addressed (FEFAC, 2021). Furthermore, a number of documents from the Commission list the need to change the existing legislation to allow it to adapt to "scientific and technological progress" (European Commission, 2021b, 2022g; Sacristán Sánchez, 2022). This justification was also mentioned in several other documents (ISF, 2021; JD Supra, 2022). Additionally, the current legislation is seen as limited because it "does not take into account whether products have the potential to contribute to sustainability" and fails to consider the "different risk profiles" of NGTs (European Commission, 2022g, p.2). There is also a perceived need to ensure that the EU keeps up with the latest global regulatory changes, thereby leading to greater harmonisation and reducing trade barriers that have been created by the current legislation (European Commission, 2021c; Wetzels, 2021). Additional issues associated with detecting the presence of gene editing and working with the current regulations have reportedly also led to "implementation and enforcement challenges" (European Commission, 2021c, 2021d). The argument that the current legislation creates an unequal playing field for small and medium-sized enterprises was also listed in the Commission's study (European Commission, 2021c). These arguments have reportedly led the Commission and other actors to conclude that the current GMO legislation is "not fit for purpose" (Begemann, 2021; Delegation of the European Union, 2021; ELO, 2021; EuropaBio, 2021; European Commission, 2021a, 2021b, 2022g; Foote, 2021; Fortuna & Foote, 2021).

5.4.2. Subtheme 2: "Still Fit for Purpose"

In contrast to the arguments presented above, others presented the view that the EU's GMO legislation is still appropriate to the current context and should, therefore, not be changed. Interviewee 5, for example, argued that the current legislation, despite its potential flaws, "is still fit for purpose" [#5]. Similarly, another interviewee stated that "there's no reason to change that regulation because it helps us to keep transparency, to keep risk assessments, safety checks and also traceability" [#4]. This interviewee elaborated on this point by saying that they "consider that the current GMO regulation is there for a good reason" and allows consumers to be aware of the contents of their food while protecting GMO-free farms [#4]. Furthermore, Interviewee 3 stated: "we are not against innovation, so we don't say ban the GMOs, we say put them through the regulation and the EU legislation as it exists today, the directives involved,

that require robust risk assessment – in line with the precautionary principle" [#3]. Some of the interviewees also noted the need to keep the current legislation in place due since the consequences of using NGTs might not be fully understood [#3, #4]. Additionally, in response to the harmonisation argument presented above, Interviewee 5 argued that changes to EU legislation to adapt to changes elsewhere would "be going backwards", especially considering the fact that the EU aims to be "a front runner in terms of sustainability in the food system" [#5]. This interviewee also pointed out that the Commission has not invested sufficiently in detection methods and argued that there are many examples of other products, such as fair-trade products, that cannot be detected through testing, which indicates that GM crops would still be able to fulfil the labelling and traceability requirements of the current legislation [#5]. Furthermore, with regards to innovation, Interviewee 3 argued that the current legislation has not reduced innovation possibilities but has rather placed GMOs "under scrutiny" [#3].

The view that the current legislation is still fit for purpose was also visible in the documentary analysis. For example, different organisations have noted the need to keep the current legislation with its labelling and traceability in place (Demeter, 2021; Gamota Jr., 2021) and have argued that the current legislation "is fit for purpose" (FoEE, 2021a) since "the current EU GMO legislation has proven its worth" (Gamota Jr., 2021). Others also shared the view that the current legislation was appropriate to the current context (ENGA, 2022a) and argued that the Commission should instead be focusing on "systems-based solutions that are already available" (IFOAM, 2021, p.1). The BfN further stated that "[o]nly a case-by-case analysis as performed under the current legislation can ensure a high level of safety" and argued that detection of GMO products is still possible even if they have been created using NGTs (Engelhard et al., 2021, p.5-14). This agency also argued in its report that the claim that traceability issues in the current legislation "could lead to barriers to trade is not credible" (Engelhard et al., 2021, p.15). Furthermore, according to Via Campesina (2022), several EU member states have "reaffirmed their views that the current GMO legislation is fit for purpose" (Via Campesina, 2022), thereby shedding light on other perspectives in the EU.

6. ANALYSIS & DISCUSSION

Having thereby presented the findings of the interviews conducted for this thesis and the supplementary documentary analysis, this next section will be dedicated to discussing the themes outlined above in light of the theoretical framework and the literature review presented in Sections 2 and 3. To improve the clarity of this section, the discussion will follow the themes-based structure used in Section 5, after which a number of initial recommendations will be presented that may be of use to the stakeholders active in this field and future research on this topic.

6.1. Theme 1 Analysis

6.1.1. Subtheme 1: Achieving Policy Goals

Starting with the first theme, which focuses on the policy goals of the Commission and the EU as a whole, one could argue that the first subtheme is clearly in line with the basic principles of public interest theory. Given that this subtheme places emphasis on the public policy objectives of the EU and the Commission as well as the attainment of these objectives, a theoretical link can be made to the notion that perceptions of the public interest may motivate the introduction of new regulations or regulatory change. As outlined above, the main policies and objectives mentioned in the documents and interview transcripts included the European Green Deal, the Farm to Fork Strategy, the Biodiversity Strategies and the UNSDGs, which can all be linked to specific values and goals in the European context. For example, these specific policy goals all focus heavily on values and broader goals such as sustainability, biodiversity protection, food security, food quality, combatting climate change, and building a more resilient agricultural system in the EU, which could be seen as being in the public interest. These values and goals have arguably all grown in importance over the past few years, considering the increased awareness surrounding climate change and the need for more sustainable alternatives to protect the climate and the planet's biodiversity. The geopolitical crisis caused by the war in Ukraine and the subsequent food security issues may also have drawn attention to the need for a more robust agricultural system in the EU. Thus, given the fact that the public interest theoretical framework views regulatory change as a potential consequence of changing perceptions of the public interest as outlined above, one could argue that this perspective is in line with public interest theory as outlined above, which may help to

explain the Commission's policy initiative on NGTs. This subtheme could also be seen in light of Baldwin & Cave's (1999) longer-term objectives justification for new regulation.

This is also further supported by the focus on specific traits to achieve the policy goals of the EU as specified in the interviews and documents outlined above. These particular traits, such as climate change resistance, herbicide and pesticide tolerance, increased efficiency, and pest resistance, can all be seen as connected to the policy goals outlined above and the EU's drive to ensure a sustainable and resilient agricultural system for its citizens. As stated in some of the interviews and documents, herbicide and pesticide-tolerant crops may be used to reach the F2F Strategy's goal of reducing chemical use, whereas the increased efficiency and improved yields may help to improve the security and independence of the EU's food system. This may also be seen in the fact that these policy goals are seen as priorities for the EU (Delegation of the European Union, 2021), with some actors even arguing that it would be challenging for the agricultural sector to achieve these goals and priorities without these new technologies (ELO, 2021). Hence, in this subtheme, potentially revising the EU's legislation is seen as contributing to the public interest by making use of the benefits of NGTs to attain broader goals which the Commission perceives as being in the public interest, which would be in line with Expectation 1.

6.1.2. Subtheme 2: Contradicting Policy Goals

In contrast to the first subtheme, the arguments presented in this subtheme cannot easily be categorised in the theoretical frameworks presented above. Nevertheless, given the fact that the Commission's policy initiative was described from this perspective as potentially contradicting the goals it sets out to achieve and the principles upon which the EU has been built, this subtheme leans more towards the private interest theory explanation of regulation and regulatory change. The perspectives and information in the documentary analysis and interviews that are categorised under this subtheme point to political arguments and commercial goals rather than furthering the public interest, which would also be more in line with the expectations of private interest theory. The claim that the benefits of NGTs are unsubstantiated could also be viewed through the theoretical lens of private interest theory, as this would indicate that the policy initiative could be based on promises of the private sector. Interestingly, the policy contradiction arguments also appear to be in line with the expectation in private interest theory that certain regulations, policy initiatives or reforms may be presented

as being in the public interest despite being informed by private interests (Chu & Major Pau, 2020).

In contrast, the argument put forth by one of the interviewees that the Commission may see NGTs as an "easy tool" [#4] to attain these goals despite the alleged unfulfilled promises of the biotechnology sector combined with the pressures from farmers could, to an extent, be interpreted as incorporating elements from both theories. On the one hand, this interviewee believed that the Commission was trying to find a way to help farmers respond to environmental pressures while also looking for an accessible and easy solution to the current societal, economic, and environmental problems, which appears to be in line with public interest theory. On the other hand, this interviewee also mentioned that the Commission was "answering the pleas of the agribusiness sector" [#4], which would be more in line with private interest theory. Thus, even though these arguments may perhaps be interpreted in different ways, this subtheme appears to lean mostly towards private interest theory with some public interest elements when looking at the Commission's initiative to potentially revise the existing GMO legislation.

6.2. Theme 2 Analysis

6.2.1. Subtheme 1: Narratives & Bias

With regards to this subtheme, one could argue that the arguments presented by the interviewees and authors in this section appear to be largely in line with private interest theory as outlined above. As put forward by some interviewees and authors, the claim that the Commission is following the agenda or the narratives of certain industries or sectors appears to indicate that the Commission is being influenced by these interests, which would point more towards private interest theory. This is particularly visible in one of the interviews where it is alleged that some actors are attempting to "circumvent" the existing GMO legislation by pushing for a specific agenda in favour of NGTs [#3], which indicates that these interviewees believe that the Commission's policy initiative is influenced by these private interests. This also applies to the claims that the Commission's consultations on its policy initiative are biased towards the biotechnological companies and organisations by reportedly reflecting the interests of this sector in the framing of the questions. This is also reflected in the argument put forth by some organisations that views against NGTs were purportedly not being heard by the Commission, which also points more towards private interest explanations.

The counterarguments presented in one of the interviews and some of the documents could also be categorised under this theoretical perspective. This could be seen, for example,

in the claims that anti-GMO organisations have tried to influence the Commission's consultation with prepared responses and are reportedly presenting a narrative that the Commission is pushing through regulatory change without public support. One could perhaps argue that this argument fits, to some extent, with the private interest perspective, given that consumers and interest groups can be considered to be the source of these private interests that may try to influence the regulator or regulatory agency. (J. Den Hertog, 2010b). Hence, the perspectives and counterarguments presented in this subtheme are, to some extent, in line with Expectation 2.

6.2.2. Subtheme 2: Lobbying & Corporate Influence

The arguments presented under the second subtheme arguably fit well with the main theoretical expectations of private interest theory. The influence of private interests was mentioned in the interviews as well as the documentary analysis conducted for this thesis and several research participants and authors discussed the importance of lobbying in relation to the Commission's policy initiative on NGTs. More specifically, the type of lobbying that was mentioned in the Corporate Europe Observatory's report that allegedly took place prior to the publication of the Commission's study on NGTs would likely be consistent with the second manifestation of private sector influence as specified by Etzioni (2009). According to this perspective, private interests may engage in lobbying after a regulation has been introduced that affects their interests to change the existing regulation (Etzioni, 2009). Thus, the lobbying of national representatives, the creation of a lobbying platform and the funding allegedly given to a think tank to promote these technologies through "climate narratives" as claimed by the CEO (2021) could be argued to be an example of this type of private interest influence at the EU-level, especially considering the fact that the CEO specifically mentions deregulation as a goal of these activities. This thereby provides some evidence in favour of the private interest perceptions as outlined in Expectation 2. This is further supported by the interviewees' perception of the existence of strong lobby influence at the EU-level and the alleged existence of revolving door practices in this sector [#3, #4, #5]. In the documents analysed for this thesis, this is supported by the claim that several powerful groups are active in the EU that have purportedly attempted to change the existing GMO legislation through lobbying. The specific use of the terms corporate control and corporate capture in some of the interviews and documents, as well as the massive amounts of lobbying resources these organisations are claimed to have, also further support the classification of these arguments under private interest theory. Thus, overall, the arguments presented under this subtheme appear to support a private

interest explanation of the Commission's policy initiative to potentially revise the EU's GMO legislation as specified in Expectation 2.

6.3. Theme 3 Analysis

6.3.1. Subtheme 1: Problems with the Existing Legislation

Moving onto subtheme 3.1, one could argue that the perspective that the problems with the existing legislation represent a major motivation for legislative change are in line with public interest theory's explanation of regulation and regulatory change. Firstly, the argument that the strictness of the current legislation has created an imbalance in the EU's internal market between large multinational corporations and small & medium-sized enterprises is consistent with the notion of regulatory failure, which occurs when regulation fails to solve the issue it aims to tackle or creates unintended consequences (van der Heijden, 2022, p.7-8). This is particularly visible in the enforcement and detection issues which the Commission listed in its study on NGTs, which reportedly contributed to the need for a new policy initiative. Due to the legislation's inability to deal with the reported lack of reliable detection methods for NGTs, the Commission is underequipped to enforce the traceability and labelling of NGTs, especially considering the fact that one interviewee argued that GMOs produced with NGTs might enter the EU's internal market through trade with third parties without being identified as such. If this were to happen, this would arguably be an example of regulatory failure as the Commission would be unable to ensure the implementation of the current legislative requirements. The trade issues and barriers that are said to arise from the EU's current legislative framework on GMOs could also be argued to be another form of regulatory failure as the existing regulation is perceived as creating new market failures by leading to an unfavourable economic position for the EU and European companies. Additionally, Keeler's (1984) argument that regulatory change may be necessary when the structural and technological context changes also appears to be consistent with the arguments presented in this subtheme. Hence, given that these arguments suggest that these issues represent a major motivation for the Commission to pursue regulatory change, one could argue that this perspective is consistent with the expectations of public interest theory.

The legislative uncertainty emphasised in both the interview transcripts and the documents analysed for this thesis also appears to be consistent with the regulatory failure explanation of change in public interest theory as explained by Van der Heijden (2022), considering the complaints regarding the legal status of NGTs, the lack of specific definitions, and the ambiguity created by the CJEU's 2018 judgment. This is also visible in the belief that

the current legislation "is not fit for purpose" (European Commission, 2021d), which is consistent with the regulatory failure perspective in public interest theory. However, this is contradicted by Interviewee 5's view that there are commercial goals involved, which points towards a private interest explanation.

Moreover, considering the fact that the Commission's study argued that the current legislation is limited due to the fact that it does not consider the sustainability benefits of GM products (European Commission, 2021c), one could argue that the current costs of the regulation could be seen as outweighing its benefits since the sustainability potential of these products remains largely untapped. Furthermore, reduced innovation as a by-product of the current regulation could be seen as an unintended consequence that has increased the costs of regulation, which supports the theoretical link between these arguments and public interest theory. Lastly, the view that the current legislation is too strict and thereby prevents the EU from adapting to the latest developments is consistent with the idea that overregulation can lead to regulatory failure (van der Heijden, 2022). Hence, the arguments presented under this subtheme, aside from the counterargument presented by one interviewee, appear to fully support the view that the Commission's policy initiative can be explained through public interest theory as specified in Expectation 1.

6.3.2. Subtheme 2: "Still Fit For Purpose"

The counterarguments used by the interviewees and authors with a more negative stance on NGTs contradict the idea that the EU's GMO legislation is no longer appropriate in the current context. The perspectives presented under this subtheme challenge the regulatory failure, technological change, and cost-benefit explanations outlined above, which indicates that this subtheme's arguments are not in line with the theoretical expectations of public interest theory. Interviewee 5's claim that harmonisation with other jurisdictions as a motivation for change would "be going backwards" [#5] further contradicts the public interest perspective. Similarly, the perspectives outlined in this subtheme also do not bear the hallmarks of typical private interest theory arguments, which makes this subtheme difficult to classify. This could indicate that this thesis is missing a theoretical perspective that could help to explain these arguments, which presents an important limitation to consider.

However, what is clear from these arguments is that these interviewees and authors do not agree with the statement that the current legislation is no longer suited to the current context. This is visible in the fact that some authors and research participants noted the need to preserve the regulations as they currently stand, while others emphasised the value of the existing

traceability and labelling requirements and highlighted the ways in which producers and traders of GM crops and products could fulfil these legal obligations. One could, therefore, argue that these arguments imply that the Commission must have other motivations for potentially pursuing regulatory change. However, considering the fact that the interviewees mentioned under Theme 3.2. also presented arguments categorised under Themes 1.2, 2.1, and 2.2, which either partially leaned towards or reflected the expectations of private interest theory, it is likely that the arguments presented under this subtheme are, to an extent, also connected to these private interest explanations. This connection is also the case for some of the documents analysed in this subtheme. Hence, while these arguments are, by themselves, difficult to categorise in the two theoretical frameworks presented in Section 3, the connection with other themes appears to offer some support for Expectation 2.

6.4. Preliminary Conclusions

Overall, the discussion of the different themes indicates that there are contradictory perceptions of the Commission's policy initiative to pursue new regulations for NGTs. Whereas subthemes 1.1 and 3.1 appear to support public interest explanations, subthemes 2.1 and 2.2 are in line with the expectations of private interest theory. While the other subthemes portray a more mixed perspective, the findings show that different actors and stakeholders have conflicting views of the underlying motivations for this initiative, which points towards a mixed theoretical perception of these regulatory developments.

6.5. Research Limitations & Initial Recommendations

Having thereby discussed this paper's results in light of the theoretical frameworks presented in Section 3, a number of research limitations remain that need to be discussed. Starting off, it is important to note that the claims made by the interviewees and authors of the texts cannot be verified independently by the author of this thesis. Thus, future research may need to delve deeper into the factual claims made by both sides of the debate. Furthermore, given that this thesis focuses primarily on the perspectives of different organisations and individuals that are active in this field, it is possible that the views presented above do not all accurately reflect the motivations of the Commission for pursuing policy change. However, this thesis still arguably represents a valuable addition to the existing literature by providing preliminary insights into the ways in which different actors perceive this policy initiative and the Commission's policy actions on GMOs and NGTs. Additionally, while this thesis is by no means an exhaustive overview of all the different perspectives on this topic, it is important to note that this paper is meant to pave the way for future research concerning the regulation of

GMOs and NGTs in the EU. While the Commission is yet to present a definitive proposal for policy action in this field, this thesis has attempted to capture perceptions of the initial decision to pursue policy action as well as the policymaking and consultation process associated with this initiative. Thus, future research may focus on the proposal that the Commission aims to present in 2023 and the subsequent legislative process or may build on the perspectives-based research presented in this thesis.

Another important limitation to consider is the fact that this thesis could have been improved with additional interviews. However, as addressed above, research participants were hard to find, which is why a combination of interviews and documentary analysis was used in this paper. The triangulation of data sources also helps to mitigate some of the biases inherent in qualitative research and arguably provides a more extensive overview of the variety of perspectives held by individuals and organisations in this field. Lastly, the discussion and analysis of the different themes have indicated that some of the arguments and perspectives may not fully fit into the two theoretical frameworks presented in Section 3. Thus, further research may be needed that includes more theoretical perspectives for a more detailed theoretical discussion of this topic.

7. CONCLUSIONS & FURTHER RECOMMENDATIONS

Overall, this paper has delved into the different perceptions of the Commission's recent initiative regarding the status of NGTs under the EU's current GMO legislation and the regulations that apply to such technologies. While the Commission is yet to present a final proposal for its policy initiative, this thesis has paved the way for future research by providing a preliminary overview and analysis of the arguments and perspectives put forth by individuals and organisations on this topic. The theoretical analysis has primarily focused on private and public interest theories of regulation, which have functioned as guiding theoretical frameworks for the categorization and analysis of these perspectives. By combining interviews with documentary analysis, this paper has presented a wide range of perspectives on the potential motivations for pursuing regulatory change in the form of three overarching themes. Specific arguments and counterarguments on both sides of the debate were incorporated into these themes to provide the most accurate overview of the diverse range of arguments that can be identified in the texts and interview transcripts.

Reflecting on the discussion and analysis section presented above, several observations can be made in relation to the theoretical expectations described in Section 3. On the one hand, subthemes 2.1 and 2.2 fit well within the private interest explanations of regulatory change.

The arguments used by the interviewees and authors seem to support the idea that certain narratives are being followed and that there is a lobbying effort in this field. This view is also supported by the claims and allegations that the policy initiative is biased towards certain viewpoints and sectors. The corporate capture and control arguments are also consistent with this theoretical perspective and the type of lobbying mentioned by the interviewees and authors appears to conform to the framework outlined by Etzioni (2009). Furthermore, subthemes 1.2 and 3.2 also present some arguments that appear to lean more towards private interest theory when combined with the other perspectives presented in the interviews and texts, which supports Expectation 2 to a certain extent.

On the other hand, the perspectives advanced in subthemes 1.1 and 3.1 arguably support the claim that the Commission's policy initiative is driven by public interest motivations. The issues mentioned in these subthemes reflect the theoretical expectations of regulatory failure, legislative inefficiency, legal ambiguity as well as changing conceptions of the public interest over time. When looking at the policy initiative from this perspective, the pursuit of regulatory change can be explained by the potential benefits of GMOs produced with NGTs and the role these novel technologies can play in achieving broader goals as embodied in the EGD, the F2F Strategy, the Biodiversity Strategies and the UNSDGs. These arguments are in line with the theoretical expectation that new regulations may be introduced if they are perceived as being in the public interest. This is also supported by the fact that the existing GMO legislation is perceived as causing market imbalances, trade barriers, reduced innovation, and an overly stringent regulatory environment, which is in line with the overregulation and regulatory failure components of public interest theory. This, therefore, contradicts the earlier conclusions and points more towards Expectation 1.

Hence, neither Expectation 1 nor Expectation 2 can be fully accepted or rejected due to the conflicting perceptions of the Commission's initiative. Rather, the contradictory evidence and perspectives of the policy initiative point towards an explanation in which elements of both theoretical frameworks are present. Furthermore, it is also interesting to note that, overall, individuals and organisations with a more negative stance on NGTs and GMOs tended to present arguments in line with private interest theory, whereas those with a more positive stance on these topics usually presented arguments in line with public interest explanations for regulatory change. Similarly, the Commission documents analysed for this thesis also contained arguments that could be categorised in the public interest framework.

Thus, while the findings suggest a mixed theoretical perspective, future research may be needed to reflect on the positions of the different individuals and organisations active in this

field and how this may inform their perceptions of this policy initiative. This mixed theoretical perspective also suggests that future research should perhaps move away from the public versus private interest dichotomy and rather view these theories as interconnected despite each framework's shortcomings. As mentioned briefly above, further research will also be needed when the Commission proposes its final proposal in the second quarter of 2023 to see whether the perspectives and arguments of these actors have changed over time. Lastly, in terms of policy implications, the results from some of the interviews have shown that some organisations and individuals continue to view this initiative with suspicion. Hence, if the Commission wishes to move forward with this initiative, it would be advisable to engage with different stakeholders and citizens more often in a direct and transparent manner to create an environment that is conducive to constructive dialogue between actors on opposing sides of this debate. The Commission should also attempt to address the doubts, concerns, and reservations of the organic food sector - as seen in some of the interviews - as well as consumers in the European Union while balancing the need for greater legal clarity, sustainability, security, transparency, and increased innovation in the food value chain.

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9. APPENDICES

9.1. Documentary Analysis Overview

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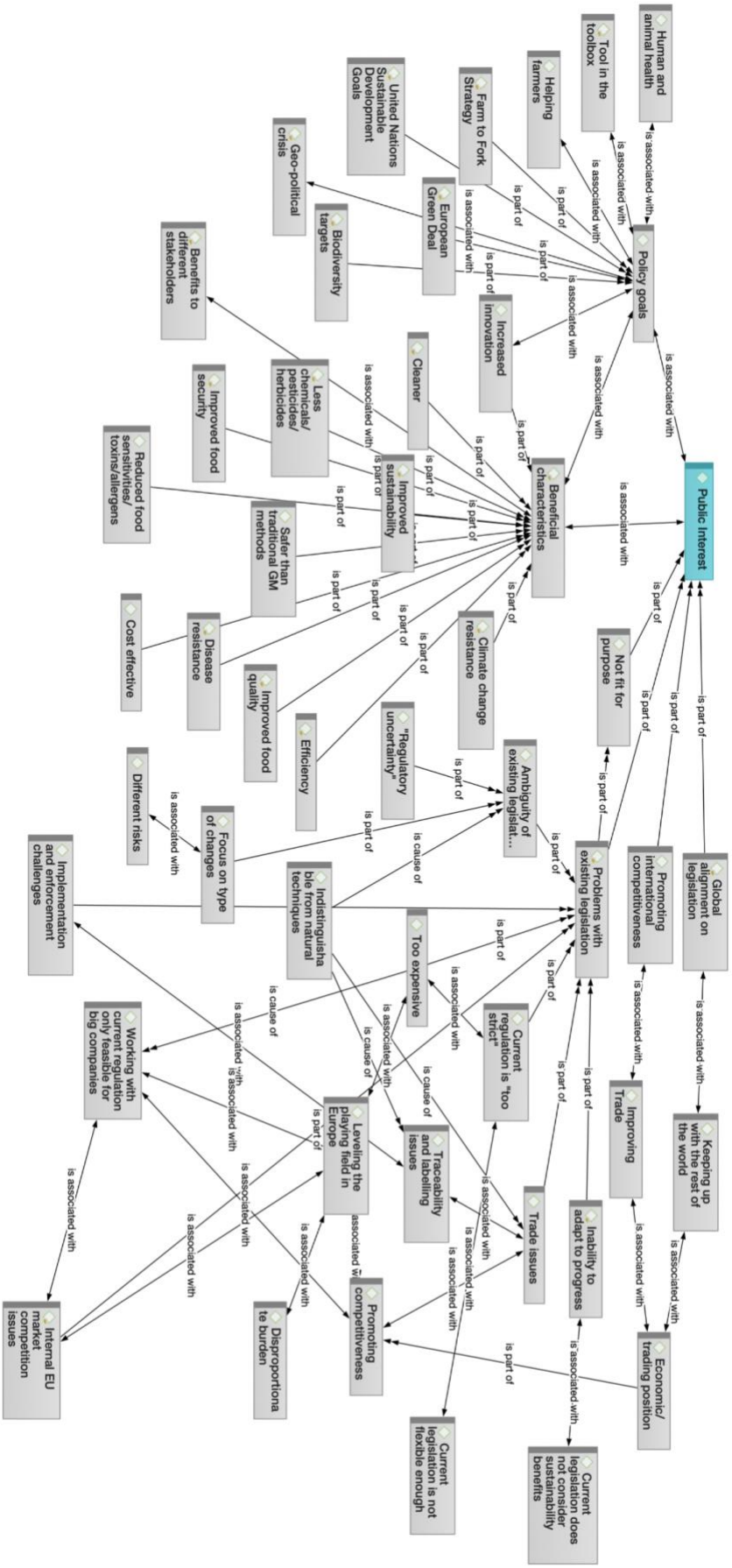
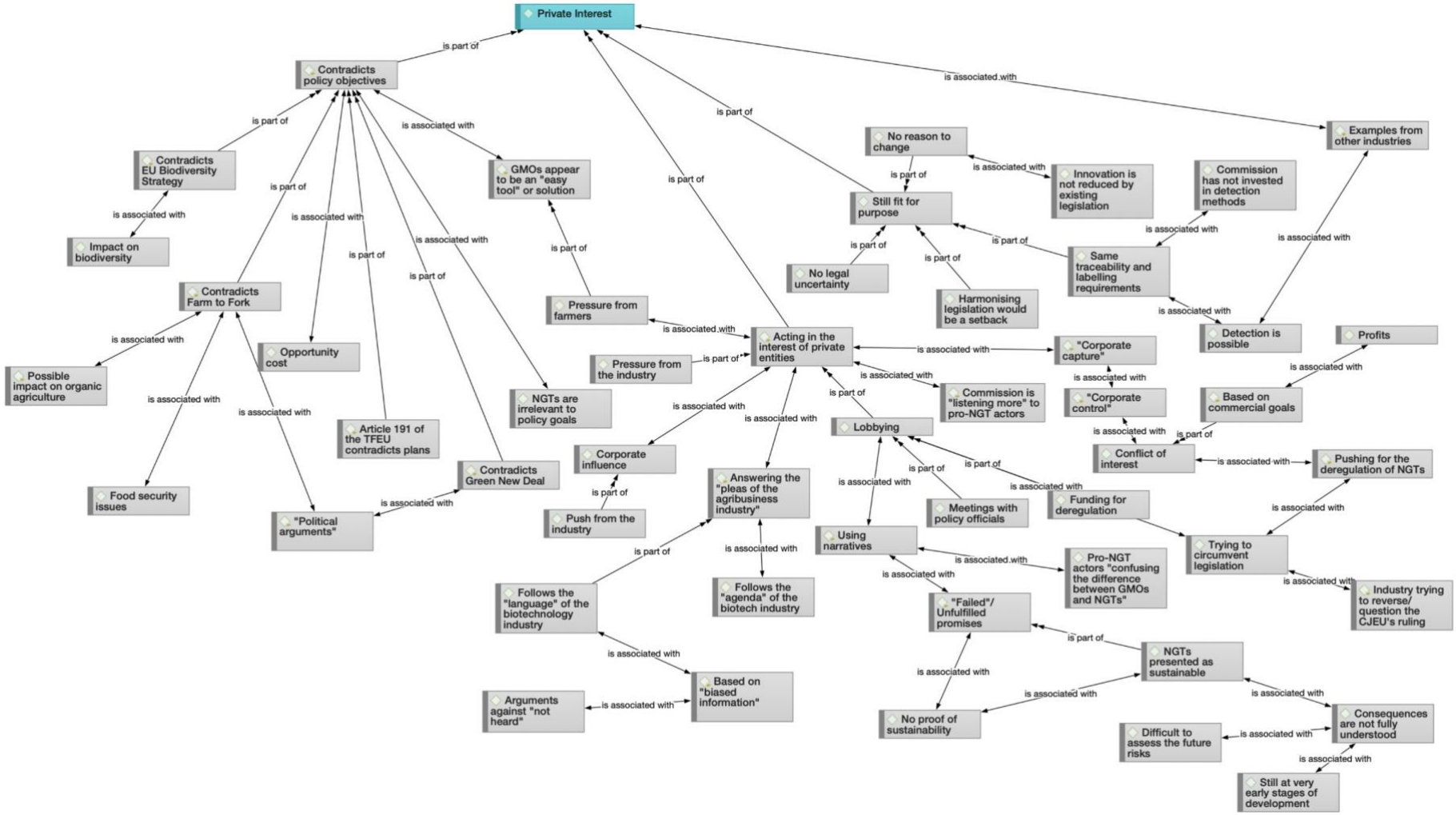
9.2. Coding Trees




Private Interest
Contradicts policy objectives
Contradicts EU Biodiversity Strategy
Impact on biodiversity
Contradicts Farm to Fork
Possible impact on organic agriculture
Food security issues
Opportunity cost
"Political arguments"
Article 191 of the TFEU contradicts plans
Contradicts Green New Deal
GMOs appear to be an "easy tool" or solution
Pressure from farmers
Push from the industry
NGTs are irrelevant to policy goals
Corporate influence
Pressure from the industry
Acting in the interest of private entities
Answering the "pleas of the agribusiness industry"
Follows the "language" of the biotechnology industry
Follows the "agenda" of the biotech industry
Based on "biased information"
Arguments against "not heard"
Lobbying
Using narratives
"Failed"/ Unfulfilled promises
No proof of sustainability
Meetings with policy officials
Commission is "listening more" to pro-NGT actors
"Corporate capture"
"Corporate control"
Conflict of interest
Funding for deregulation
Pro-NGT actors "confusing the difference between GMOs and NGTs"
NGTs presented as sustainable
Difficult to assess the future risks
Still at very early stages of development
Consequences are not fully understood
Trying to circumvent legislation
Industry trying to reverse/ question the CJEU's ruling
Pushing for the deregulation of NGTs
Based on commercial goals
Profits
Examples from other industries
Detection is possible
Same traceability and labelling requirements
Commission has not invested in detection methods
Innovation is not reduced by existing legislation
No reason to change
Still fit for purpose
No legal uncertainty
Harmonising legislation would be a setback
is part of
is associated with
is associated.with