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Analyzing Regulatory-induced Economic Challenges on the Adoption of Transgenic Crops: Selected Cases

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List of Frequently Used Acronyms

AATF	African Agricultural Technology Foundation
AC	Appeal Committee
C/AC	Council/Appeal Committee
APHIS	Animal and Plant Health Inspection Service
BCC	Banker, Charnes, Cooper
BRS	Biotechnology Regulatory Services
CCR	Charnes, Cooper, Rhodes
CRS	constant returns to scale
DEA	data envelopment analysis
DMU	decision-making unit
DRS	decreasing returns to scale
EC	European Commission
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
EU	European Union
GE	genetically engineered (the noun form of this term)
GM	genetically modified
GMO	genetically modified organism
IP	intellectual property
IRMA	Insect Resistant Maize for Africa Project
IRS	increasing returns to scale
ISAAA	International Service for the Acquisition of Agri-biotech Applications
M	million
M&A	merger and acquisition
MS	Member State
NARO	National Agricultural Research Organisation of Uganda
NGO	non-governmental organization
NPV	net present value
OECD	Organisation for Economic Co-operation and Development
OLS	ordinary least squares

OTE	overall technical efficiency
PPP	public-private partnership
PTE	pure technical efficiency
QM	qualified majority
R&D	research and development
RHS	right hand side
SCFCAH	Standing Committee on the Food Chain and Animal Health
SE	scale efficiency
SFA	stochastic frontier analysis
SH	Smith and Haddad (2015)
SSA	Sub-Saharan Africa
SME	small and medium enterprise
SWOT	strengths, weaknesses, opportunities and threats
UNCST	Uganda National Council for Science and Technology
US	United States
USD	United States Dollars
USDA	United States Department of Agriculture
VRS	variable returns to scale
WEMA	Water Efficient Maize for Africa
WHO	World Health Organization

Zusammenfassung

Diese Dissertation enthält fünf wissenschaftliche Artikel. Jeder Artikel befasst sich eingehend mit regulatorisch bedingten sozioökonomischen Herausforderungen, mit denen sich die Gesellschaft im Hinblick auf die Akzeptanz bzw. Annahme gentechnisch veränderter Kulturpflanzen konfrontiert sieht.

In Kapitel 3 werden die sozioökonomischen Herausforderungen der Bioökonomie einer wirtschaftlich weit entwickelten Region (Europa) sowie einer wirtschaftlich weniger weit entwickelten Region (Subsahara-Afrika) untersucht. Die Bereiche, in denen Afrika von den Erfahrungen Europas profitieren und Nutzen aus eigener Expertise ziehen könnte werden im Rahmen einer qualitativen Analyse der jeweiligen Chancen und Herausforderungen der Bioökonomie aufgezeigt. Europa eröffnet die Bioökonomie neue Wege, im globalen wirtschaftlichen Wettbewerb zu bestehen. Jedoch wird die Wettbewerbsfähigkeit in Europa wie auch in Afrika durch die geringe gesellschaftliche Akzeptanz grüner Biotechnologie und die relativ strengen Regularien für die Autorisierung von Innovationen wie beispielsweise gentechnisch veränderten Kulturpflanzen geschmälert.

Ein Patentrezept für Innovationserfolg in den Biowissenschaften scheint nicht zu existieren. Jede Region sollte Wege einschlagen, die zu ihren Voraussetzungen und Standortbedingungen passen, um die Bioökonomie nachhaltig zu entwickeln. Solche Wege erfordern in jedem Fall ein konfliktfreies und stabiles politisches Umfeld. Europa und Afrika sollten über politische Strategien und Maßnahmenpläne verfügen, die darauf abzielen, eine nachhaltige bioökonomische Entwicklung zu fördern. Einflussreiche Persönlichkeiten aus Politik, Bildung, Forschung und Wirtschaft sollten den Herausforderungen der Bioökonomie gemeinschaftlich und proaktiv begegnen, um im globalen Wettbewerb Schritt zu halten und Wohlfahrtsverluste zu vermeiden. Regierungen sollten die Bioökonomie durch Maßnahmen wie etwa bevorzugte Beschaffung und finanzielle Anreize für Vorhaben, die einen nachhaltigen gesellschaftlichen Mehrwert schaffen, ankurbeln. Zu diesen gehören klimasmarte landwirtschaftliche Praktiken und die Erzeugung ‚grünen' Stroms. Investitionen des öffentlichen und privaten Sektors in Forschung und Entwicklung (sowohl Forschungsinfrastruktur als auch Wissensaufbau) sollten erhöht werden, um die Innovationstätigkeit in der Bioökonomie zu beschleunigen. In Afrika sollten insbesondere Ausgaben in den Bereichen Kommunikation und Transportinfrastruktur steigen. Auf diese Weise kann der Transport von Erzeugnissen aus ländlichen Gebieten zu Märkten und wertschöpfenden Verarbeitern koordiniert

werden und schließlich erfolgen. Ferner sollten Systeme zur klaren Regelung von Landbesitzverhältnissen bestehen. Europa und auch viele afrikanische Staaten müssen regulatorische Anforderungen in Bezug auf die rechtliche Autorisierung von Innovationen abschwächen, vor allem hinsichtlich gentechnisch veränderten Kulturpflanzen. Staaten in Subsahara-Afrika sollten Regularien zur Autorisierung gentechnisch veränderter Pflanzen harmonisieren und Verordnungen zur Biosicherheit einführen, die die Nutzung in wirtschaftlich hoch entwickelten Ländern bereits genehmigter Innovationen ermöglichen.

Kapitel 4 analysiert die Dauer von Genehmigungsverfahren für neue gentechnisch veränderte Kulturpflanzen in den Vereinigten Staaten von Amerika (USA) – dem weltweiten Zentrum für biotechnologische Innovationen, in dem die Mehrzahl neuer gentechnisch veränderter Pflanzen entwickelt und zugelassen wird – und der Europäischen Union (EU). Die USA und die EU sind auf globaler Ebene wichtige Handelspartner für diese Güter. Generell kann in jedem Regulierungssystem eine Entwicklung hin zu kürzeren Zulassungszeiträumen erwartet werden. Folglich wird die Hypothese getestet, dass Zulassungsverfahren für gentechnisch veränderte Kulturpflanzen sowohl in den USA als auch in der EU mit der Zeit an Dauer verlieren. Mit diesem Ansatz wird das Ziel verfolgt, die Forschung zur Zulassungsdauer gentechnisch veränderter Kulturpflanzen durch eine Untersuchung 1) des Beitrags jedes einzelnen Schrittes des Zulassungsverfahren zum gesamten Regulierungsverfahren sowie 2) des Einflusses bestimmter Kulturpflanzencharakteristiken hinsichtlich der Zulassungsdauer auf den neuesten Stand zu bringen.

Eine Reihe Kleinst-Quadrate-Regressionsmodelle (OLS) bilden das methodische Fundament, um zu prüfen, ob Unterschiede in der Dauer von Zulassungsverfahren von Pflanzeneigenschaften oder externen, unabhängigen Faktoren abhängen.

Die Ergebnisse im Fall der USA zeigen, dass die Gesamtgenehmigungsdauer anfänglich, zwischen 1988 und 1997, abnahm. Die durchschnittliche Zulassungsdauer betrug 1.321 Tage. Zwischen 1998 und 2015 konnte weder ein zunehmender noch ein abnehmender Trend beobachtet werden. Durchschnittlich nahm ein Zulassungsverfahren 2.467 Tage in Anspruch. Im Jahr 1998 konnte ein Strukturbruch hinsichtlich des Trends der Genehmigungsdauer identifiziert werden. Statistisch signifikante Korrelationen zwischen Pflanzeneigenschaften und Zulassungsdauer konnten nicht entdeckt werden.

In der EU verkürzte sich die Zulassungsdauer zwischen 1996 und 2015 zunächst und blieb gegen Ende der Periode konstant. Die durchschnittliche Dauer pro Genehmigungsverfahren betrug 1.763 Tage. Der Prozessschritt der Risikobewertung zeigte hinsichtlich der Prüfungsdauer einen ansteigenden Trend. Bei Einreichungen von neuen Sorten, die eine gentechnische Veränderung zur Resistenz gegenüber Insekten aufwiesen, war eine um 150% (88 Tage) längere Bearbeitungsdauer im Vergleich zu Sorten mit Herbizidtoleranz zu beobachten. Einreichungen auf dem Gebiet der Nichtlebensmittel bzw. Futter benötigten in der Prüfung 208% (559 Tage) länger als ‚Lebens- und Futtermittel'-Einreichungen. Bezüglich der Gesamtzulassungsdauer konnte kein Hinweis auf statistisch signifikante Unterschiede zwischen europäischen und außereuropäischen Herstellern, herbizidtoleranten und Insektizid-wirkenden Kulturpflanzen oder Kulturpflanzen der Kategorien ‚Lebens- und Futtermittel' und Nichtlebensmittel/Futter gefunden werden.

Die Politik spielt hinsichtlich des Autorisierungsverfahrens für gentechnisch veränderte Pflanzen in der EU – einer politischen Union aus unterschiedlichen Mitgliedstaaten (MS) mit jeweils komplexen regulatorischen Vorgaben für gentechnisch veränderte Pflanzen – eine entscheidende Rolle. In Kapitel 5 wird das Wahlverhalten von EU-Mitgliedstaaten bei Abstimmungen zu Zulassungsanträgen für gentechnisch veränderte Kulturpflanzen zwischen 2003 und 2015 analysiert. Manche Mitgliedstaaten (‚swing states') haben entscheidenden Einfluss auf das Ergebnis jeder Wahl. Die Forschungsfragen lauten: (1) Sind die Charakteristiken einzelner Mitgliedstaaten entscheidender für ihr Wahlverhalten als andere Faktoren wie etwa die Kulturpflanzenart? Und (2) Das Wahlverhalten welchen Mitgliedstaats sollte sich ändern, um einen Stillstand bei Zulassungen zu verhindern?

Logistische Regressionen wurden verwendet, um zu prüfen, ob Eigenschaften eines Mitgliedstaats, der Sitz des einreichenden Unternehmens sowie genetische Merkmale einer Kulturpflanze geeignete, die Wahlentscheidungen von Mitgliedstaaten erklärende Variablen darstellen.

Spezifische Eigenschaften von Mitgliedstaaten wurden als wesentlicher, die Wahlergebnisse beeinflussender Faktor identifiziert. Diese Erkenntnis spricht für die Hypothese, dass der Erfolg von Zulassungsanträgen stark von MS-Spezifika abhängt. Die Charakteristiken von Kulturpflanzen wie auch deren Nutzung beeinflussten das Wahlverhalten nicht. Frankreich, Deutschland und Italien sind die drei entscheidenden ‚swing states', deren Wahlverhalten stärker von einem ‚Pro-Gentechnik'-Gedanken geprägt sein müsste, um Zulassungsverfahren überhaupt erst zu ermöglichen.

In den meisten Regionen Subsahara-Afrikas sind Nahrungspflanzen das Grundnahrungsmittel der Einwohner. Pflanzenschädlinge und Dürren sorgen vielerorts für Mindererträge dieser Pflanzen. Dies führt zu einer Gefährdung der Nahrungsmittelsicherheit und zu häufigerem Auftreten von Unterernährung, insbesondere bei Kindern. Zu den erwähnten Nahrungspflanzen gehören: Kochbananen (Matoke) in Uganda, die empfindlich auf einen die Blattfleckenkrankheit Schwarze Sigatoka auslösenden Pilz reagieren; Augenbohnen in Benin, im Niger und in Nigeria, die durch Fressraupen gefährdet sind; Mais in Kenia, der durch Insekten und feuchtigkeitsbedingte Beanspruchung Schaden nimmt. In Kapitel 6 wird der folgenden theoretischen Frage nachgegangen: Was ist der durch verzögerte Zulassung verbesserter Sorten entgangene Nutzen in den entsprechenden afrikanischen Staaten?

Auf Grundlage des "Santaniello Theorem of Irreversible Benefits" wurde ein theoretisches Modell entwickelt, mit dem die Kosten und der Nutzen von Zulassungsverfahren für gentechnisch veränderte Kulturpflanzen mittels Realoptionsanalyse untersucht werden können.

Der theoretisch entgangene Nutzen, ausgedrückt in Konsumenten- und Produzentenrente, einer um ein Jahr verzögerten Zulassung einer gentechnisch veränderten Augenbohnensorte in Benin, im Niger und in Nigeria beläuft sich auf 2-2,4 Mio. US-Dollar (USD), 14,9 Mio. USD und 33,1-46,6 Mio. USD. Unter der Annahme einer 40%igen Akzeptanzrate nach 10 Jahren entsprechen diese Zahlen 10, 4 und 401 Menschenleben. Die entgangene Konsumenten- und Produzentenrente einer um ein Jahr verzögerten Zulassung einer genetisch veränderten Maissorte in Kenia sowie einer genetisch veränderten Kochbananensorte in Uganda beträgt 21,9-49,8 Mio. USD und 56,9-97,3 Mio. USD. Wird wieder eine 40%ige Akzeptanzrate nach 10 Jahren unterstellt, so entsprechen diese Werte 572 und 862 Menschenleben.

Die Saatgutindustrie ist ein wesentlicher Bestandteil von Wertschöpfungsketten der Agrar- und Ernährungswirtschaft. Sie war in den vergangenen Jahrzehnten geprägt von einer stetigen privatwirtschaftlichen Konsolidierung, aus der ein paar wenige relativ große Firmen hervorgegangen sind. Diese sind sowohl durch erfolgreiches Wirtschaften als auch durch Fusionen und Übernahmen entstanden. Alle Saatguthersteller setzen herkömmliche Züchtungsmethoden zur Entwicklung neuer Produkte ein. Manche setzen zudem auf technologieintensive Methoden wie die Gentechnik. Die Vermarktung gentechnisch veränderter Kulturpflanzen unterliegt jedoch einem Regularium. Vor diesem Hintergrund lauten die Forschungsfragen von Kapitel 7: (1) Welche technische Effizienz erreichten die neun größten Saatguthersteller im Zeitraum 2008-2015? Und (2)

Besteht ein Zusammenhang zwischen Unternehmensgröße und Effizienz? Unternehmen, die Kritik im Hinblick auf ihren Beitrag zur Saatgutmarktkonzentration ausgesetzt sind, sind Teil der Studie.

Die Methode Data Envelopment Analysis mit der Spezifikation Window Analysis wurde zur Datenanalyse herangezogen. Über alle Unternehmen hinweg betrug die durchschnittliche technische Effizienz 93,5% und 94,3% in den Fenstern 1 und 5. Die leichte Zunahme um 0,8 Prozentpunkte deutet auf Stabilität der unternehmerischen Managementfähigkeiten hin. Dow bildete in dieser Hinsicht die Ausnahme mit einem Gesamtzuwachs von 7,75 Prozentpunkten. Ein klarer Zusammenhang zwischen reiner technischen Effizienz und Vermögensgröße scheint nicht gegeben zu sein. Auf der Ebene einzelner Unternehmen wirtschafteten DuPont Pioneer und Syngenta unter steigenden Skalenerträgen, während Monsanto und Dow konstante Skalenerträge, die produktivste Skalengröße, erreichten. DLF Trifolium und Takii erreichten diese Skalengröße annähernd. Sakata und Bayer zeigten einen inkonsistenten, sägezahngleichen Trend beim Verhältnis von reiner technischen Effizienz zu Betriebsgröße. Ein Zusammenhang zwischen Skaleneffizienz und Vermögensgröße konnte nicht nachgewiesen werden. DuPont Pioneer erreichte Skaleneffizienz in drei aufeinanderfolgenden Fenstern, während DLF Trifolium, Dow und Monsanto dies in lediglich einem (aber nicht dem gleichen) Fenster schafften. Alle anderen Unternehmen wiesen konstante Skalenineffizienz auf. Die niedrigsten Skaleneffizienzwerte erreichte Sakata (87,5-91,7%). Bezogen auf die Gesamteffizienz ergab die Analyse zur reinen technischen Effizienz, dass die Unternehmenstätigkeiten der meisten Firmen in den Bereichen Fusionen und Übernahmen theoretisch gerechtfertigt waren (Bayer bildete hier die Ausnahme).

Summary

Five pieces of scientific research comprise this dissertation. Each piece delves into socioeconomic challenges brought on by regulations that society faces in the adoption of genetically engineered (GE) crops.

Chapter 3 investigates the socioeconomic challenges of the bioeconomies of Sub-Saharan Africa (SSA) and Europe, which are considered developing and developed, respectively. The areas in which Africa could learn from Europe’s experiences and harness its expertise is revealed by a qualitative assessment of their bioeconomies’ challenges and opportunities. The bioeconomy offers Europe an avenue for competing in the global economy. The public acceptance of especially green biotechnology and the relatively stringent regulatory requirements for authorizing innovations like GE crops in Europe and many African states potentially compromise the competitiveness of their bioeconomies. The research question asked is: What pathways are there for unlocking the potential of the bioeconomies of Europe and Africa?

There is no blanket approach for innovation success in the biosciences. Each region should tailor pathways unique to its circumstances for sustainably developing its bioeconomy. Pathways to success require a conflict-free and stable political environment. Europe and Africa should have policies targeted at supporting sustainable bioeconomic development. Influential leaders in government, education, and business should address the bioeconomy challenges together, and proactively, to avoid their global competitiveness from being compromised and welfare lost to competitors. Governments should stimulate their bioeconomies through policies such as preferential procurement programs and providing financial incentives for initiatives that will be of long-term benefit to society, for example: climate-smart farming and the generation of ‘green’ electricity. Public and private sector research and development investments and capacities (infrastructure and expertise) should be increased to accelerate innovation development in the bioeconomy. In Africa, investments in communication and transport infrastructure should be increased for coordinating and transporting produce in rural areas to markets and value-adding facilities, and secure land tenure systems should be implemented. Europe and many African countries need to lighten their regulatory requirements for authorizing innovations, especially GE crops. SSA states should harmonize regulations for authorizing GE crops, and implement biosafety regulations allowing for the adoption of innovations approved elsewhere.

Chapter 4 analyses the trends in approval time of new GE crops in the United States (US)—the global center for biotechnological innovations where the majority of new GE crops are developed and first approved for use—and the European Union (EU), which are two globally important trading partners in these commodities. A trend towards shorter approval times in a given regulatory system is expected. The hypothesis tested is that approval times of GE crops in the US and EU shorten over time. This research is an updated analysis of the time taken for GE crops to be approved by analyzing: (1) each step in the regulatory 'path' for its contribution to the overall regulatory process, and (2) crop characteristics' impact on regulatory time.

A set of ordinary least squares (OLS) regression models for testing if differences in the regulatory process' time-line could be explained by plant characteristics, or external, independent factor(s) was used.

The results for the US show that initially, from 1988 until 1997, the trend in overall approval time decreased with a mean approval time of 1,321 days. From 1998-2015, the trend almost stagnated with a mean approval time of 2,467 days. In 1998, there was a break in the trend of the overall approval time. No statistically significant correlations between crop characteristics and regulatory time were found.

In the EU, from 1996-2015, the overall temporal trend for approval decreased and then flattened off, with an overall mean completion-time of 1,763 days. The duration of the 'risk assessment' step tended to increase. Applications with the insect resistance trait took 150% (88 days) longer than those for herbicide tolerance. Applications for non-food/feed took 208% (559 days) longer than those for 'food and feed' purposes. For the overall approval time, there was no robust evidence for statistically significant differences between domestic and foreign developers, herbicide tolerant and insecticide resistant crops, or 'food and feed' and non-food/feed crops.

Politics plays a decisive role in the authorization process of GE plants in the EU—a political union comprising a broad spectrum of Member States (MSs) with a complex regulatory framework for GE plants. Chapter 5 analyzes the voting behavior of EU MSs for voting results on applications of GE crops for authorization from 2003 through 2015. Some MSs ('swing states') have a key influence on the outcome of any given ballot. The research questions are: (1) Are individual MS characteristics more relevant for explaining their voting behavior than other factors such as crop type? And, (2) Which MSs' voting behavior should change to avert a gridlock for approval?

Logistic regressions were used for testing whether an MS's identity, an applicant's domicile, and a crop plant's genetic trait are suitable explanatory variables for explaining an MS's voting decision.

MS fixed effects was the major factor explaining the voting results supporting the gridlock hypothesis. Crop characteristics and crop use played no apparent role in MSs' voting behavior. France, Germany, and Italy are the three important 'swing states' whose voting behavior should change to a 'for' vote to avert a gridlock for approval.

In most regions of SSA, food crops comprise the staple diet of their inhabitants. Pests significantly reduce the yields of some of these crops, as do droughts. The result is lowered food security and increased levels of malnutrition, especially for children. Examples of these crops include: cooking banana (matoke) in Uganda that is susceptible to a fungus causing black sigatoka (leaf spot) disease; cowpea in Benin, Niger, and Nigeria, that is susceptible to a pod boring insect; and corn[1] in Kenya that is susceptible to insects and moisture stress. In Chapter 6, the following theoretical question is asked: What are the foregone benefits of delaying the approval of these food crops in their respective African states?

A theoretical model is developed for assessing the benefits and costs of approval processes for GE crops using a real option framework that calls upon the "Santaniello Theorem of Irreversible Benefits".

The theoretical foregone benefits in terms of consumer and producer surplus of a 1-year delay in the approval of the GE cowpea in Benin, Niger, and Nigeria is estimated to be 2-2.4 million (M) US Dollars (USD), 14.9 M USD, and 33.1-46.6 M USD, and in terms of lives lost for a 40% adoption ceiling after 10 years: 10, 4, and 401 lives, respectively. The foregone consumer- and producer surplus benefits of a 1-year delay in the approval of GE corn in Kenya and GE cooking banana in Uganda is 21.9-49.8 M USD and 56.9-97.3 M USD, and in terms of lives lost for a 40% adoption ceiling after 10 years: 572 and 862 lives, respectively.

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[1] The terms ***corn*** and ***maize*** are used interchangeably (i.e., synonyms) in this dissertation. Both terms refer to the same crop: ***Zea mays L***.

The seed industry is part of the first link in the agri-food value chain. Consolidation has taken place in the private sector with the emergence of a small number of relatively large firms, which have grown both organically and through merger and acquisition (M&A) activities. All seed-producing firms use conventional plant breeding methods for developing new products. Some of them also employ technology intensive methods for developing GE crops, the commercialization of which are subject to regulation. Chapter 7’s research questions are: (1) What are the efficiency levels of the nine largest seed firms for the period: 2008-2015, and (2) Is there a relationship between firm size and efficiency? Firms criticized for contributing to the concentration of the global seed market are included in this study.

Data envelopment analysis using windows analysis was used to analyze the data. The mean overall technical efficiency (OTE) was 93.5% and 94.3% in window (W) 1 and W5, respectively, an increase of 0.8%, which reflects stability in these firms’ managerial ability. Dow was the exception with an overall increase in OTE of 7.75%. There is no clear relationship between pure technical efficiency (PTE) and asset size. On a firm level, DuPont Pioneer, Syngenta, Monsanto, and Dow operated under increasing returns to scale with the latter two reaching constant returns to scale (CRS)—the most productive scale size. DLF Trifolium and Takii operated at, or close to CRS. Sakata and Bayer displayed an inconsistent sawtooth-shaped trend in PTE versus size. No obvious overall relationship between scale efficiency (SE) and asset size is apparent. DuPont Pioneer was scale efficient in three consecutive windows, while DLF Trifolium, Dow, and Monsanto achieved this outcome in one (but not the same) window. All other firms were consistently scale inefficient with Sakata having the lowest SE scores (87.5-91.7%). In terms of efficiency, the PTE analysis revealed that the corporate activity (M&As) of most firms was theoretically justified (Bayer is the exception).

Chapter 1

1 Introduction

1.1 Background

The last two-and-half centuries have seen the world's human population grow exponentially from below one billion in 1750 to almost seven billion in 2010. Most of this expansion has occurred since 1950 (Steffen et al., 2015). Humankind has overcome ecological limitations and met its increasing demand for nutrition, and raw materials for basic needs such as clothing and shelter by employing a range of innovations (Weinberger et al., 2017). Humans domesticated flora to cultivate, amongst others, fruits, vegetables, and grains, and fauna mainly for producing meat, milk, fiber and fuel, and for providing draught power. Noteworthy innovations include artificial fertilizers and modern irrigation systems to boost plant production; agrochemicals to protect crops against pests and diseases; agro-pharmaceuticals to protect livestock; and replacing draught power with mechanical power. The use of conventional animal and plant breeding techniques have resulted in the increased production of animal and plant products, respectively. Scholars captured the important contribution to the total economy by these and related activities by coining the term 'bioeconomy'. Thus, the bioeconomy encompasses economic activities that use renewable biological resources, and produce food, feed, and bio-based products and energy. Its scope is broad, and at least one definition refers to its strong innovation potential (Newton et al., 2017).

Genetic engineering is a field where the bioeconomy's innovation potential is substantial. Harnessing biotechnology for improving the genotypes of organisms spawns innovations, such as genetically engineered (GE) crops[2]. Compared with traditional plant breeding techniques, advantages of using this sub-discipline of green biotechnology are that a broader spectrum of genetic traits can be improved and quicker. The widespread adoption of this technology has not been straightforward. According to Huesing et al. (2016), contributing factors include, but are not limited to: (1) "poor public understanding of [genetically modified] GM technology and the need for enhanced communication strategies, [(2)] nonharmonized and prescriptive regulatory requirements, and [(3)] limited experience with regulations and product development within some public sector programs."

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[2] ***GE crops*** are also known as ***genetically modified organisms (GMOs)***, or ***genetically modified (GM) crops***, or ***transgenic crops***. In this thesis, these terms are synonyms.

The heterogeneous international regulatory environment gives rise to an ‘uneven playing field’ for both developers and users of GE crops. Despite these hurdles, the worldwide adoption of GE crops during the first 20 years of their commercialization, starting in 1996, was a 100-fold increase in the area planted, thereby making GE crops “the fastest adopted crop technology in recent times” (James, 2015).

In the early stages of this nascent technology’s development, governments introduced legal frameworks to regulate its products. Governments were responding to potential risks and benefits associated with its application (Jaffe, 2004; McHughen and Smyth, 2008). Thus, regulations were enacted to ensure the safety of these products for humans and the environment (Lynch and Vogel, 2001).

Adhering to regulations is costly for innovators of GE crops (Davison, 2010; Miller and Bradford, 2010), and time consuming. No two jurisdictions have identical regulatory processes because attitudes towards risk differ. Thus, the international regulatory framework is heterogeneous, which leads to asynchrony amongst trading partners in the approval of new GE crops. The socioeconomic and environmental impacts caused by this asynchrony are numerous and significant.

The direct costs of regulating the seed industry are high (Kalaitzandonakes et al., 2007; Davison, 2010; Miller and Bradford, 2010). The foregone benefits to society of either rejecting or delaying approvals are meaningful (Wesseler et al., 2011). The high costs involved in overcoming regulatory hurdles impede innovation as they act as barriers to entry for innovators with modest financial resources (Bradford et al., 2005; Giddings et al., 2013).

Thus, factors identified as contributing to the array of regulatory barriers facing developers of GE crops can be used to empirically analyze their socioeconomic impacts on society. Policy makers can use this information in their assessments aimed at changing (i.e., lowering or removing) these barriers. Other actors in the value chains of GE crops can use this information to better understand how changes in regulations impact them and how they can respond. The broad aim of my thesis is to contribute research findings to this field and the associated debates that both support and oppose this branch of green biotechnology.

1.1.2 Aim and Structure of the Thesis

My dissertation collates five pieces of scientific research that delve into aspects of the socioeconomic challenges, brought on by regulations, which society faces in the adoption of new products of green biotechnology, namely GE crops.

In **Chapter 2**, I provide an overview of applied concepts and the research methods employed.

My scientific inquiry begins in **Chapter 3**—a book chapter—with a regional level investigation of the socioeconomic challenges of the bioeconomies of Sub-Saharan Africa (SSA) and Europe, which are considered developing and developed, respectively. The areas in which Africa could learn from Europe's experiences and harness its expertise is revealed by a qualitative assessment (scientific literature was the information source for the strengths, weaknesses, opportunities and threats (SWOT) analysis) of these two bioeconomies' challenges and opportunities. The bioeconomy offers Europe an avenue for competing in the global economy. The public acceptance of especially green biotechnology and the relatively stringent regulatory requirements for authorizing innovations like GE crops in Europe and many African states potentially compromise their bioeconomies' competitiveness. The essential research question asked in this chapter is: What pathways are there for unlocking the potential of the bioeconomies of Europe and Africa? (Table 1-1.) The answers to this question will be of interest to policy makers in these regions who are searching for practical ways to foster unlocking the potential of their bioeconomies.

Chapter 4 is a country/regional-level study of two globally important trading partners in GE crops. It presents a paper that analyses the trends in approval time of new GE crops in the United States (US)—the global locus for biotechnological innovations where the majority of new GE crops are developed and first approved for use—and the European Union (EU).

A trend towards shorter approval times in a given regulatory system is expected (Pray et al., 2005a). The hypothesis tested is that approval times of GE crops in the US and EU shorten with the progression of time. This paper is an updated analysis of the time taken for GE crops to be approved by analyzing: (1) each step in the regulatory 'path' for its contribution to the overall regulatory process, and (2) crop characteristics' impact on regulatory time (Table 1-1). The approval time for these innovations is of significant economic interest to stakeholders in their value chains (Stein and

Rodríguez-Cerezo, 2009; Nowicki et al., 2010), ranging from developers of these innovations through to potential adopters and consumers, to policy makers who influence their regulation and therefore potential for commercialization.

Politics plays a decisive role in the authorization process of GE plants in the EU—a political union comprising a broad spectrum of Member States (MSs) with a complex regulatory framework for GE plants. Here, GE crops are approved for one or more uses, namely, (1) import, (2) industrial use, and (3) cultivation, or (4) any combination of these uses. Essentially, MSs' representatives vote in a consecutive two-tier process starting with a risk assessment followed by risk management. The voting mechanism is called qualified majority (QM) voting where each MS's vote is weighted according to its population (less-populous states have a proportionally larger weighting). A QM is achieved when the number of votes cast ('for' or 'against') equal or exceed a threshold value calculated as a percentage of the maximum possible number of votes. Most applications end in a political gridlock.

In **Chapter 5**, I present a paper focused at the country level that analyzes the voting behavior of EU MSs for voting results on applications of GE crops for authorization from 2003 through 2015. In any given ballot, a MS's vote can be influenced by a myriad of factors. Some MSs have a key influence on the outcome of any given ballot due to them being so-called 'swing states'. The key research questions are: (1) Are individual MS characteristics more relevant for explaining their voting behavior than other factors such as crop type? And, (2) Which MSs' voting behavior should change to avert a gridlock for approval? (Table 1-1.) The answers to these questions are of relevance to MS policy makers who are responsible for, inter alia, food security, biosafety, agriculture, environmental protection, and consumer affairs. Policy makers responsible for regulating the voting rules at the EU may also be interested to see the impact of the QM voting on the approval of GE crops, and how changes to rules could obviate the preponderance of future voting gridlocks. Representatives of the 'swing states' may be interested in the meaningful impact that they have on the approval of GE crops in the EU.

In most regions of SSA, food crops comprise the staple diet of their inhabitants. Pests significantly reduce the yields of some of these crops. Lowered food security and increased levels of malnutrition, especially for children, result. Examples of these food crops include:

- cooking banana (also known as matoke) in Uganda that is susceptible to a fungus causing black sigatoka (leaf spot) disease (Ploetz, 2001),

- cowpea in Benin, Niger, and Nigeria, that is susceptible to a pod boring insect, and
- corn in Kenya that is susceptible to insects, and environmental (moisture) stress in the form of droughts.

Varieties of these crops were developed using genetic engineering to be resistant to the abovementioned crop-specific pests. The insect-resistant corn variety was also developed to withstand moisture stress. When this research was conducted, these crops were unavailable to the public as they were awaiting approval by the regulatory authorities in these countries. **Chapter 6** is a country-level study that presents a paper asking the following theoretical question: What are the foregone benefits of delaying the approval of these crops in their respective African states? (Table 1-1.) The answer to this question will be of particular interest to policy makers and organizations that are seeking practical, cost-effective means of alleviating poverty; policy makers involved with the regulation of GE crops; and protagonists of GE crops who advocate for their adoption in settings where the primary benefit is saving lives that are lost through malnutrition.

The seed industry is part of the first link in the agri-food value chain (Food and Agriculture Organization of the United Nations (FAO), 2019), and makes an important contribution to the sustainability of the global agri-food system and to food security. The global commercial seed industry comprises around 7,500 firms ranging in size from very small, specialist enterprises to large multinationals (most of them have origins in the chemical sector) (Bonny, 2017). Firms primarily use conventional plant breeding techniques for developing new seeds. However, some firms also employ technology intensive methods for developing GE crops. Consolidation has taken place in the private sector with the emergence of a small number of relatively large firms, which have grown both organically and through merger and acquisition (M&A) activities.

GE crops are subject to regulations that are costly for firms developing these innovations to conform with (Kalaitzandonakes et al., 2007; Davison, 2010; Miller and Bradford, 2010; Phillips McDougall, 2011b). Thus, most of the approved GE crops are the intellectual property (IP) of an oligopoly: a small number of large firms that can afford these high sunk costs. The market concentration in the seed sector (Mammana, 2014; Lianos et al., 2016) has, and continues to appropriate these firms with perceived power and influence on global food production at the start of the agro-food chain (Bonny, 2014). Empirical studies supporting allegations about this sector are scarce. Bonny (2014) states that there is “a lack of precise appraisals and analyses” for the seed sector, and in 2017, she states that an “analysis of the seed sector is a particularly difficult task given the extent of partial or biased analyses, as well as a lack of data on certain aspects [, …furthermore,] the economic data are heterogeneous and sometimes non-concordant.” She notes that representatives of seed companies involved in M&A activities justified their intentions by emphasizing that “their assets and activities were complementary, and how consolidation would lead to better efficiency and to an enhanced capacity for innovation, which in turn would benefit all stakeholders.” To the best of my knowledge, no empirical studies support this claim. **Chapter 7**—my final research chapter—is a sector-level scholarship of the nine largest seed firms for the period: 2008-2015. The research questions are: (1) What are the efficiency levels of these firms, and (2) Is there a relationship between firm size and efficiency? Firms criticized for contributing to the concentration of the global seed market are included in the dataset (Table 1-1). Answers to these questions may be of interest to policy makers and critics of these firms as they demonstrate empirically the impact of corporate activity on firm efficiency in the seed sector.

Table 1-1. Contributions of each chapter

Chapter and Topic	**Research Question / Hypothesis**	**Contribution**
Chapter 3: The social and economic challenges for a bioeconomy.	What pathways are there for unlocking the potential of the bioeconomies of Europe and SSA?	A qualitative analysis of the bioeconomies of Europe and SSA. How unlocking the potential of each region's bioeconomy could contribute positively to their development and global competitiveness.
Chapter 4: Trends in GE crops' approval times in the US and the EU.	Approval times of GE crops in the US and EU shorten with the progression of time.	An updated analysis of the time taken for GE crops to be approved by analyzing: (1) Each step in the regulatory 'path' for its contribution to the overall regulatory process, and (2) Crop characteristics' impact on regulatory time.
Chapter 5: EU MSs' voting for authorizing GE crops: A regulatory gridlock.	Are individual MS characteristics more relevant for explaining their voting behavior than other factors such as the crop type? Which MSs' voting behavior should change to avert a gridlock for approval?	Factors that are statistically the most significant for driving voting behavior in the EU. Revealing the most important swing states in the QM voting for authorizing GE crops in the EU.
Chapter 6: Foregone benefits of important food crop improvements in SSA.	What are the theoretical costs for delaying the approval of three GE food crops in five SSA states? (Fungus resistant cooking banana in Uganda; insect resistant cowpea in Benin, Niger, and Nigeria; drought tolerant and insect resistant maize in Kenya.)	Many studies on GE crops have focused on the economic surplus at farm, regional, or sector levels. We contribute to the literature by also considering the effects of GE crops on malnutrition.
Chapter 7: Decomposition of efficiency in the global geed industry: a nonparametric approach.	What are the efficiency levels of nine of the largest commercial seed producing firms globally for the period 2008-2015, and is there a relationship between firm size and efficiency?	We generate empirically-derived efficiency scores (overall technical efficiency, pure technical efficiency, and scale efficiency) for these seed firms from 2008-2015 and assess if there is a relationship between firm size and efficiency.

Chapter 2

2 Conceptual Framework and Methodological Overview

2.1 Introduction

The broad subject common to all research chapters of this dissertation is: socioeconomic challenges in the adoption of GE crops. Each chapter investigates a unique setting in which society faces socioeconomic challenges where products of this novel biotechnology provide potential remedies. Concurrently, the development and adoption of these products vary worldwide due to, inter alia, differing regulatory requirements and inconsistent social acceptance.

This chapter is a review of the concepts and methods deployed in the pieces of research comprising this thesis. As the studies cover a broad spectrum of issues, and the analytical methods used are setting-specific, no single overarching research method or concept was used. Each chapter's methodology is presented separately, including **Chapter 4** and **Chapter 5**, despite them sharing a similar analytical approach.

2.2 Methodology for Chapter 3

My thesis starts with a wide-angled view by investigating several of the diverse challenges of the bioeconomies of Europe and SSA. The adoption of GE crops represents one practical opportunity from which these bioeconomies could benefit. Yet a combination of authorities' precaution and burdensome bureaucracy deny these bioeconomies of the potential benefits of cultivating certain GE crops.

Chapter 3 is a qualitative study of the bioeconomies of Europe and SSA. An extensive review of published scientific literature covering this broad topic forms the cornerstone for this research. Information gleaned from the literature were used for the descriptions of the bioeconomies; formed the basis for analyzing their relative strengths (S), weaknesses (W), opportunities (O), and threats (T) in a SWOT analysis; was the foundation for remaining sections covering the socioeconomic issues of the bioeconomy (research and development (R&D): for whom and the role of the public and private sectors; sustainable implementation of bioscience R&D; innovation diffusion;

addressing uncertainties in the bioeconomy; and globalization and governance), and for possible pathways to success.

2.2.1 SWOT Analysis

A SWOT analysis (also referred to as: situational analysis) is a framework for identifying and analyzing the threats and opportunities of an entity's (in my case: a geographical region) external environment (i.e., exogenous factors), and assessing the entity's weaknesses and strengths (i.e., endogenous factors) (Weihrich, 1982). The four parameters used in this framework are presented in a 2 x 2 matrix. Each parameter serves as a heading under which its factors are entered.

The SWOT analysis technique is a tool for planning purposes and "analyzing organizations [including countries and industries] for recommended strategic actions" (Helms and Nixon, 2010), i.e., it is usually applied during strategic planning (Namugenyi et al., 2019). Valentin (2001) cited by Helms and Nixon (2010), criticize the SWOT analysis in that "the procedural guidelines for using the methodology consist largely of catchall questions devoid of explicit theoretical underpinnings. Thus, the analysis often produces shallow, misleading results." Further criticisms are that SWOT is simplistic and produces lists (for example: Kay (1993, 1999) cited by Helms and Nixon (2010)) and that there is insufficient context for adequate strategy optimization (Haberberg (2000) cited by Helms and Nixon (2010)). By contrast, Pickton and Wright (1998) pen that "SWOT analysis has been praised for its simplicity and practicality …. but, generally, its use has been accepted uncritically". Nonetheless, analysts often use a SWOT analysis to initiate a strategy planning process (Warren (2002) cited by Helms and Nixon (2010)).

Hill and Westbrook (1997) conclude in their empirical analysis of the use of SWOT analysis by consultants that the outputs were a description rather than an analysis. Their finding represents a weakness of the technique's application. Pickton and Wright (1998) suggest that the inherent weaknesses of the SWOT analysis framework can be overcome by using devices such as "Performance-Importance, Opportunity and Threat matrices and Vulnerability Analysis".

The use of a SWOT analysis and its outcome should be viewed in light of the abovementioned critique.

2.3 Methodology for Chapter 4

2.3.1 Background

Chapter 4 narrows the view both by region and theme. It analyzes the approval times for GE crops in the US and EU. These regions develop GE crops, but have divergent approval processes and attitudes towards the adoption of this relatively novel biotechnology. The methodological approach was to analyze each region separately. The rationale for not drawing direct comparisons of the total time taken for GE crops passing through each jurisdictions' regulatory pipeline is that endogenous inconsistencies would make it theoretically flawed.

Bayer et al. (2010) studied the cost of compliance for GE crops in the Philippines. They noted that a country's regulatory costs appear to fall with time as experience is gained, while regulatory costs are lower for products that have already been approved elsewhere. Thus, a declining trend in regulatory time in a given jurisdiction should be observed. Furthermore, they conclude that: "the largest potential constraint to commercialization … is regulatory delay".

The descriptive statistics of the approval times for GE crops in the US revealed a structural break approximately midway (1998) during the study period of 1988-2015. The notion of whether the structural break holds in a multivariate regression framework was investigated. Theoretically, what appears to be a structural break may be a sudden shift in the type (category) of application. For example, the characteristic of a GE plant like its lifecycle, i.e., a shift from annual to perennial. Alternatively, the political 'climate' may have caused a shift, thus erroneously indicating a structural break, which was actually the result of unobserved factors. The analytical approach was to use a set of ordinary least squares (OLS) regression models for testing if differences in the regulatory process' time-line could be explained by plant characteristics, or external, independent factor(s).

Characteristics about each GE crop and their developers were used in a stepwise multifactorial setting to investigate if any of these characteristics played a statistically significant role in their approval times.

Two periods (labelled 'early' and 'late') separated in 1998 by a structural break were identified in the US. Differences in the time taken for applications completing the 'scientific' step, 'bureaucratic' step, and the overall approval process (‘scientific-’ and ‘bureaucratic’ step combined), were captured by including dichotomous variables. Subsequently, additional control variables were included for netting out effects unrelated to the structural break, such as differences in the time taken between applications grouped according to the following parameters: developer’s domicile (domestic or foreign developer); crop use (food or non-food plants); and the number of GE traits that each crop has (single or multiple). If the variable identifying ‘early’ and ‘late’ applications reflects a substantial and statistically significant difference after adding controls, evidence for the existence of a structural break is the interpretation.

A similar strategy was followed for testing the robustness of the trend for the EU displayed in Figure 4-5: a convex development for the overall approval time, with long durations for submissions during 1996 and 1998, and the absence of a clear trend for the remaining period. This relationship was modelled in model 1—the baseline model—with two metric variables: ‘year’ and the ‘square of the year’ expecting them to have negative and positive signs, respectively, indicating the aforementioned convex-shaped relationship. Signs and sizes of the variables: ‘year’ and ‘year (squared)’ confirm the development of a convex shape (Table 4-8). Variables were added for controlling other potential effects such as the developer’s domicile; the crop’s GE trait; and the crop’s intended use (‘food and feed’ vs. non-food/feed).

2.3.2 The Multiple Regression Model

The multiple regression model used follows:

(2-1) $$Y_{ijt} = \alpha + \beta_1 * \mathrm{T} + \beta_2 * \mathrm{X} + \varepsilon$$

As for the US, approval times (Y_{ijt}) are modelled as a function of a constant (α); a variable indicating if an application was submitted in before 1998 (T) or afterwards (reference category); and a vector of control variables (X), including the developer’s domicile, crop use, and the number of GE traits; ε denotes the error term. To test for a structural break, the parameter β_1 is of interest. The magnitude of β_1 and standard errors indicate economic and statistical significance, respectively. Other parameters referring to control variables are interesting in their own right as they illuminate the nature of the regulatory process, but are primarily used as a means to limit bias originating from a change in the sample composition.

As for the EU, the only difference between the US setup refers to the vector (T) in the aforementioned formula (2-1). Here, T contains two variables, a linear and a squared term to test for a non-linear relationship between approval times (Y_{ijt}) and time.

2.4 Methodology for Chapter 5

2.4.1 Background

Chapter 5 shifts the scene to the approval process of GE crops in the EU where a gridlock persists (Vogel, 2003; Swinnen and Vandemoortele, 2010). The voting behavior of the EU MSs was analyzed to gain insights about the gridlock. Authorization of GE crops in the EU follows a consecutive two-tier process. It starts with a risk assessment (for determining a crop's safety) followed by risk management (a political decision-making process (European Food Safety Authority (EFSA), 2013) when MSs' representatives vote at the EU for authorization (OJEU, 2001)). A full consensus (unanimity) within the EU at MS level for authorizing GE crops has never been reached—an unusual result considering a high and stable level of consensus over time at Council level on other topics (Jensen, 2010).

The literature assessing the EU's policy on approving these crops is limited. Graff et al. (2009a) explain the low number of approvals by political economy factors. The political economy forces opposing the approval of GE crops are stronger in the EU than in other countries. The expectation is that these forces would have weakened with time here, tempered by the positive experiences of the technology in other regions and the catching-up of the European plant breeding and chemical industry on the technology. As Swinnen and Vandemoortele (2010) argue, a change in voting behavior, not to mention a change in regulation, will become more difficult once a regulation has been in place. The forces establishing a policy gridlock (Vogel, 2003) are further strengthened if the uncertainty about the political outcome of a change in policy is strengthened (Wesseler and Zilberman, 2014).

The voting results are used to test whether or not individual MS characteristics are more relevant for explaining the voting behavior supporting the aforementioned argument of a policy gridlock (Vogel, 2003; Swinnen and Vandemoortele, 2010) than other factors such as the crop type, e.g., maize or oilseed rape, or the transgenic trait such as insect resistance or herbicide tolerance. (This investigation does not attempt at identifying and testing which MS characteristics, if any, can be used to explain voting behavior as Mühlböck and Tosun (2015) did.) The results are used to identify possibilities for achieving a QM in favor of approval, i.e., which MSs would need to change their voting behavior. The results are discussed in light of the Directive (EU) 215/412 for MSs to restrict or prohibit the cultivation of GE crops in their territories—the ‘opt-out’ directive (OJEU, 2015) — as a change in regulation for overcoming the policy gridlock.

2.4.2 Qualified Majority Voting

A mathematical description of the QM voting is as follows:
At any given time, the EU MSs comprise a set *N* denoted i.
The votes of MS i are denoted as V_i:

(2-2) $$V_i = \begin{cases} 1 & if\ MS_i\ votes\ 'for' \\ 0 & if\ MS_i\ votes\ anything\ but\ 'for' as\ described\ below \end{cases}$$

$V_i = 0$ if a MS i votes ‘against’ including any form of ‘against’ (i.e., an abstention, or absent from the ballot).
Each MS i, has a vote weight, w_i
For each ballot, the total number of ‘for’ votes, Q is calculated as follows
(2-3) $$Q = \sum_{i \epsilon N} w_i V_i$$

A positive decision (i.e., approval) is reached if $Q \geq t$, where t is the QM threshold value of ‘for’ votes for a given decision (ballot).

An important assumption is that each MS casts its ballot independently—uninfluenced by exogenous factors. The only positive contribution towards achieving a QM is a ‘for’ vote. Each ballot was scrutinized for all MSs that prevented a QM, namely those who voted: ‘against’, abstained, or who were absentees. The following were found from this subset of voters: (1) the minimum number of MSs needed to achieve a QM, and (2) who they were. Continuing with the previous mathematical notation: without loss of generality, the members of set *N* were ordered according to their vote weights, i.e.,

(2-4) $$w_i \geq w_j \ \forall \ (i, j) \in N$$

The minimum number required for a QM, M, is calculated as follows:

(2-5) $M = t - Q$

MSs who voted anything but 'for' (i.e., all forms of 'against' as previously explained) comprise A, which is a subset of N such that:

$A\colon \{i \in N | V_i = 0\}$

Now, for finding the voters who prevented a QM, find the minimum subset R of A that satisfies the following condition:

(2-6) $\sum_{i \epsilon R} w_i \geq M,$

In practice, these MSs' votes were sequentially added until a QM could theoretically have been achieved. When counting the number of MSs in this subset for ballots where more than one MS of equal rank (vote weight) could have contributed to the total, all of them were counted (consistent with the assumption of independence).

2.4.3 Logistic Regression

Every 'for' vote was treated as a positive statement for supporting a GE crop's authorization. The 'against' and 'abstain' votes, and several forms of absenteeism were interpreted as negative statements opposing authorization as they prevented a QM (Jensen, 2010).

Odds ratios in a set of logistic regressions were used for testing whether a MS's identity, an applicant's domicile, and a crop plant's genetic trait are suitable explanatory variables for explaining a MS's voting decision. This was done by first testing a MS's identity, and then stepwise adding additional explanatory variables. The rationale for using this method is to assess whether voting decisions can be explained by factors associated with a MS's characteristics (i.e., endogenous factors), or whether MS-specific effects prevail if explanatory variables based on qualitative information (e.g., crop type, or the crop's intended use) are added to the model. Theoretically, what appears to be a MS-specific effect may in fact reflect either a MS-specific concern or opportunity leading to a negative or positive vote, respectively. For example, Scandinavian MSs tend to accept (vote 'for') GE crops, but it is unknown whether these MSs' voting behavior is related to liberal and open-minded societies, or whether their positive votes are associated with, for example, factors favoring these MSs' bio-economies (agricultural and biotech sectors). A set of logistic regression models were used for disentangling these factors and for testing if they can be used for explaining the variation in voting behavior.

Equation (2-7) below illustrates the estimation strategy for testing the relationship between a positive vote and a set of explanatory factors, where μ represents a binary variable that is unity for a positive vote of MS *i*, at time *t*, for crop *j*, and zero otherwise. The dependent variable is assumed to be a function of MS fixed effects (*C*) that are included to reflect MS-specific voting patterns. The vector *X* includes controls for plant-related features such as: type of trait, plant type, intended crop use, and the developer's (applicant) domicile. The aim is to capture a time trend (*T*) to observe any temporal changes in voting pattern; α and ε represent a constant and the error term, respectively.

$$\mu_{ijt} = \alpha + \beta_1 * \mathrm{C} + \beta_2 * \mathrm{X} + \beta_3 * \mathrm{T} + \varepsilon \tag{2-7}$$

2.5 Methodology for Chapter 6

2.5.1 Background

Chapter 6 pans the view away from the US and EU to SSA, which is a large heterogeneous area where the yields of several staple food crops are compromised by pests and or environmental stress. Here, the efforts of plant breeders using genetic engineering have been rewarded by the successful development of three pest-resistant crops. In one case, in addition to pest resistance, the crop (corn) is also tolerant to an abiotic factor, namely, moisture stress. However, the approval of these crops for cultivation remains (at the time of publishing **Chapter 6**) unauthorized. This delay represents important foregone benefits to the inhabitants of these regions who could potentially be benefiting from these crops by, inter alia, cultivating and consuming them, and trading with them.

2.5.2 Real Options Model

Here, a theoretical model is developed for assessing the benefits and costs of approval processes for GE crops using a real option framework that calls upon the "Santaniello Theorem of Irreversible Benefits" (Wesseler, 2009). Santaniello (2005) supported agricultural biotechnologies. He was "aware of and concerned about the social and political issues surrounding the technology…[and] emphasized the irreversible benefits that the technology provides in debates with people concerned about the irreversible costs of the technology" (Wesseler, 2009). The relevance of irreversible costs for decisions is known in the economic literature with Arrow and Fisher (1974), cited by Wesseler (2009), being “the first authors to explicitly mention that irreversible costs matter differently than reversible costs for decision making.” To paraphrase Wesseler (2009), the possibility of postponing a decision, including irreversible costs, has an extra value that needs to be considered. With time, additional information may become available that can be used by decision makers to update the expected benefits and costs. This update facilitates the reconsideration of previous decisions. The model developed in this research explicitly considers the standard welfare measures of changes in producer and consumer surplus.

The foregone benefits caused by a delay in approval under irreversibility and uncertainty, and threshold values that would justify a delay, are calculated. Differences in the approval time of a new GE crop are considered, and the equilibrium conditions (where the net-benefits of the technology equal potential costs) that would justify a delay are derived. The model is calibrated for the three GE crops under scrutiny to indicate the magnitude of the effects, and the economic and humanitarian consequences of delaying approvals.

2.5.2.1 The General Analytical Model

A modified welfare economic framework is developed for a national government regulating the approval of GE crops. The framework is dynamic and it considers the effects that the introduction of a GE crop will have on: consumers’ and producers’ surplus, the perceived uncertain negative external social cost (similar to Wesseler and Zilberman, 2014), and directly on malnutrition. The negative external effects include implications for international trade, domestic social unrest, and potential negative impacts on the environment and human health. The assumptions are a simplification, and can be justified by the studies investigating the political debates of introducing GE crops in developing countries. Many societal groups have declared their intention to protest against the introduction of GE crops (e.g., Friends of the Earth Europe website, 2016), and warn about the negative implications for international trade and long-term implications for agricultural sustainability (Paarlberg, 2008; Herring, 2015; Rausser et al., 2015). The public debates following the FAO’s 2004 SOFA [The State of Food and Agriculture] report on “Agricultural Biotechnology: Meeting the Needs of the Poor?” (FAO, 2004), which has been heavily criticized for its “pro GMO” view or similarly, and the 2009 report of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) (McIntyre et al., 2009), which has been criticized by The World Bank (2010) for paying insufficient attention to the possibilities of modern biotechnology to address food security, are examples highlighting the differing views about the impacts of GE crops by highly influential international organizations. These divergent views contribute to generating uncertainty for policy makers in developing countries.

The introduction of a GE crop is denoted as a change in food policy $F(t)$, $\Delta F(t)$, from the current food policy, F_0, to a new food policy, F_1. At time *t=0* the government's view is that the perceived costs, G_c, of introducing the GE crop exist and are high, $G_c \gg 0$, while other benefits and costs (discussed in more detail below) are assumed to be known. Hence, all remaining uncertainty is captured under perceived costs. Over time, further information about the perceived costs arrives, and at time, *T*, either the strategy will be successful and perceived costs be small, $\underline{G_c}$, with probability, (*1-q*), or confirmed to be high, $\overline{G_c}$, with probability, *q*. Hence, the introduction mainly depends on the perceived costs of introducing GE crops. Based on this, the national government may decide that the strategy will be introduced immediately, (*T=0*), or postponed, (*T>0*), with, *T*, the optimal time to introduce the GE crop.

Considering these uncertainties, the objective of the decision maker can be described as follows:

$$\max_T E_o \int_o^\infty (\Delta CS_t, \Delta PS_t, \Delta M_t, C_t, G_c)dt, \tag{2-8}$$

with E_0 the expectation operator, ΔCS_t the change in consumer surplus, ΔPS_t the change in producer surplus, $\Delta\, M_t$ the change in malnutrition, C_t the discounted sum of known costs the government will face if it introduces the new technology, G_c defined as follows with a symmetric rise or fall indicating that decision makers, a priori, are biased towards neither benefits nor costs, i.e., the future can be either good or bad:

$$E[G_c] = \begin{cases} \overline{G_c} = (1+d)G_{c0}, \ \mathit{with\,probability}\ q = 0.5 \\ \underline{G_c} = (1-d)G_{c0}, \ \mathit{with\,probability}\ (1-q) = 0.5 \end{cases} \tag{2-9}$$

and the current value of $G_{c0} \triangleq (0.5(1+d)G_{c0} + 0.5(1-d)G_{c0})$.

The annual change in producer and consumer surplus can be derived from a partial equilibrium mode. If linear supply and demand functions are assumed, we get (see for, e.g., Alston et. al., 1998):

$$\Delta CS = \int_0^\infty \big(P_T Q_T Z_t (1 + 0.5 Z_t \eta)\big) e^{-rt} dt, \tag{2-10}$$

$$\Delta PS = \int_0^\infty \big(P_T Q_T (K_t - Z_t)(1 + 0.5 Z_t \eta)\big) e^{-rt} dt, \tag{2-11}$$

where $Z_t = K_t \varepsilon / (\varepsilon + \eta)$, $K_t = \left[\frac{\Delta y}{\varepsilon} - \frac{\Delta VC}{1+\Delta y}\right] a_t$, ε the supply elasticity, η the absolute value of the own-price elasticity of demand, *P* the product price, and *Q* the product quantity at time *T* of the introduction of food policy *F₁*, *Δy* the percent yield increase of the GE crop, and *ΔVC* the relative change in variable costs. Both ΔCS and ΔPS can be converted into average annual surpluses by multiplying both by *r* and will be denoted by CS_a and PS_a, respectively.[3]

2.5.2.2 Measuring Changes in Malnutrition

Malnutrition, M_t, is defined as a state variable, which captures the many dimensions of hunger (UNICEF, 2013). Malnutrition is controlled by food policies, *F(t),* that affect food deficiency and are translated by the factor $\beta > 0$ to malnutrition, i.e., the higher the level of food deficiency at time *t*, the higher the level of malnutrition. There is also an exogenous decline in malnutrition by other factors not directly related to the quantity and quality of food supply, which include improvements in childcare, feeding practices, and household environment (UNICEF, 2013).

The change in malnutrition is: $dM = M(F_t)dt$ with $dM(F_o) = 0$ and $dM(F_1) = M_t dt$. The annual level of malnutrition reduction benefits, M_t, is measured as the number of stunted individuals in a population younger than 5 years old—a common measure of malnourishment (UNICEF, 2013) in rural areas—multiplied by the percentage change in calorie intake, *c*, by the GE crop measured, where the percentage change in crop consumption is the same as the change in yield, valued by the average annual costs of stunting, *m*:

(2-12) $$mM_t = mn_t c$$

with $n = fa(t)$, where *f* is the fraction of stunted children reached. The total benefits in reduction of malnourishment is: $M_0 = \int_0^\infty (mn_t c)\, e^{-rt}$ and dividing this by *r* provides the average annual benefits: $M_a = M_0/r.$

2.5.3.3 Food Policy Change

The new policy allows producer and consumer surplus to change, and malnutrition to reduce with the new technology (adoption of the GE crop) to F_1, introduced at T, hence $F_t = F_0 | t < T$ and $F_t = F_1 | t \geq T$. At time, *T,* introducing the new technology only pays if $G_{cT} = \underline{G_c}$ and not otherwise, also implying that it does not necessarily pay to introduce F_1 immediately at $t = 0$. Further, there is no future uncertainty after T, i.e., whatever G_{cT} will be, and it will remain at that level until infinity. Three cases can now be assessed.

---

[3] Note: for the spreadsheet model this was simplified by calculating $K_t = (\Delta y \epsilon) a_t$, which allows calculating the changes in variable costs as a residual and linking changes in the supply elasticity to changes in variable costs.

First, the technology will never be adopted. The value of the decision:

(2-13) $$D^N = 0.$$

Second, the technology is adopted immediately, i.e., $F = F_1$:

(2-14) $$D^0(F_1) = \int_0^\infty (CS_a + PS_a + M_a)e^{-rt}dt - G_{c0}$$
$$= \frac{CS_a+PS_a+M_a}{r} - G_{c0}.$$

Applying standard cost-benefit analysis, adopting the policy would be economical if:

(2-15) $$D^0 - D^N = \frac{CS_a+PS_a+M_a}{r} - G_{c0} > 0.$$

Third, the technology will be introduced at time T, when the government knows whether or not the social costs will be high, $G_{cT} = \overline{G_c}$ or low $G_{cT} = \underline{G_c}$. If the social costs are high, the introduction of GE crops will not be useful, and their value is zero. If the social costs are low, it would be beneficial from the government's perspective to introduce the crops. The value of introducing the GE crop at time, *T*, considering $(1 - q) = 0.5$ (see Eq. 2-9), from today's perspective is:

(2-16) $$D^T\left(\overline{G_c}, \underline{G_c}, F_1\right) = \frac{1}{2}\frac{CS_a+PS_a+M_a}{r}e^{-rT} - \frac{1}{2}\underline{G_C}$$

The results can now be used to identify whether or not it pays to wait by calculating the difference between postponed and immediate introduction:

(2-17) $$\Delta D^T = D^T\left(\overline{G_c}, \underline{G_c}, F_1\right) - D^0(F_1)$$
$$= \frac{1}{2}\frac{CS_a + PS_a + M_a}{r}e^{-rT} - \frac{1}{2}\underline{G_C} - \frac{CS_a + PS_a + M_a}{r} + G_{c0}$$
$$= G_{c0} - \frac{1}{2}\underline{G_C} + \left(\frac{1}{2}e^{-rT} - 1\right)\frac{CS_a+PS_a+M_a}{r}.$$

Substituting $\underline{G_C}$ with $(1 - d)G_{c0}e^{-rT}$ provides:

(2-18) $$\Delta D^T = G_{c0}\left(\frac{2e^{rT}-1+d}{2e^{rT}}\right) + \left(\frac{1}{2}e^{-rT} - 1\right)\frac{CS_a+PS_a+M_a}{r}.$$

Equation 2-18 can now be used to identify the threshold level of the government's costs that would result in $\Delta D^T > 0$, provding:

(2-19) $$G_{c0} > \frac{2e^{rT}-1}{2e^{rT}+d-1}\frac{(CS_a+PS_a+M_a)}{r}.$$

The second term on the right-hand side (RHS) is the net present value (NPV) of consumer and producer surplus plus the benefits from reducing malnutrition. The first term on the RHS shows that the perceived costs by the government have to be lower by the factor $\frac{2e^{rT}-1}{2e^{rT}+d-1} < 1$ for each unit of NPV. Using values of r = 0.04, d = 0.5, and T =1 provide a value of 0.68. Hence, the government's perceived costs have to be only 68% of the NPV. Note that care needs to be taken with changes in the discount rate as this affects the first and the second term on the RHS of equation 2-19.

Equation 2-19 is a well-known result from the literature on decision-making under uncertainty and irreversibility (Arrow and Fisher, 1974; Dixit and Pindyck, 1994). While most studies develop models considering uncertainty about future reversible benefits and costs, the simple model developed here considers uncertainty about irreversible costs. The model can be advanced by adding an additional cost function (e.g., Balikcioglu et al., 2011)—this is of less relevance in the context of the problem we are interested in as the crops would be introduced as part of existing dissemination strategies by either the public- or the private sector. Further, adding additional sophistication to the model easily results in problems that cannot be solved analytically, where the mathematical techniques for finding appropriate solutions are currently inadequately developed, thereby easily resulting in problems that are difficult to solve (Balikcioglu et al., 2011).

Now a model is available to identify under what conditions it would be sensible from an economic perspective to either immediately approve or postpone the introduction of a new GE crop, i.e., wait until uncertainty has been resolved and introduce, if G_c is low.

The argument here is that by delaying the approval by 1 year, $T = 1$, decision makers assess that the costs exceed the benefits. The marginal costs justifying a delay are identified $\Delta D^T = 0$ by adjusting G_c. This results in the following proposition:

Proposition

An increase in uncertainty over the policy costs of the introduction of a GE crop, ceteris paribus (c.p.), increases the likelihood that the policy will be introduced later rather than earlier.

Proof: from equation 2-18 it can be seen that $d\Delta D^T\left(\underline{G_C}, \overline{G_c}\right) = \frac{\partial \Delta D^T}{\partial \underline{G_c}} d\underline{G_c} + \frac{\partial \Delta D^T}{\partial \overline{G_c}} d\overline{G_c} < 0$.

Corollary 1

Activities resulting in an increase in uncertainty over the costs of a policy on the introduction of a GE crop, c.p., increases the likelihood that the policy will be introduced later rather than earlier.

Corollary 2

Groups opposing the policy have, c.p., an interest in increasing the uncertainty about the net benefits of the policy.

2.6 Methodology for Chapter 7

2.6.1 Background

In **Chapter 7**, I scale down the scope to the commercial seed sector and sharpen the focus on the firm level where seeds are produced. All of the firms in my study produce seeds using conventional plant breeding methods. Some firms also use genetic engineering for producing their seeds. Empirical studies reporting on the efficiency of production by firms in this sector are scant.

2.6.2 Data Envelopment Analysis

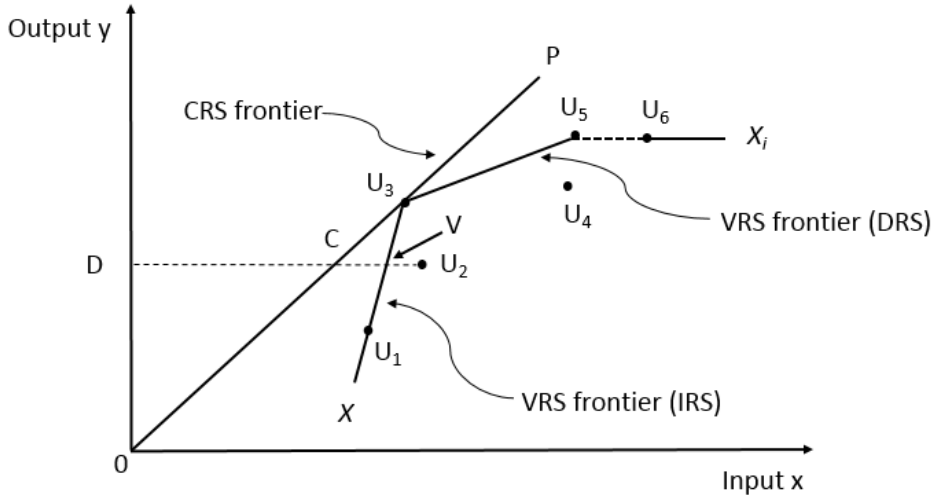
The concept of efficiency for a given production setting is the ratio of inputs to outputs. Resources (inputs) are used by a firm in ways that minimize waste and maximize outputs for parameters such as quality, cost, and production (Cooper et al., 2000).

Data envelopment analysis (DEA) is a technique that "combines the estimation of the technology with the measurement of performance as related to this technology". DEA can be defined as a mathematical programming method for estimating best practice production frontiers and evaluating the relative efficiency of different decision-making units (DMUs) (Bogetoft and Otto, 2011). Two widely applied techniques for measuring efficiency are: (1) the econometric approach (the parametric stochastic frontier analysis (SFA)), and (2) the mathematical programming approach (non-parametric DEA) (Berger and Humphrey, 1997). The important difference between the two approaches is the way in which each one treats the random noise (Fried et al., 2008). The calculation of efficiency in SFA is based on the choice of a particular functional form, and on specific distributional assumptions of the statistical noise and the inefficiency term. Since empirical findings from a stochastic frontier are susceptible to parametric assumptions, modeling biases and incorrect inferences may arise.

The DEA framework allows for overcoming the limitation of SFA. In **Chapter 7**, the nonparametric DEA method proposed by Charnes et al. (1978), which is known as the Charnes, Cooper, Rhodes (CCR) model, is employed. Essentially, the CCR model measures the efficiency of each DMU, which is obtained as a maximum of a ratio of weighted outputs to weighted inputs. The CCR model has a precondition, namely, that there is no significant relationship between the scale of operations and efficiency. This precondition is met by assuming constant returns to scale (CRS). The CRS precondition is only reasonable when all DMUs are operating at an optimal scale (Sufian and Majid, 2007; Řepková, 2014). The model's outcome is overall technical efficiency (OTE), which indicates a DMU's ability to maximize output from a given set of inputs (Ma et al., 2002).

In reality, it is unlikely that all DMUs operate at optimal scale, i.e., DMUs may face either economies- or diseconomies of scale. In such a scenario where CRS is assumed, the OTE scores are tainted with scale efficiencies (SEs) (Sufian and Majid, 2007). This restriction is overcome in the Banker, Charnes, Cooper (BCC) model, which assumes variable returns to scale (VRS) (Banker et al., 1984). If a change in inputs results in a disproportional change in outputs, the DMU operates under VRS. The BCC model measures pure technical efficiency (PTE) by ignoring the impact of scale size, which is achieved by comparing DMUs of similar scale (Ma et al., 2002). According to Al-Refaie et al. (2019), PTE is an indication of how a DMU uses resources under exogenous (non-discretionary resources or products (Bogetoft and Otto, 2011)) environments: the higher the score, the greater the efficiency with which the DMU manages its resources. In short, PTE measures OTE without SE effects.

Figure 2-1 illustrates the simplest form of the DEA method. DMUs use a single input to produce a single output. This example has six DMUs whose inputs and outputs are denoted x_i and y_i (i = 1, 2, ..., 6), respectively. Their input-output combinations are labelled as U_s (s = 1, 2, ..., 6). The input-output combinations for the firms labelled U_1, U_3, and U_5 form the frontier, which displays the characteristic of convexity (Bogetoft and Otto, 2011). The line connecting these DMUs is the efficient part of the frontier. DMUs U_2 and U_4 are inefficient because they lie inside the frontier. Although DMU U_6 provisionally lies on the frontier, it is inefficient (the same output can be produced with less input).



Legend:
CRS = constant returns to scale; VRS = variable returns to scale
IRS = increasing returns to scale; DRS = decreasing returns to scale

Figure 2-1. The DEA production frontier (Source: Webb, 2003).

The DEA efficiency model of DMU_n can be computed from the following programming problem. Following Řepková (2014), let us consider *N* DMUs (*n* = 1, 2, ..., *N*) observed in T (t = 1, 2, ... , T) periods using *r* inputs to produce *s* outputs. Let DMU_n^t represent a DMU_n in period *t* with an *r* input dimensional vector $x_n^t = (x_n^{1t}, x_n^{2t}, \dots, x_n^{rt})'$ and an *s* dimensional output vector $y = (y_n^{1t}, y_n^{2t}, \dots, y_n^{st})'$. If a window (see section 2.6.3 below for an overview of windows analysis) starts at time k ($1 \leq k \leq$ T) with window width *w* ($1 \leq w \leq \mathrm{t} - k$), then the inputs metric is given by:

(2-20) $$x_{kw} = (x_1^k, x_2^k, \dots, x_N^k, x_1^{k+1}, x_2^{k+1}, \dots, x_N^{k+1}, x_1^{k+w}, x_2^{k+w}, \dots, x_N^{k+w})',$$

and the outputs metric is given by:

(2-21) $$y_{kw} = (y_1^k, y_2^k, \dots, y_N^k, y_1^{k+1}, y_2^{k+1}, \dots, y_N^{k+1}, y_1^{k+w}, y_2^{k+w}, \dots, y_N^{k+w})',$$

The CCR model of the DEA window problem for DMU_t^k is given by solving the following linear program:

(2-22)
$$\begin{aligned} &\min \theta, \\ &\text{subject to} \\ &\theta' X_t - \lambda' X_{kw} \geq 0, \\ &\lambda' Y_{kw} - Y_t \geq 0, \\ &\lambda_n \geq 0 \, (n = 1, 2, \ldots, N \times w). \end{aligned}$$

where θ is a measure of efficiency and λ' is the vector of intensity variables representing the weight of each DMU in the efficient frontier. By adding the restriction: $\sum_{n=1}^{n} \lambda_n = 1$, the BCC model formulation can be obtained (Banker et al. (1984) cited by Řepková (2014)). The objective values of the CCR model and the BCC model are designated OTE and PTE, respectively.
The BCC model is shown as:

(2-23)
$$\begin{aligned} &\min \theta, \\ &\text{subject to} \\ &\theta' X_t - \lambda' X_{kw} \geq 0, \\ &\lambda' Y_{kw} - Y_t \geq 0, \\ &\sum_{n=1}^{n} \lambda_n = 1 \\ &\lambda_n \geq 0 \, (n = 1, 2, \ldots, N \times w). \end{aligned}$$

The BCC model allows for the OTE score to be decomposed to PTE and SE scores as follows:

(2-24) $$SE = \frac{OTE}{PTE}$$

SE is a measure of how scale size affects efficiency (Al-Refaie et al., 2019). Furthermore, a difference between the OTE and PTE scores for a given DMU indicates scale inefficiency (Sufian and Majid, 2007).

Figure 2-1 displays an interpretation of VRS as the frontier *XX_i*. Any DMU on the efficient border 0P is overall efficient (U_3). DMUs not appearing on this frontier appear inefficient. Thus, after accounting for VRS, U_1 and U_5 are reported as efficient and operate under IRS and DRS, respectively. As previously depicted by the BBC model, the following relationships exist:

(2-25) $$\text{OTE (or CRS Efficiency)} = \frac{DC}{DU_2}$$

(2-26) $$PTE = \frac{DV}{DU_2}$$

(See Eq. 2-24) $$SE = \frac{DC}{DU_2}$$

with all measures being bound by zero and one. Therefore, CRS efficiency for a DMU is decomposed into PTE and scale efficiency. If CRS = VRS then, by definition, a DMU operates under CRS (Webb, 2003).

2.6.3 Windows Analysis

DEA windows analysis is a method allowing for the assumption of time invariance of the frontier. Windows analysis repeats the DEA model in time segments, called windows, across the time continuum of a panel dataset that comprises both time series and cross-section samples (Al-Refaie et al., 2019).

Windows analysis works on the principle of moving averages (Řepková, 2014). This method facilitates the capturing of temporal variations in efficiency, which is achieved by treating each DMU as a different entity in each time period (Sufian and Majid, 2007). We used this method because it increases the number of DMUs when a limited number of them is available (Jia and Yuan, 2017), as is the case in this study.

Chapter 3

3 The Social and Economic Challenges for a Bioeconomy

Pages 172-190. From: Creating Sustainable Bioeconomies, Edition 1 by Ivar Virgin and E. Jane Morris (Editors), Copyright © 2017 by Routledge. Reproduced by permission of Taylor & Francis Group.

Authors' contributions: This contribution is a book chapter that was written with Justus Wesseler. Richard Smart did the literature research and the bulk of the writing. Justus Wesseler provided the concept and he provided Richard Smart with technical guidance. Justus Wesseler contributed in a minor way to the writing of the text.

Note: The original text was written in British English.

3.1 Introduction

Developing a sustainable bioeconomy in Europe and Africa is a key societal challenge. Meeting this multifaceted challenge requires both technical and socioeconomic competencies that are able to exploit economic opportunities, design effective government policies, facilitate public communication, and address cultural differences.

The bioeconomy has many definitions (Virgin and Morris, 2017) and is complex, involving biological, technical, social and economic dimensions. Its activities range from primary to tertiary production and include supplying a number of services. The bioeconomy's scope can be harnessed to find sustainable solutions to society's interwoven challenges such as food security, natural resource scarcity, fossil resource dependence, and climate change (EC, 2012). The success of the bioeconomies in Europe and Africa depends on advancements in the biological and technical sciences and timely action by politicians to implement enabling policies.

This chapter focuses on selected socioeconomic challenges facing the bioeconomies of Europe and Africa. Despite the macro-level differences between these regions' bioeconomies, both are internally heterogeneous—contributing to the complexity of the demands they face.

We start in section 3.2 by describing each region's bioeconomy that includes a qualitative analysis of their main challenges and opportunities using a SWOT analysis, which is followed by section 3.3 where we investigate:

- steps for ensuring that bioscience R&D (public and private) contribute to sustainable development;
- the public and private sectors' roles and the power relations between them;
- factors affecting innovation diffusion;
- uncertainties and how can they be addressed;
- the impact of globalization, and how governance issues can be addressed.

We conclude the chapter with section 3.4 by discussing possible pathways to success.

3.2 The Bioeconomies of Europe and Africa

3.2.1 Description

Europe's bioeconomy is embracing a knowledge-intensive phase. Its market size has been assessed to be worth about €2 trillion providing 22 million jobs, which constitutes about 9% of the EU's labor force (Table 3-1) as of 2009. There is scope for growth and improvement through innovation—contributing to the region to remain globally competitive (McCormick and Kautto, 2013). The development of "innovation-friendly framework conditions" is expected to support the sustainable growth of the bioeconomy (EC, 2014), especially as it needs enabling policies (Carus et al., 2011; Wesseler and Kalaitzandonakes, 2011) reducing regulatory burdens (e.g., Wesseler et al., 2015). The sustainability of the bioeconomy strategy is challenged because of its potential adverse impact on the environment (Co-operative Research on Environmental Problems in Europe, 2011), while innovations within the bioeconomy such as herbicide tolerant and insect resistant crops have contributed to reduce negative impacts on the environment (through the reduced use of agrochemicals, amongst others) (Wesseler and Smart, 2014), and are expected to continue to do so (Wesseler, 2015).

The turnover of Africa's bioeconomy is substantially smaller than that of the EU (Table 3-1). We emphasize that these data ignore that the shadow economy plays a much larger role in Africa than in Europe. A large proportion of Africa's population (c. 70%) relies on agriculture for employment and income (Paarlberg, 2008). SSA is, according to the Global Hunger Index, the most malnourished region globally (von Grebmer et al., 2014). Projections to 2030 show that the largest relative gains in the world's population are expected in SSA (OECD, 2009). The agricultural sector contributes 60% (up to 90% in some countries) and 25% to Africa's total employment and gross domestic product, respectively. In the first decade of the twenty-first century, Africa accounted for 2.8% and 2.5% of global exports (mostly unprocessed) and imports, respectively. Africa's growth rate was about 4% in 2013 (5% for SSA), better than that of the global economy (3%) thus demonstrating the continent's economic prospects. Noteworthy is that growth performance is inconsistent across Africa, which reflects differences in stages of economic development, availability of natural resources, climate, and political and social stability (OECD/AfDB/UNDP, 2014).

Table 3-1. The sector turnover of the bioeconomies of the EU and Africa for 2009

Sector	**Turnover (billion €)**	
	EU [1]	**Africa**
Food	965	no reliable data
Agriculture	381	136 [2,3]
Paper/Pulp	375	0.1 [2,4]
Forestry/Wood Industry	269	2.2 [2,4]
Fisheries and Aquaculture	32	1.5 [2,5]
Bio-chemicals and Plastics	50	export only 4.6 [2,6]
Enzymes	0.8	export only 0.7 [2,7]
Biofuels	6	0.5 [2,8]
Total	2,078.8	145.6

Source:
[1] For the entire column: European Commission (EC) (2012)
[2] Conversion used: €1 = US$1.4 (X-RATES website, 2015)
[3] Gross production value (FAOSTAT, 2015)
[4] FAOSTAT (2015)
[5] FAO (2015)
[6] Organic chemicals and plastics and articles thereof (African Development Bank Group, 2015)
[7] Albuminoids, modified starches, glues, enzymes (African Development Bank Group, 2015)
[8] Biodiesel, ethanol production (African Development Bank Group, 2015); prices estimated from OECD/FAO (2011)

3.2.2 SWOT Analysis

A qualitative analysis of the bioeconomies of Europe and Africa using the SWOT technique helps to identify internal strengths and weaknesses, and external opportunities and threats (Armstrong, 2012) considered important for achieving a successful and sustainable bioeconomy. The results (Table 3-2) reflect each region's contrasting phase of economic development with Europe 'developed' and Africa 'developing'. Europe's strengths: born from a high level of formal education (expertise, skilled labor) with a well-established logistics and communication infrastructure; few, stable currencies; a reliable judicial system; and strong institutions (banks, input suppliers, knowledge transfer), are contrasted by Africa’s weaknesses resulting from lower levels of formal education (Obonyo et al., 2011); inadequate infrastructure; a poor judiciary; food insecurity; pockets of political instability; asymmetrical and obstructing regulations (Paarlberg, 2008); costly supply chains (Chambers et al., 2014); low investments in bioscience R&D; multiple currencies with volatile exchange rates (Kirchner, 2014); and poor information networks (World Bank, 2006). Africa’s strengths include its ‘enormous transformative potential’ (Chambers et al., 2014), abilities to cope with and to adapt to crises (Hall and Clark, 2010), and the availability of land and labor for developing value-adding activities. Europe’s weaknesses are reflected by its demography (aging population, low birth rates (Eurostat, 2014)), stifling regulatory policies and divergent views on green biotechnology. Opportunities exist for bilateral cooperation between Europe and Africa, especially for developing the latter’s bioeconomy by adapting existing technology. Threats to Europe’s bioeconomy stem from regulations (Wesseler and Kalaitzandonakes, 2011) and a loss of expertise and investments to more accommodating and developed bioeconomies such as that of the US (Dunwell, 2014; Malyska and Twardowski, 2014), whereas Africa is vulnerable due to its weak position in the global economy, inaction by its political leaders and weak governance.

Table 3-2. A qualitative SWOT analysis of the bioeconomies of Europe and Africa

Europe	**Africa**	**Europe**	**Africa**
Strengths (endogenous)		**Weaknesses (endogenous)**	
• Favorable climate for biomass production • High average levels of education • Skilled labor force • Well-functioning judicial system • Developed logistics infrastructure (road, rail, port) • High-tech communications infrastructure • Coordinated framework for policy-making • Strong institutions for policy implementation • Large customer base for innovations • Low number of currencies • Strong biotech (red, grey, white) sector • High level of R&D expertise and allied infrastructure • Food secure	• Relatively inexpensive land for development • Availability of relatively inexpensive labor • Institutional willingness for improvement • Ability for coping with crises • Ability to adapt • ‘Islands’ of willingness to improve • Favorable regulations and business environment for foreign fixed investments (some countries) • Biobased production and agriculture a key pillar in the economy in many countries	• Limited possibilities for expanding primary production • Relatively expensive land and labor • Aging population, low birth rates • Slow pace of innovation • Low R&D investments • Stifling policies for green biotechnology • Divergent views on green biotechnology • Weak networking between science, education, industry • Incoherent and uncoordinated polices for moving Europe towards a modern bioeconmy	• Low levels of education (literacy, numeracy), low investments in human capital • Limited expertise for R&D • Unfavorable ratio of skilled to unskilled labor • Political instability (regional) and lethargy • Weak judicial systems • Net importer of food (insecure) • Expertise, capacity asymmetries for biosafety and other regulations • Divergent views on green biotechnology • Weak information networks • Poor performance of public sector providing basic services and infrastructure • Inadequate infrastructure • Large distances to ports for international trade, weak supply chains • Slow (in some cases: none) regulatory mechanisms and weak institutions • Falling per capita public spending on agricultural science • Internal trade barriers, asynchronous regulations • Productivity, earnings: vulnerable to weather
Opportunities (exogenous)		**Threats (exogenous)**	
• Expertise available for identifying opportunities in Africa • Strong ties with African countries • Africa presents many opportunities for cooperation with Europe Potential for: • job creation • resource and energy efficient, climate-smart productive agricultural systems • integrating into global markets • value-adding activities • improving productivity • recycling energy and material flows	• Strong ties with Europe, common languages, religions, similar time zones • Foreign direct investment in the bioeconomy, especially in developing value chains • Capacity for bilateral cooperation in R&D • Potential for adopting foreign innovations Potential for: • job creation; value-adding • increasing agro-productivity, fish production • connecting smallholder farmers to markets, value chains, and agro-processing • revitalize rural communities • modernizing the African agro-process sector • converting agro-waste to useful products	• Asynchronous regulations with offshore trading partners • Loss of human capital/expertise to competitors • Competition from other developed regions	• Productivity, earnings: vulnerable to international commodity markets • Volatile exchange rates • Risk averse policies of foreign investors • Negative influence of politicians, and lobbyists from abroad • Asynchronous regulations with offshore trading partners • Trading barriers of offshore trading partners • Changing offshore consumer attitudes, preferences

3.3 Socioeconomic Issues of the Bioeconomy

3.3.1 R&D: For Whom and the Role of the Public and Private Sectors

The private sector's role in the bioeconomy includes: R&D, developing expertise, bringing innovations (products, services) to the market, cooperating with the public sector, providing employment, and contributing to economic growth and development. An increasing proportion of R&D in the bioeconomy is done in the private sector and in small and medium enterprises (SMEs) in particular (OECD, 2009). Their primary target is developing and commercializing bioscience technologies for 'high' profit markets. The public sector plays an important role in the 'low' profit, region-specific, and local bioscience innovations that are important for small-scale farmers. An African example is the public sector's involvement in genetically engineering bananas for resistance to bacterial wilt (African Agricultural Technology Foundation (AATF), 2015a).

A strong public and private sector research base is necessary for developing human capital, making promising knowledge-intensive bioscience technologies widely available, for addressing social and environmental needs, and shortening the time from R&D to market. This can be organized by the public as well as the private sector or by public-private partnerships (PPPs). The public sector plays a significant role—particularly in Africa—in adopting and disseminating innovations to agricultural (especially smallholder farming systems) and agro-processing actors, and for addressing societal needs such as food security, adaptation to climate change, and protecting the environment. Although public R&D is important for inclusive knowledge development, innovation and deployment, public organizations have often been less effective in shifting ideas and technologies beyond research. Linking public and private institutions through various kinds of innovation platforms, as is the aim of the EU's Knowledge and Innovation Community Food4future (2020Horizon, 2015) for example, is expected to improve the chances of innovations reaching a broader set of market actors. These links can stimulate bioeconomic activity and the establishment of new enterprises and governments can support initiatives fostering such linkages and knowledge exchange (Schmid et al., 2012).

Thriving SMEs generally promote diversification and establish a base for economic growth (The Banking Association South Africa, 2014). SMEs constitute 95% of firms in SSA, but their contribution is meaningful only when a country is in a persistent phase of economic growth (Fjose et al., 2010). Despite many SMEs in Africa facing high market risks, being trade oriented, and infrequently engaged in R&D and innovation efforts, examples of successful SMEs in the biotechnology sector are presented in a feature article by Al-Bader et al. (2009). SMEs form the backbone of the EU's economy comprising about 99% of all businesses (EC, 2015a). Here, they are more engaged in innovation and R&D, but are negatively affected by regulatory barriers, and in the case of GM crops, by negative public and political perceptions (Wesseler, 2014).

Public and private institutions often cooperate in PPPs by pooling complementary resources and expertise. European examples include the Bio-Based Industries Joint Undertaking (BBI, 2016) and the Top Sectoren strategy in The Netherlands (Top Sectoren, 2016). Spielman and Zambrano (2013) point out that in Africa these "valuable learning and information exchange opportunities" are often stifled by regulatory hurdles, and institutional and organizational barriers. Thus, governments exercise market power as they control the approval processes of innovations (Wesseler and Zilberman, 2014).

When PPPs form, it is crucial that actors discuss and agree upon framework conditions beforehand, as demonstrated by an ex-ante study on introducing GM cotton in Uganda. Establishing clarity about the participants in seed propagation and distribution and the government's involvement as a price broker both for the technology fee and the final product contributed to the project's success (Horna et al., 2013).

Scholars (Moschini and Lapan, 1997; Falck-Zepeda et al., 2000) and international organizations are concerned that private multinationals could exercise monopolistic power in developing countries by, for example, charging unfair prices for their products or limiting access to innovation. Moreover, negative views exist about the increased involvement of the private sector in this arena as "one more example of corporate control of agriculture and its activities" (Falck-Zepeda et al., 2013a). Well-planned projects with good governance could quell these concerns—especially as preventing them would deny Africans access to much-needed innovations. According to Chambers et al. (2014), in Africa there is much scope for the private sector's involvement in biotechnology.

Although the public sector has initially been the major player in the innovation process in Africa for GM crops (Sithole-Niang et al., 2004), the private sector was responsible for bringing them to the market. South Africa developed strategies in 2001 and 2013 for public sector involvement in, and for the creation of incentives for, growing its biotechnology sector (Department of Science and Technology, 2013). Importantly, a number of PPPs in Africa are involved with bioscience projects for developing solutions for local challenges (e.g., field-testing in Kenya of maize developed for drought and insect resistance) (Chambers et al., 2014), demonstrating a sharing of power. In the EU, the public and private sectors are divesting from crop genetic engineering mainly because of stifling regulations and adverse public opinion (Dunwell, 2014), with the possibility of negatively affecting other parts of the bioeconomy.

In summary, an increasing proportion of bioscience R&D is being done by the private sector: a trend that many fear may exclude some farming communities and value chain actors—especially in Africa—from the benefits of innovations. A more inclusive bioeconomy could be developed by, amongst others, increasing funding for public R&D, strengthening its linkages to markets and private sector actors, and lowering regulatory hurdles (for more details see e.g., Juma et al., 2007). This could broaden the R&D agenda and promote a sustainable, more resource-efficient, inclusive and climate-smart agricultural and agro-processing sector on both continents.

3.3.2 Sustainable Implementation of Bioscience R&D

Translating and implementing bioeconomy strategies and R&D agendas varies among countries, stakeholders and actors. Europe and Africa can benefit from developing a common understanding, strategies, actions, plans, and visions about what a modern bioeconomy should lead to, how to get there, and importantly, take action.

The bioeconomy is responding to the increased demand for food, bioresources for renewable energy and fuels, biobased products and materials, and processing, and the need for reducing greenhouse gas emissions (EC, 2012; Pfau et al., 2014). R&D has primarily been targeted at the agricultural and renewable energy sector, especially in the EU (Schmid et al., 2012), although the focus has recently shifted to chemicals and materials. A successful bioeconomy can be developed by focusing R&D so that outcomes can be sustainably implemented (EC, 2012; OECD, 2009). No single ‘recipe’ for success exists. Importantly, the sustainable use of natural resources—many of which are public goods—must be integrated into these plans (Schmid et al., 2012). Therefore, such work would reveal—on a case-by-case basis—information about where the greatest challenges (including economic, social, political, environmental) lie along the most important value chains, the R&D and institutional capacities, the available resources and the regulatory environment. Actors, and in particular the private sector, would then be able to prioritize, plan, coordinate and schedule R&D activities, and identify where capacity-building for extension services and institutions needs to be established (or strengthened) for sustainably implementing bioscience-derived solutions. The EU's new Bio-Based Industries Joint Undertaking, a PPP referred to earlier, provides funding for biobased innovations, including demonstration and flagship projects.

The level of development and focus of Europe's bioeconomy are more advanced than that of Africa, where for example, food security is still a priority. In Europe, the following are current focus areas: renewable energy, bioplastics, plant-produced pharmaceuticals, and recycling. Public R&D funds have been prioritized for providing solutions to key societal demands, such as improving the resource and energy efficiency of the agricultural sector, making it climate-smart and more environmentally friendly under the Horizon 2020 research program including broadening the diversity of agricultural products produced and involving new industrial value chain actors in the search for new agro-products. Although solving the challenge of food security in Africa remains a priority for its bioeconomy, developing other promising areas (e.g., the pharmaceutical sector) can provide important contributions towards economic growth and in particular attract much needed foreign direct investments.

In the bioeconomy, actors' opinions become important for developing strong supply chains. Efficient and effective communication platforms can help reduce potential R&D overlaps or duplications, better identify opportunities for cooperation (establishing PPPs, for example) and communicate with consumers (Chambers et al., 2014) and other stakeholders to inform them about current bioscience developments and how they can benefit from them.

Europe has capacity for providing Africa with expertise for training personnel for specific tasks such as the establishment of innovation platforms and aiding with establishing appropriate structures (e.g., integrated supply chains). Such cooperation can aid technology transfer by accelerating capacity building and contributing to the sustainable implementation of innovations. Spielman and Zambrano (2013) suggest incentivizing closer public-private collaboration for public-interest research, and where ventures could be "spun off from public research agencies". Furthermore, proven methods like the 'honest broker' model can be used where non-profit third-party organizations like The Bill and Melinda Gates Foundation, The Syngenta Foundation for Sustainable Agriculture, and UK aid "facilitate interactions between the sectors, manage the research, and assume responsibility for the use of proprietary knowledge and technology" (see for example AATF, 2015b).

Socioeconomic issues that the EU's bioeconomy strategy focuses on include job creation, increasing competitiveness, sustainability, knowledge and skills transfer, involving society, research, developing infrastructure, and improving supply chains (EC, 2012). This strategy's value lies in its effective implementation. South Africa is the only African country that has a formalized bioeconomy strategy, the benefits of which will be limited if commercialized innovations cannot be exported because of weak demand and/or regulatory hindrances/deficiencies with trading partners. Immediate steps, according to Chambers et al. (2014), for Africa to reduce these obstructions include finding ways for eliminating confusion about bioscience innovations, coordinating regulatory initiatives, building regional regulatory harmonization, and developing confidence in national regulatory frameworks. Finally, a coordinated multidisciplinary bioeconomy development plan at regional level could form the foundation for the growth of Africa's bioeconomy.

In both regions, social innovation in the bioeconomy needs to be strengthened. This 'bottom up', interactive, social process can be used for empowering groups that are facing common problems (e.g., inadequate rural development contributing to declining local populations, sinking service levels from government, an uncompetitive agricultural sector) to seek solutions, and for rehabilitating dysfunctional (rural) markets (Schmid et al., 2012). An important aspect in this context is to pay attention to strengthening individual rights and to avoid an authoritarian "knowing it all" approach to, in particular, avoid mistakes made in the past (see e.g., Easterly, 2014).

Another related aspect is to avoid having a too narrow view on the bioeconomy that may result in excluding approaches linked to agro-ecology that center around "enhancing farmers' knowledge of natural resources" (Birch et al., 2010). In our view, a successful bioeconomy strategy has to build on farmers' knowledge. We see this as being a natural synergy to improving the efficiency of natural resource use.

3.3.3 Innovation Diffusion

An innovation usually results from translating an idea into a commercially available good or service for which customers are willing to pay. Innovation diffusion is a complex "process by which an innovation is communicated through certain channels over time among the members of a social system" (Rogers, 1962). It is influenced by, amongst others, societal values, everyday practices, infrastructure, local economy, technical knowledge, and social self-identity.

Adopting an innovation is a crucial element of its diffusion and is affected by factors such as tacit knowledge (Nightingale, 2012), tradition, religion, laws, environment, lifestyle, human behavior (Prasad, 2011), availability of information, administrative decisions, government interventions, market price and “thresholds of perceived profitability and risk being crossed” (Scandizzo and Savastano, 2010). McCormick and Kåberger (2005) distinguish between technological, organizational, and social innovation; sometimes the former two are seen as being a part of social innovations (BEPA, 2011). Nevertheless, understanding the links between these can contribute to formulating sustainable bioeconomy strategies.

A key challenge in the transition towards a modern bioeconomy is how bioscience innovations reach the market. The question of demand and the connected market externalities will be challenges in this sphere. In Africa, constraints for adopting and deploying bioscience innovations include:

- a low level of formal education;
- unfavorable conditions for entrepreneurship development (e.g., weak or no markets, unfavorable and disconnected policy regimes, financing and credit constraints).

Similarly, in Europe the main constraints are connected to stringent regulatory systems, but favorable conditions for entrepreneurship and access to financing prevail. Innovation diffusion is strongly influenced by economic incentives (Horna et al., 2013), whereas doubts spawned from ungrounded fears have a negative impact (Fok et al., 2007). In Africa, it is structurally impeded by deficiencies in its biosafety regulatory capacity, incoherent regulatory instruments, and in some cases, the weak enforcement of regulatory procedures (Obonyo et al., 2011) and slow regulatory processes (if existing at all (Spielman and Zambrano, 2013)).

Similar problems exist in Europe, but they are less pronounced. In Africa, farmers’ adoption of bioscience innovations such as improved seed varieties depend on their access to, interaction with, and the arrangement of input and output markets, together with their access to credit and technical support. When these markets are deficient (Gouse et al., 2005; Fok et al., 2007), innovation diffusion is hampered. And from work done in Greece, Genius et al. (2013) concluded that “both extension services and social learning are strong determinants of technology adoption and diffusion, while the effectiveness of each of the two informational channels is enhanced by the presence of the other”.

In summary, innovation diffusion is affected by many interacting socioeconomic factors and actors. In Africa, access to finance, technical support, and markets are important for farmers adopting bioscience innovations. Governments, through their regulations, can either hamper or promote innovation diffusion. The prospect of innovations bringing financial benefits stimulates their diffusion.

3.3.4 Addressing Uncertainties in the Bioeconomy

One cannot predict what innovations will be discovered, how consumers will respond to them, how politicians will continue to exercise their power through regulations, or what will determine political decisions. But, as previously mentioned, a modern bioeconomy can contribute to solving current socioeconomic and environmental challenges.

Socioeconomic uncertainties can hamper the growth and development of the respective bioeconomies of Europe and Africa. Addressing some key issues can contribute to overcoming these uncertainties:

- financing and funding the transition towards a bioeconomy;
- sharing of information on the social, economic, and environmental effects of a modern bioeconomy;
- frameworks for assessing socioeconomic risks and benefits of bioscience innovations; and
- a coherent bioeconomy policy strategy.

Financial incentives and the ease of conducting business can promote the private sector’s involvement in the bioeconomy, where numerous opportunities for developing innovations exist. But, when regulations are too burdensome—especially for SMEs—the private sector’s involvement is often limited to multinational firms.

In Africa, little information for making informed decisions about the bioeconomy is available. Linked to this is the uncertainty of how to consistently keep high-level, influential politicians informed, and motivated to act. Targeting research to find answers to explicit questions on the socioeconomic impact of moving towards a bioeconomy is one route to take. Information about the potential social and economic impacts of introducing an innovation can be garnered from ex ante studies, which can also be used to model the impacts of precautionary regulations (e.g., Wesseler and Zilberman, 2014). Their estimates show that a decade’s delay in the authorization of ‘Golden

Rice' (rice genetically engineered to contain vitamin A) by the Indian regulators may have resulted in at least 1.4 million cases of blindness. In a more recent study, Zilberman et al. (2015) estimated the forgone benefits for delays in the approval of corn, rice, and wheat to be between about 33 and 77 billion USD per year. Assessing and weighing potential/perceived benefits with risks of innovations may contribute to easing current negative public perceptions about them (e.g., Kikulwe et al., 2013), but will not result in immediate policy change.

A conflict-free and stable political environment facilitates economic growth. Where conflicts and political turmoil exist, avenues for neutralizing them need to be sought. Such a path may be paved by the bioeconomy through developing value chains in which jobs are created, food production is raised, and earnings are improved. We do not know when Africa's politicians will show sufficient urgency to put policies in place that promote local bioscience-derived innovations. The consequences of their inaction have been quantified by socioeconomic studies on the forgone benefits caused by these delays (e.g., Zilberman et al., 2015; Kikulwe et al., 2014) and observed by visiting affected areas such as those in Uganda suffering from the destruction of banana plantations by bacterial wilt.

3.3.5 Globalization and Governance

Globalization "has effects on the environment, on culture, on political systems, on economic development and prosperity, and on human physical well-being in societies around the world" (The Levin Institute, 2015). At this macro level, governance is needed for enhancing the prosperity and viability of Europe and Africa. Protection from exploitation and unfair competition, which could result in joblessness, the dispossession of property, and the loss of biodiversity, for example, is important (Richardson, 2012).

Governance encompasses strategies, policies, regulations, and controlling bodies that are ideally shaped via participatory, transparent, and knowledge-driven processes. Governance takes place at the firm level through self-regulatory mechanisms (e.g., setting of quality standards and formal contracts), and nationally and internationally through standards and laws. Disputes at an international level could be resolved through litigation. Governance issues play a core role in the efficient functioning of the bioeconomy, especially as it influences the commercial fate of innovations.

Modern biosciences have the potential to link smallholder farmers to markets, value chains and agro-processing opportunities locally and abroad. Thus, bioscience innovation can assist African countries to establish better connections with regional and global trading markets, which in turn would enhance their agricultural sectors. Similarly in Europe, investments in bioscience innovations targeted at the agricultural and agro-processing sectors can improve their global competitiveness (EC, 2012). Strengthening local knowledge and capabilities by complementing them with outside expertise and teaching can contribute to enhancing diversity and complexity, thereby adding resilience to the bioeconomy (Schmid et al., 2012).

Domestic policies in one region can have a negative impact on another (e.g., subsidies for cotton in the US have rendered its production in parts of SSA uncompetitive (Sumner, 2013)). Unharmonious regulations or the lack thereof (e.g., very few African countries currently authorize GE crops) and exchange rate fluctuations, border controls, and other forms of governance (e.g., fishing quotas, restrictions on logging natural forests, climate-change policies, biosafety regulations, and bioenergy policies) hamper trade and disturb the power relations between trading partners. These disequilibria can be addressed via bilateral negotiation, third-party mediators, or in the case of serious disputes, the International Court of Justice, and lead to improvements in governance and hence to a more productive bioeconomy.

In short, globalization means that the bioeconomies of Europe and Africa are impacted by international actors and cross-border governance issues. Governance is necessary for ensuring a balance of power between actors in the bioeconomy, promoting prosperity especially in rural areas, and preventing exploitation.

3.4 Pathways to Success

No ‘one-fits-all’ path for innovation success in the biosciences exists. Each region will have to tailor pathways unique to its circumstances for sustainably developing its bioeconomy. The successful implementation of technical solutions will largely depend upon the institutional environment and public acceptance. Socioeconomic and technical challenges and opportunities of bioeconomies must be addressed simultaneously (Fok et al., 2007). Schmid et al. (2012) underline the need for socioeconomic research “to inform strategies, pathways and stakeholder cooperation towards sustainability goals”. Pathways to success require a conflict-free and stable political environment.

Europe and Africa at policy level can benefit from formulating and implementing bioeconomy plans that coordinate their internal approaches and actions with clear visions, aims, schedules, and systems for measuring and monitoring their progress to implement corrective action when needed, and have policies targeted at supporting sustainable bioeconomic development. Immediate action and bold leadership are often required to translate these plans into tangible outputs to benefit society. Influential leaders in government, education, and business need to address the bioeconomy challenges together proactively, as was done in Berlin in November 2015 (Global Bioeconomy Summit 2015, 2015), otherwise their global competitiveness will be compromised and welfare lost as opportunities and their benefits will be lost to competitors from other regions (e.g., the US and Asia).

Africa can benefit from the establishment of an open-source bioeconomy information system to facilitate efficient decision-making (Chambers et al., 2014; Spielman and Zambrano, 2013). Existing infrastructure and expertise of a regional organization such as the African Development Bank could be used and further developed for this purpose (African Development Bank Group, 2014).

Governments could stimulate their bioeconomies through policies such as preferential procurement programs and providing financial incentives for initiatives that will be of long-term benefit to society such as climate-smart farming or the generation of ‘green’ electricity. Important for Africa will be to combine this with strengthening the rights of local people, and to increase investments in education so that knowledge about the bioeconomy can expand and be applied to solve local challenges. An increase in public and private sector R&D investments and capacities (infrastructure and expertise) is needed to accelerate innovation development in the bioeconomy—traditionally a sector with low R&D investments, especially in Africa.

The EU is speeding up its efforts in promoting bioscience entrepreneurship and innovation for it to remain globally competitive. In Africa, current efforts could be enhanced by introducing new financing models and establishing strategically located bioscience and business incubator parks. Adopters of innovations need access to financial and technical support in the form of credit and extension services, respectively. More investments in communication and transport infrastructure are needed in Africa for coordinating and transporting produce in rural areas to markets and value-adding facilities.

Hardy agricultural value chains across a spectrum of commodities can be helpful. These will yield economic and social knock-on effects like catalyzing job creation (especially in rural areas) and contributing to regional stability. Improved production in the cotton industry and higher coffee exports from northern Uganda and Rwanda, respectively, serve as recent, inspiring examples (OECD/AfDB/UNDP, 2014).

In Africa, the implementation of secure land tenure systems is important to avoid controversies about land use such as ‘land grabbing’. Fair and equitable employment conditions need to be upheld to prevent the exploitation of workers. Support for women farmers needs to be enhanced to improve gender inequality by including them in economic and education activities, amongst others. Value-added activities need to be established in rural areas to keep the bioeconomy decentralized and sustainable (World Bank, 2012; Pfau et al., 2014; Wiggins et al., 2015), and to reduce pressure on urbanization.

Europe and many African countries need to lighten their regulatory ‘millstones’ (Chambers et al., 2014; Spielman and Zambrano, 2013) for authorizing innovations, especially GE crops. This, together with improved public acceptance of biotechnology, are crucial challenges facing the success of these regions’ bioeconomies. McCormick and Kautto (2013) highlight participatory governance (general public and key stakeholders) and commitments to innovation by government (via “ ‘pro-active’ ” policies (Hall and Clark, 2010)) and industry for promoting a competitive bioeconomy.

Africa has the potential to overcome its capacity, expertise and funding limitations by centralizing risk assessment (Adenle et al., 2013), harmonizing regulations, and facilitating cooperation through regional economic communities (Chambers et al., 2014). Africa could reap the benefits of existing innovations approved elsewhere by adopting them without lengthy and costly regulatory delays, which could generate substantial immediate economic benefits (e.g., Kikulwe et al., 2011). Having practical and implementable biosafety regulations is one way of achieving this.

We have identified and summarized some of the more important hurdles that need to be overcome for facilitating pathways leading to the successful development of the bioeconomies of Europe and Africa. There are many unknowns and fears, but a knowledge-based bioeconomy has the potential for yielding a net positive effect on the socioeconomic situation in Europe and in Africa. This will, in part, depend upon these regions having a sufficiently broad innovation agenda deploying new technologies and products benefitting the majority of the population, empowering peoples' rights and especially those of smallholder famers in Africa. Ultimately, well-planned, targeted and rights-based interdisciplinary actions with a sustainable focus are needed for these bioeconomies to sustainably advance.

Chapter 4

4 Trends in Genetically Engineered Crops’ Approval Times in the United States and the European Union

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Authors’ contributions: Matthias Blum and Justus Wesseler[4] are the co-authors. Justus Wesseler provided the concept and guided the theoretical approach, and provided oversight. Richard Smart collected the data, prepared them for empirical analysis, conducted the literature review, and wrote the bulk of the text. Matthias Blum performed and interpreted the econometric analysis.

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Abstract

GE crops are subject to regulatory oversight to ensure their safety for humans and the environment. Their approval in the EU starts with an application in a given MS followed by a scientific risk assessment, and ends with a political decision-making step (risk management). In the US approval begins with a scientific (field trial) step and ends with a ‘bureaucratic’ decision-making step. We investigate trends for the time taken for these steps and the overall time taken for approving GE crops in the US and the EU. Our results show that from 1996-2015 the overall time trend for approval in the EU decreased and then flattened off, with an overall mean completion-time of 1,763 days. In the US in 1998 there was a break in the trend of the overall approval time. Initially, from 1988 until 1997 the trend decreased with a mean approval time of 1,321 days; from 1998-2015, the trend almost stagnated with a mean approval time of 2,467 days.

Keywords: GE; genetically modified organism (GMO); transgenic; US; EU; regulatory oversight; authorization.

JEL Classifications: O32, O38, O57, Q16

4.1 Introduction

GE crops are innovations that need to clear all regulatory hurdles of a given jurisdiction before they can be commercialized—a time-consuming process. In theory, these regulations ("governmental oversight") are used by governments to ensure the safety of new biotech products for humans and the environment (Lynch and Vogel, 2001).

Complying with regulations is costly (Davison, 2010; Miller and Bradford, 2010) (the mean total cost of introducing a new GE crop for the period 2008-2012 was 136 M USD of which 35.01 M USD (25.8%) were for meeting regulatory requirements (regulatory science (17.9 M USD); registration and regulatory affairs (17.2 M USD)) (Phillips McDougall, 2011b). Kalaitzandonakes et al. (2007) identified compliance costs for insect resistant and herbicide tolerant maize of 7.1-15.4 M USD and 6.2-14.5 M USD, respectively, often affordable only by large private organizations (Bradford et al., 2005; Giddings et al., 2013).

Numerous investigations have shown a spectrum of benefits (pecuniary, non-pecuniary, and environmental) of adopting first generation GE crops (e.g., Benbrook, 2012; Bennett et al., 2013; Mannion and Morse, 2013; Brookes and Barfoot, 2014). A meta-analysis by Klümper and Qaim (2014) shows that "the average agronomic and economic benefits of GM crops are large and significant". Second-generation GE crops such as micronutrient enriched food crops are expected to improve the health, life-expectancy, and welfare of especially impoverished consumers (Wesseler and Zilberman, 2014; De Steur et al., 2015).

The international regulatory framework is fragmented (Vigani and Olper, 2015) and "highly heterogeneous" because of differences, inter alia, in standards for GMOs, endogenous policy and the market for information, which affects welfare distribution (Vigani and Olper, 2013). Delays in authorizing GE crops postpone their benefits and cause economic losses in foregone profits. Losses are further exaggerated by asynchronous approval processes, which cause market disruptions (Vigani et al., 2012), and lead to strained trading relations (Henseler et al., 2013; de Faria and Wieck, 2015; De Steur et al., 2015) that in some cases have escalated to formal international disputes (Punt and Wesseler, 2016). Potential environmental and human health benefits are also delayed (Wesseler et al., 2011).

The period for applications successfully moving through the GE crop regulatory pipeline, extended by unforeseen regulatory delays, and the asynchrony in approval between trading partners, is of economic importance for participants in a new GE crop's value chain (Stein and Rodríguez-Cerezo, 2009; Nowicki et al., 2010). In their study on the cost of compliance in the Philippines, Bayer et al. (2010) note that a country's regulatory costs appear to fall over time as experience is gained, while regulatory costs are lower for products that have already been approved elsewhere (and by implication, regulatory time is shorter). These authors conclude that: "the largest potential constraint to commercialization … is regulatory delay". Temporal aspects of regulations have socio-political implications for their regulators and policy evolution due to the opposing pressures exerted on this 'ecosystem' by the antagonists and protagonists of this type of green biotechnology who lobby for stricter and more lenient regulations, respectively. Antagonists have contributed to regulatory delays through legal recourse (DeFrancesco, 2013), state action (e.g., the de facto moratorium in the EU lasting from 1998-2004 (Cararu, 2009; Davison, 2010)), and social protest activities such as destroying field trials (Bonneuil et al., 2008; Morris and Spillane, 2010).

We investigate the time taken for GE crops to pass through the regulatory pipelines of the US and the EU—"first movers" worldwide in implementing regulations for GE crops (Vigani and Olper, 2015) and important trading partners in these commodities. We identify the trends that have developed since the first GE crop was approved in the US, and provide an improved understanding of the time taken for each regulatory step in these jurisdictions. We deliberately avoid any statistical comparison of the two regions' total approval time (see **Synthesis** below). Because the 'economic clock' theoretically never stops, we ignore any technical stoppages that a 'regulatory clock' might accommodate (e.g., regulators' requests for additional information).

We add to current knowledge (The European Association for Bioindustries, 2011) by giving an updated analysis of the time taken for GE crops to be approved by analyzing: (1) each step in the regulatory 'path' for its contribution to the overall regulatory process, and (2) crop characteristics' impact on regulatory time.

In the section 4.2 we describe the regulatory processes in the US and EU to show their differences and similarities, and to set the scene for our research method. In section 4.3 we describe the data we used and the statistical analyses done. Thereafter, in section 4.4, we discuss our results, and end with our conclusions in section 4.5.

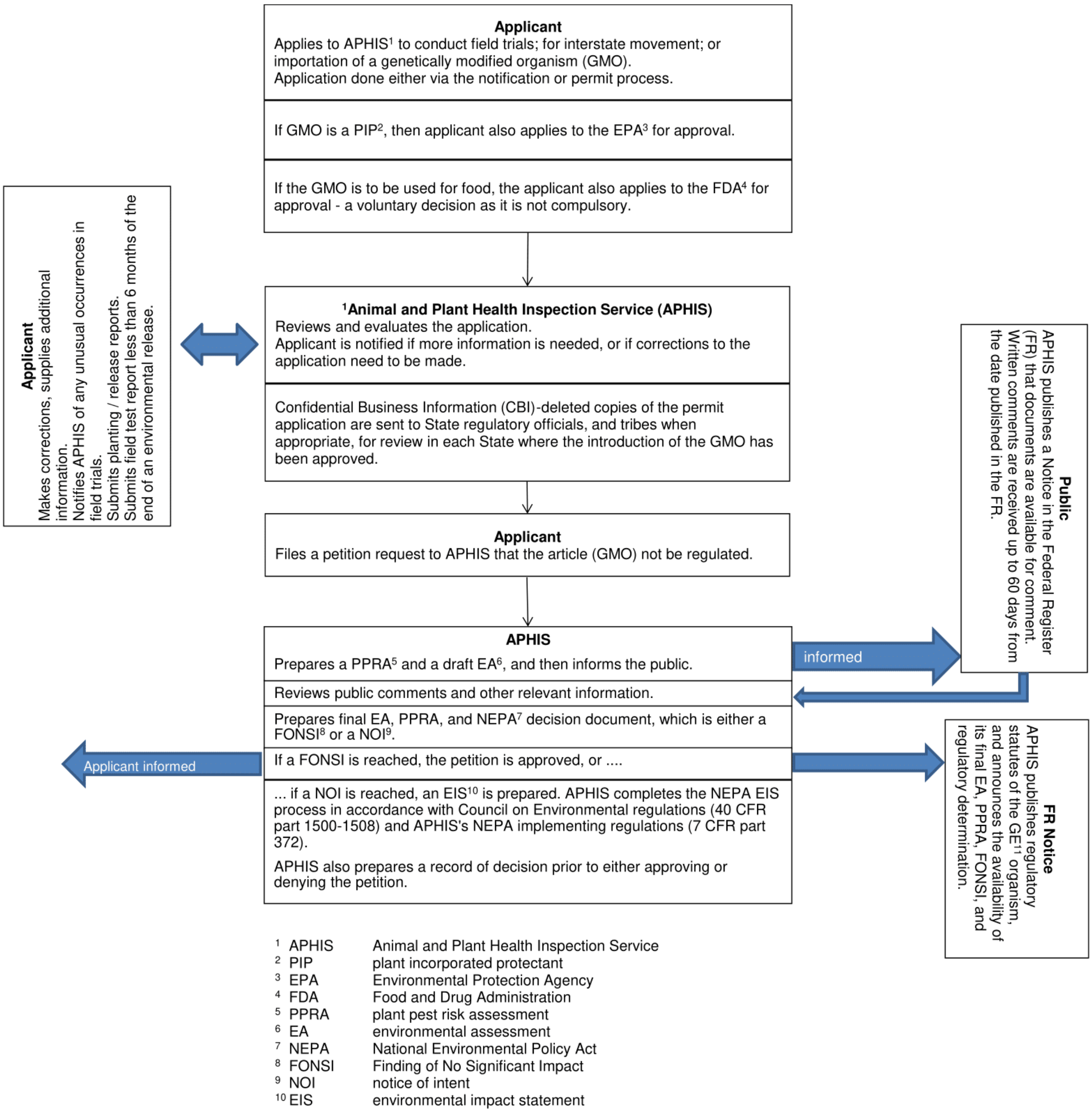
4.2 The Regulation of GE Crops in the US and the EU

4.2.1 Introduction

Although a new GE crop typically follows a seven-stage development process (see Phillips McDougall, 2012), regulatory oversight in the US begins with stage six involving the scientific evaluation of a new crop's safety and ends in a 'bureaucratic' decision-making step. In the EU however, there is an additional political decision-making step (Lynch and Vogel, 2001; Davison, 2010).

4.2.2 United States

The US Department of Agriculture (USDA) takes the lead role for approving GE crops, and is supported by the Environmental Protection Agency and the Food and Drug Administration (Office of Science and Technology Policy, 1986). We consider the start of the regulatory process (i.e., when the 'economic clock' starts) to be when a developer first seeks permission at the USDA's Animal and Plant Health Inspection Service (APHIS) for conducting field trials on a regulated article—the name for GE crops not yet approved—irrespective of when its first field trial actually starts. This 'scientific' (field trial) step ends when the developer submits its petition dossier to the APHIS petitioning for non-regulated status, which in turn marks the beginning of the 'bureaucratic' step during which the scientific evidence of its safety is assessed. This step ends when the regulated article is assigned non-regulated status. The petitioner is then legally permitted to market the GE crop. Details of this process up to the end of February 2012 are shown in Figure 4-1. From March 2012 the process was changed to facilitate earlier public involvement, and the way in which public comments are solicited and used (Figure 4-2) (USDA APHIS, 2012).



Applicant
Applies to APHIS[1] to conduct field trials; for interstate movement; or importation of a genetically modified organism (GMO).
Application done either via the notification or permit process.

If GMO is a PIP[2], then applicant also applies to the EPA[3] for approval.

If the GMO is to be used for food, the applicant also applies to the FDA[4] for approval - a voluntary decision as it is not compulsory.

[1]Animal and Plant Health Inspection Service (APHIS)
Reviews and evaluates the application.
Applicant is notified if more information is needed, or if corrections to the application need to be made.

Confidential Business Information (CBI)-deleted copies of the permit application are sent to State regulatory officials, and tribes when appropriate, for review in each State where the introduction of the GMO has been approved.

Applicant
Makes corrections, supplies additional information.
Notifies APHIS of any unusual occurrences in field trials.
Submits planting / release reports.
Submits field test report less than 6 months of the end of an environmental release.

Applicant
Files a petition request to APHIS that the article (GMO) not be regulated.

APHIS
Prepares a PPRA[5] and a draft EA[6], and then informs the public.

Reviews public comments and other relevant information.

Prepares final EA, PPRA, and NEPA[7] decision document, which is either a FONSI[8] or a NOI[9].

If a FONSI is reached, the petition is approved, or ....

... if a NOI is reached, an EIS[10] is prepared. APHIS completes the NEPA EIS process in accordance with Council on Environmental regulations (40 CFR part 1500-1508) and APHIS's NEPA implementing regulations (7 CFR part 372).

APHIS also prepares a record of decision prior to either approving or denying the petition.

Public
APHIS publishes a Notice in the Federal Register (FR) that documents are available for comment. Written comments are received up to 60 days from the date published in the FR.

FR Notice
APHIS publishes regulatory statutes of the GE[11] organism, and announces the availability of its final EA, PPRA, FONSI, and regulatory determination.

[1] APHIS	Animal and Plant Health Inspection Service
[2] PIP	plant incorporated protectant
[3] EPA	Environmental Protection Agency
[4] FDA	Food and Drug Administration
[5] PPRA	plant pest risk assessment
[6] EA	environmental assessment
[7] NEPA	National Environmental Policy Act
[8] FONSI	Finding of No Significant Impact
[9] NOI	notice of intent
[10] EIS	environmental impact statement

Figure 4-1. The US's approval process for GE crops pre-6 March 2012 (Source: Own depiction following USDA APHIS, 2012).

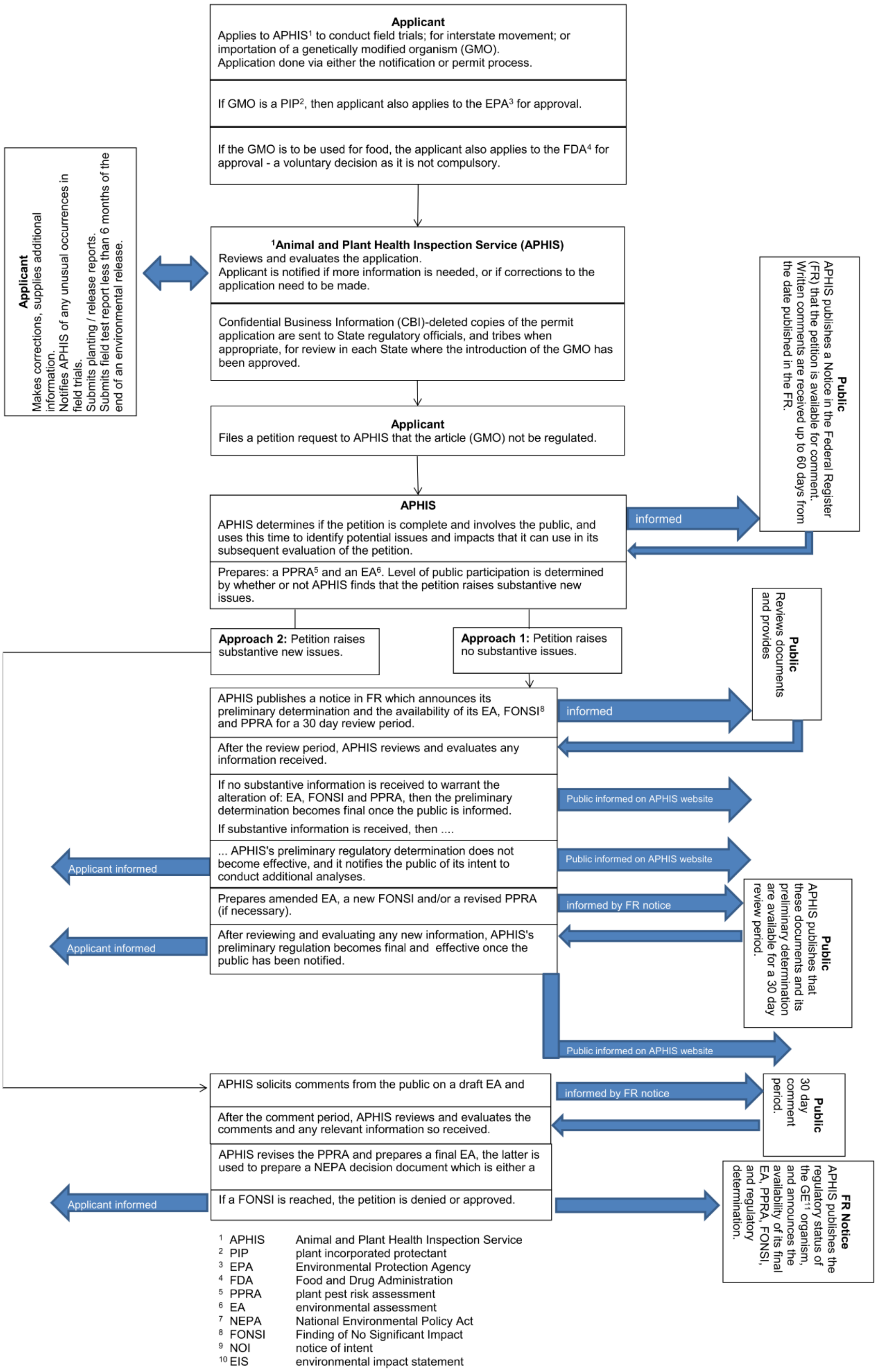


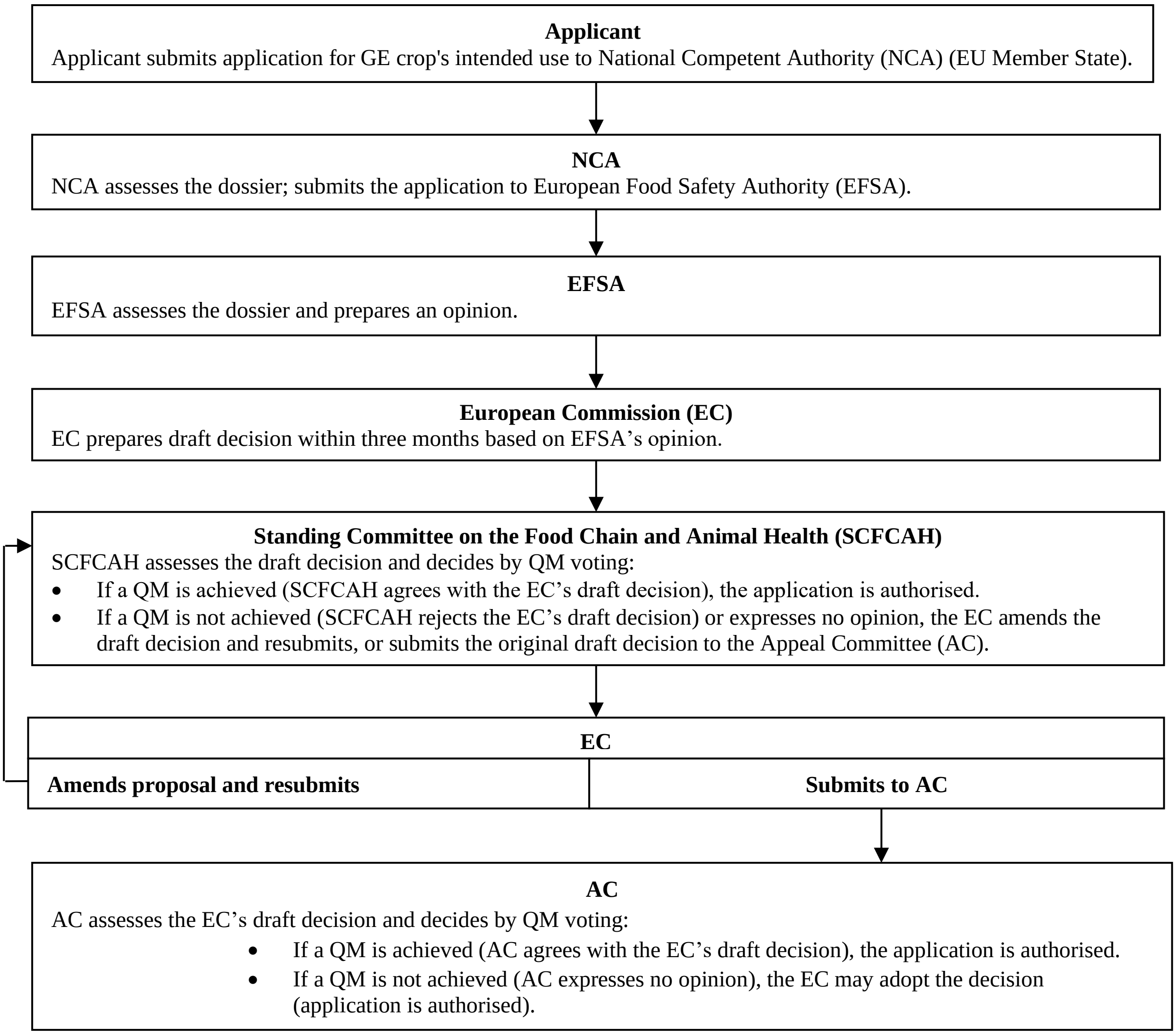
Figure 4-2. The US's approval process for GE crops from 6 March 2012 (Source: Own depiction following USDA APHIS, 2012).

4.2.3 European Union

The EU’s approval process is legally guided by the precautionary principle, and commences for the purposes of our study when a developer applies to its MS’s competent authority for approving a GE crop. Approval is for a specific use, e.g., ‘cultivation’, and or ‘food and or feed’, and or ‘import and processing’, or any combination of these. The MS passes this application on to the EFSA for assessment in terms of the Council Directive 2001/18/EC.

The EFSA is an independent body operating since 2002 for providing the European Community with scientific and technical support for food and feed safety issues, and is mandated to conduct risk assessments—“… a scientifically based process consisting of four steps: hazard identification, hazard characteri[z]ation, exposure assessment and risk characteri[z]ation …” (Council Regulation (EC) No 178/2002). This ‘risk assessment’ step (similar to the petitioning ‘bureaucratic’ step in the US) ends when the EFSA issues its opinion. This opinion is passed on to the EC for the final “risk management” (‘political’ step) phase of regulatory oversight (Council Regulation (EC) No 178/2002; EFSA, 2015).

The EC prepares a draft decision based on the EFSA’s opinion, and submits it to a committee comprising representatives of each MS—the Standing Committee on the Food Chain and Animal Health (SCFCAH)—for a decision that is reached by QM voting under Regulation 1829/2003 (if submitted under Directive 2001/18, then by the Regulatory Committee) (EC, 2016). If the SCFCAH rejects the draft decision or expresses a ‘no opinion’, the EC either amends its draft decision and resubmits it to the SCFCAH or submits the original draft decision to the Appeal Committee (AC)—a more senior level of MS representation—for a decision (EC, 2015d), also by QM voting. Similarly, approval is declined if the draft decision is rejected, but if a ‘no opinion’ is expressed, the EC may adopt the decision, i.e., approval will be granted (Figure 4-3 from Smart et al., 2015). The ‘political’ step, and therefore the approval process, stops when the Commission reaches its decision (Davison, 2010). We considered the combined duration of the MS-application, the ‘risk assessment’, and the political decision-making steps to be the total duration of the EU’s approval process.



Applicant

Applicant submits application for GE crop's intended use to National Competent Authority (NCA) (EU Member State).

NCA

NCA assesses the dossier; submits the application to European Food Safety Authority (EFSA).

EFSA

EFSA assesses the dossier and prepares an opinion.

European Commission (EC)

EC prepares draft decision within three months based on EFSA's opinion.

Standing Committee on the Food Chain and Animal Health (SCFCAH)

SCFCAH assesses the draft decision and decides by QM voting:

- If a QM is achieved (SCFCAH agrees with the EC's draft decision), the application is authorised.
- If a QM is not achieved (SCFCAH rejects the EC's draft decision) or expresses no opinion, the EC amends the draft decision and resubmits, or submits the original draft decision to the Appeal Committee (AC).

AC

AC assesses the EC's draft decision and decides by QM voting:

- If a QM is achieved (AC agrees with the EC's draft decision), the application is authorised.
- If a QM is not achieved (AC expresses no opinion), the EC may adopt the decision (application is authorised).

Figure 4-3. Approval process for GE crops with a favorable EFSA opinion and a positive draft decision by the EC (Source: Smart et al., 2015).

Most (97%) of the applications in the EU have been for 'food and or feed' and or 'industrial purposes'. For these applications, results of field trials done outside of the EU are cited (Council Directive 2001/18/EC). Field trials done in the EU are required for applications for 'cultivation' use only. Due to the low number (two applications for cultivation) of observations in our study, we excluded a 'field trial' step for our EU analysis.

4.2.4 Synthesis

It is tempting to make a direct comparison of the approval length between the US and the EU. However, a direct comparison is insensible. The approval system of the US starts with a ‘scientific’ step characterized by field trials and ends with a ‘bureaucratic’ step for assessing the applicant’s petition, while that of the EU starts when a developer applies to its MS for approval for one or more specific uses (see **Section 4.2.3 European Union** above), followed by a ‘risk assessment’ step (similar to the US’s ‘bureaucratic’ step), ending in a political decision-making process. Some of the information generated for approval in the EU relies on information generated for the approval process in the US. Further, applications in the US almost always include field trials as applications include cultivation, while the majority of the applications for approval in the EU are for “import and processing” and not for “cultivation” (Wesseler and Kalaitzandonakes, 2011). Thus, we avoid a statistical comparison of their total approval time as it would be theoretically flawed. Rather, we focus on trends exhibited in each system separately.

4.3 Analysis

We investigate the completion-time for the steps involved in the approval of GE crops in the US and the EU, and assume that the arithmetic sum of these steps is the total duration of each jurisdiction’s approval process. Because we are dealing with an ‘economic’ rather than a ‘regulatory’ clock, we do not account for stoppages. We sourced our data for all newly approved GE crops (i.e., excluding renewals) until December 2015 (the end of our study period) from internet-based databases and journals.

Our first observation in the US is December 12, 1988, the application date for permission for the first field trial for the GE tomato: Flavr Savr. Although approvals are ongoing, our final observation is December 8, 2015, the deregulation date for the GE maize event MON 87403. The corresponding dates for the EU are August 5, 1996 (submission date to Sweden’s competent authority for the GE potato event EH92-527-1) and December 4, 2015 (Commission decision for the maize events MON 87427 and NK603 x T25), respectively.

For the US, we investigate all GE crops listed on the USDA’s APHIS Biotechnology Regulatory Services (BRS) website that have been granted non-regulated status, and those that are awaiting the APHIS’s decision (USDA, 2016a). We found the date for the start of the ‘scientific’ step by cross-referencing the permit number of a GE plant’s earliest field trial (published in its petition dossier) with the BRS’s online permit information database (USDA, 2016b), which also contains the other dates we use. We use each regulated article's petition number for finding the dates when its dossier (petition document) was submitted to the APHIS—marking the end of the 'scientific' step and the start of the 'bureaucratic' step—and when non-regulated status was awarded: this signaling the conclusion of the 'bureaucratic' decision-making step, and the entire regulatory process.

The non-regulated status for two glyphosate-tolerant GE crops (alfalfa (events J101 and J163) and sugar beet (event H7-1)) was temporarily suspended due to legal action resulting in their developers having to submit an environmental impact statement; these delays were irrelevant to our empirical analysis as they occurred after their original approvals (USDA APHIS, 2010; 2011), and therefore were excluded. As most of the plants in our dataset are annuals, we excluded the field trial data for perennial crops, but included the time taken for their petitions to be reviewed in our analysis of the 'bureaucratic' step. There are no field trial data available for two annuals (flax (CDC Triffid) and soybean (BPS-CV127-9)), whose trials were done outside of the US.

For the EU, we investigate all GE crops listed on the GMO Compass website's database (GMO Compass, 2016) classified as having a risk assessment report (i.e., the 'scientific-' but not the 'political' step is complete), and a valid authorization (i.e., approved), complemented by notices published in the journal: Agrafacts (Agrafacts, 2015). We cross-reference our list with the EFSA's scientific opinion/s and the Commission's decision in the EFSA Journal and the Official Journal of the European Communities, respectively. We find the following dates for each application: submission for authorization to the EU MS (start of the MS-application step); EU MS submission to the EFSA (end of the MS-application step; start of the scientific 'risk assessment' step); the EFSA's date of adopting the application (end of the 'risk assessment' step; start of 'political' step); and the date when the Commission reached its decision for approving the GE crop (end of 'political' step, and the entire regulatory process). Where the complete date for the start of the MS-application step is not published, we assume the date to be the fifteenth day of the month during which its application was submitted to the relevant MS, and we exclude events where no evidence of a date was found from this step's analysis. Tables 4-1 and 4-2 show general trends of the regulatory processes, apparently getting longer in the US (the overall trend has a structural break dividing it into an 'early-' and 'late' period, discussed in more detail below) and shorter in the EU.

Table 4-1. Mean time (days) taken (and their mean annual changes indicated in parentheses) for completing the regulatory process for GE crops approved in the US [a] from 1988-2015

Period	Field Trial Phase (days)	Petition Phase (days)	Entire Process (days)
Early: 1988-1997	1,110 (-102.0) n = 40	210 (-6.2) n = 40	1,321 (-108.2) n = 40
Late: 1998-2015	1,614 (-20.2) n = 52	889 (16.5) n = 53	2,467 (-4.7) n = 51

[a] Data source: http://www.aphis.usda.gov/biotechnology/status.shtml.

Table 4-2. Mean time (days) taken for completing the regulatory process for GE crops approved in the EU [a] from 1996-2015

Period	Application at MS (days)	Risk Assessment (at EFSA from 2002) (days)	Risk Management (EU Commission) (days)	Entire Process (days)
1996-2015	263 n = 65	929 n = 68	594 n = 62	1,763 n = 58

[a] Data sources: http://www.gmo-compass.org/eng/gmo/db/; EFSA Journal; Official Journal of the EU.

4.3.1 Empirical Analysis

4.3.1.1 United States

We collected data for 95 observations (applications), all of which except one (awaiting the outcome of the ‘bureaucratic’ step) are now deregulated. Table 4-3 presents summary statistics of this dataset. From an initial analysis of our data, we identified a structural break in the trend for the time taken to approve GE crops (Table 4-1, Figure 4-4). We used the start date for each application for identifying two groups of applications separated by this break: (1) ‘early’ (up to and including 1997), and (2) ‘late’ (1998 onwards), representing 44% and 56% of observations, respectively. US-based and foreign developers submitted 75% and 25% of the applications, respectively, whereas 69% and 31% of the applications were for single- and multiple trait events, respectively. Fifty-one percent of the genetic modifications were for herbicide tolerance; 32% for insect resistance; and 32% for other genetic modifications such as viral resistance, freeze-tolerance, and quality improvement traits (e.g., reduced browning of apples, and reduced lignin content of alfalfa). The majority (79%) of GE plants were developed for food production; only 21% were developed for non-food purposes. GE varieties of maize were the most abundant (32%); followed by soy bean (18%); cotton (17%); tomato, and potato (6% each); the remaining 21% comprised alfalfa, apple, sugar beet, chicory, creeping bentgrass, eucalyptus, papaya, rice, rose, squash, and tobacco.

Table 4-3. Descriptive statistics for the US's dataset for the time taken for GE crops passing through the regulatory process, and those awaiting the outcome of the 'bureaucratic' step

Category	Parameter	Mean	Min	Max
Regulatory step's duration	Scientific step (ln)	7.16 (0.41)	5,58	8,06
	Political step (ln)	6.05 (0.84)	4,67	7,58
	Overall process (ln)	7.49 (0.45)	6,1	8,42
Developer's domicile	Domestic	0.75 (0.44)	0	1
	Foreign	0.25 (0.44)	0	1
Trait multiple	Single	0.69 (0.47)	0	1
	Multiple	0.31 (0.47)	0	1
Trait type	Herbicide tolerant	0.51[a] (0.5)	0	1
	Insect resistant	0.32[a] (0.47)	0	1
	Other trait	0.32[a] (0.47)	0	1
Crop's use	Food	0.79 (0.41)	0	1
	Non-food	0.21 (0.41)	0	1
Crop	Cotton	0.17 (0.37)	0	1
	Maize	0.32 (0.47)	0	1
	Soy	0.18 (0.38)	0	1
	Tomato	0.06 (0.24)	0	1
	Potato	0.06 (0.24)	0	1
	Other	0.21 (0.41)	0	1

[a] The sum of these coefficients is > 1.0. This is because of stacked events where one trait is represented in two categories simultaneously (e.g., herbicide tolerance and insect resistance together in a stacked event).

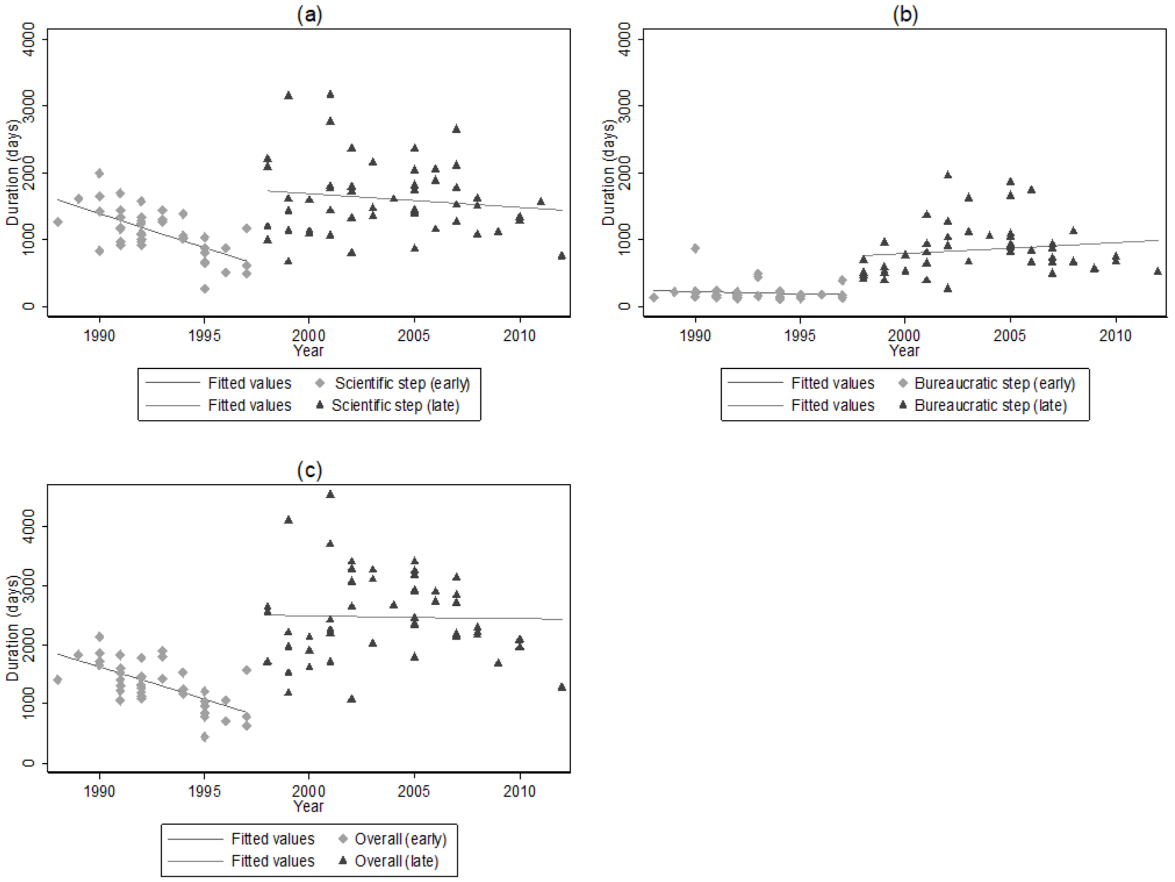


Figure 4-4. Trends in time (days) taken for the authorization, split into the scientific (field trial) (a) and political (bureaucratic) (b) steps, and overall time taken (c), for all GE crops authorized as well as those awaiting the completion of the political process, in the US.

We investigated if the structural break mentioned above also holds in a multivariate regression framework. Theoretically, what appears to be a structural break may be a sudden shift in the type of application, for example the characteristic of a GE plant like its lifecycle, i.e., a shift from annual to perennial. Alternatively, the political 'climate' may have caused a shift, thus erroneously indicating a structural break, which was actually the result of unobserved factors. We used a set of OLS regression models for testing if differences in the regulatory process' time-line could be explained by plant characteristics or an external, independent factor(s) (Figure 4-4).

We identified two periods ('early' and 'late') separated in 1998 by a structural break. We captured differences in the time taken for applications completing the 'scientific' step, 'bureaucratic' step, and the overall approval process, by including dichotomous variables. Subsequently, we included additional control variables for netting out effects unrelated to the structural break, such as differences in time taken between applications grouped according to the following parameters: developer's domicile (domestic or foreign developer); use (food or non-food plants); and the number of GE traits that each crop has (single or multiple). If the variable identifying 'early' and 'late' applications reflect a substantial and statistically significant difference after adding controls, our interpretation is that evidence for a structural break exists.

Table 4-4 illustrates the results of our regression models designed to net out effects unrelated to the structural break. Model 1 (baseline model) suggests that submissions made before the structural break took 38% less time (504 days)[5] to complete the scientific step—a robust estimate as it remained almost unaffected by the additional explanatory variables. In model 5, the minimal estimate, 'early' applications took 37% less time (496 days) than applications submitted during the 'late' period. For the 'scientific' step, neither a developer's domicile nor the genetic trait multiple contributed to differences in regulatory time. Model 5 indicates that there are no substantial differences in regulatory time between potatoes, tomatoes, soy beans, and maize plants; conversely, plants we subsume under 'other crops' took less time for approval compared with maize.

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[5] We transformed (natural log) the dependent variable as it is not normally distributed.

Table 4-4. Correlates of time taken to for completing the scientific (field trial) step of the GE crop approval process in the US, 1988-2012

	(1)	(2)	(3)	(4)	(5)
Variables	Days for scientific step (natural log)				
Early	-0.38***	-0.41***	-0.40***	-0.42***	-0.37***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Late	reference	reference	reference	reference	reference
Domestic		0.02	0.04	0.03	-0.02
		(0.821)	(0.683)	(0.797)	(0.852)
Foreign	reference	reference	reference	reference	reference
Single trait		0.16*	0.16	0.18	0.24***
		(0.091)	(0.161)	(0.108)	(0.008)
Multiple trait	reference	reference	reference	reference	reference
Cotton					-0.15
					(0.128)
Maize					reference
Soy					0.04
					(0.691)
Tomato					-0.11
					(0.263)
Potato					0.06
					(0.679)
Other crops					-0.35**
					(0.011)
Herbicide tolerant			0.02	0.01	
			(0.881)	(0.933)	
Insect resistance			reference	reference	
Other trait			-0.09	-0.10	
			(0.328)	(0.258)	
Food				0.13	
				(0.196)	
Non-food				reference	
Constant	7.33***	7.22***	7.22***	7.13***	7.27***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	92	92	92	92	92
R-squared	0.22	0.25	0.26	0.27	0.36

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at the 1, 5, and 10% levels, respectively. Dependent variable is time taken in days (natural log) for completing the scientific step. Reference category refers to a non-US (foreign) based company, submitting a multiple trait and insect resistant GE plant for non-food use during the period 1998-2012 (model 4).

We performed a similar set of analyses for the time taken for a petition passing through the US’s ‘bureaucratic’ step (Table 4-5). Petitions from ‘early’ applications have a substantial time advantage according to model 1—our baseline model. ‘Late’ period petitions took 679 days (144%) longer to be approved: a robust result for all the models. Petitions from foreign-based developers and for multiple traits took slightly longer than for local developers and single traits, respectively, but some of the corresponding coefficients are statistically insignificant. We detected no difference between herbicide tolerant and insect resistant crops. We performed the same set of tests on the total approval time (Table 4-6). The most striking discovery is that one or more events, or factors around 1998 triggered a delay in the US's

Table 4-5. Correlates of time taken for completing the 'bureaucratic' step of the GE crop approval process in the US, 1988-2012

	(1)	(2)	(3)	(4)	(5)
Variables	Days for bureaucratic step (natural log)				
Early	-1.44***	-1.41***	-1.42***	-1.43***	-1.40***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Late	reference	reference	reference	reference	reference
Domestic		-0.13	-0.17*	-0.18*	-0.13
		(0.169)	(0.081)	(0.059)	(0.194)
Foreign		reference	reference	reference	reference
Single trait		-0.18*	-0.21*	-0.20	-0.14
		(0.074)	(0.088)	(0.108)	(0.155)
Multiple trait		reference	reference	reference	reference
Cotton					-0.18
					(0.143)
Maize					reference
Soy					0.11
					(0.434)
Tomato					-0.09
					(0.471)
Potato					0.10
					(0.678)
Other crops					-0.04
					(0.771)
Herbicide tolerant			-0.08	-0.09	
			(0.446)	(0.382)	
Insect resistance			reference	reference	
Other trait			0.10	0.09	
			(0.307)	(0.388)	
Food				0.11	
				(0.294)	
Non-food				reference	
Constant	6.69***	6.89***	6.95***	6.88***	6.88***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	95	95	95	95	95
R-squared	0.74	0.75	0.76	0.76	0.77

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10% levels, respectively. Dependent variable is time taken in days (natural log) for completing the political step. The number of observations dropped to 77 as 18 applications included in table have not overcome the political process at the time this study was performed. Reference category refers to a non-US (foreign) based company, submitting a multiple trait and insect resistant plant for non-food use during the period 1998-2012 (model 4).

approval process, i.e., developers who applied to the APHIS from 1998 onwards for permission to conduct field trials for the first time on a new GE crop, spent 1,146 days longer (63%; model 1) in the regulatory pipeline than had permission for their crop's field trials been applied for in 1997 or earlier.

Table 4-6. Correlates of time taken for completing the overall approval process of GE crops in the US, 1988-2012

	(1)	(2)	(3)	(4)	(5)
Variable	Days for total time taken (natural log)				
Early	-0.63***	-0.64***	-0.63***	-0.65***	-0.60***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Late	reference	reference	reference	reference	reference
Domestic		-0.01	-0.01	-0.02	-0.05
		(0.875)	(0.923)	(0.846)	(0.561)
Foreign		reference	reference	reference	reference
Single trait		0.06	0.05	0.06	0.13*
		(0.470)	(0.624)	(0.521)	(0.080)
Multiple trait		reference	reference	reference	reference
Cotton					-0.14
					(0.125)
Maize					reference
Soy					0.06
					(0.497)
Tomato					-0.10
					(0.237)
Potato					0.06
					(0.695)
Other crops					-0.29***
					(0.009)
Herbicide tolerance			-0.02	-0.02	
			(0.858)	(0.820)	
Insect resistance			reference	reference	
Other trait			-0.05	-0.06	
			(0.503)	(0.445)	
Food				0.09	
				(0.339)	
Non-food				reference	
Constant	7.77***	7.74***	7.77***	7.70***	7.77***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	91	91	91	91	91
R-squared	0.50	0.50	0.50	0.51	0.57

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10% levels. Dependent variable is time taken in days (log) to overcome the overall process. The number of observations dropped to 73 here since 18 applications included in this table have not completed the political process at the time that this study was done. Reference category refers to a non-US (foreign) based company, submitting a multiple trait and insect resistant GE plant for non-food use during the period 1998-2012 (model 4).

4.3.1.2 European Union

We collected data for 65 observations (applications) of which 62 were approved. Table 4-7 presents these data. The oldest and most recent applications for starting the MS-application step were submitted in 1996 and 2012, respectively; 32% and 68% of the applications were by local and foreign (mostly the US) developers, respectively. Fifty-one percent of the applications were for single- and 49% for multiple-trait GE crops. In 72% and 51% of the cases, GE modifications were for herbicide tolerance and insect resistance, respectively, while 16% were for 'other' traits. Most of the applications were for 'food and feed' (88%), while

Table 4-7. Descriptive statistics for the EU's dataset for the time taken for GE crops passing through the regulatory process, and those awaiting the outcome of the 'political' step

Category	Parameter	Mean	Min	Max
Regulatory step's duration	MS Application (ln)	3.54 (1.97)	0,69	7,94
	Risk Assessment (ln)	6.64 (0.66)	5,07	7,87
	Risk Management (ln)	6.14 (0.71)	4,78	7,68
	Overall process (ln)	7.38 (0.42)	6,47	8,51
Developer's domicile	Domestic	0.32 (0.47)	0	1
	Foreign	0.68 (0.47)	0	1
Trait multiple	Single	0.51 (0.48)	0	1
	Multiple	0.49 (0.48)	0	1
Crop trait	Herbicide tolerant	0.72* (0.45)	0	1
	Insect resistant	0.51* (0.50)	0	1
	Other trait	0.16* (0.37)	0	1
Crop's use	Food	0.88 (0.32)	0	1
	Non-food	0.12 (0.32)	0	1
Crop	Cotton	0.12 (0.32)	0	1
	Maize	0.51 (0.5)	0	1
	Soy	0.21 (0.41)	0	1
	Potato	0.03 (0.17)	0	1
	Other	0.13 (0.34)	0	1

*The sum of these coefficients is > 1.0, because of stacked events where one trait is represented in two categories simultaneously (e.g., herbicide tolerance and insect resistance together).

12% were for industrial and other purposes (only two applications were for cultivation). Maize has the most applications (51%); followed by soy beans (21%); cotton (12%); potato (3%); with the remaining 13% comprising: sugar beet, flowers, and rice.

We followed a similar strategy for testing the robustness of the trend observed in Figure 4-5: a convex development for the overall approval time, with long durations for submissions during 1996 and 1998, and the absence of a clear trend for the remaining period. We modelled this relationship in model 1, our baseline model, with two metric variables: ‘year’ and the ‘square of the year’ expecting them to have negative and positive signs, respectively, indicating the aforementioned convex-shaped relationship. Signs and sizes of the variables: ‘year’ and ‘year (squared)’ confirm the development of a convex shape (Table 4-8). We added variables for controlling other potential effects such as the developer’s domicile; the crop’s GE trait; and the crop’s intended use (‘food and feed’ vs. non-food/feed). We found that some crop features are correlated with the time taken to complete the MS-application step: applications for maize

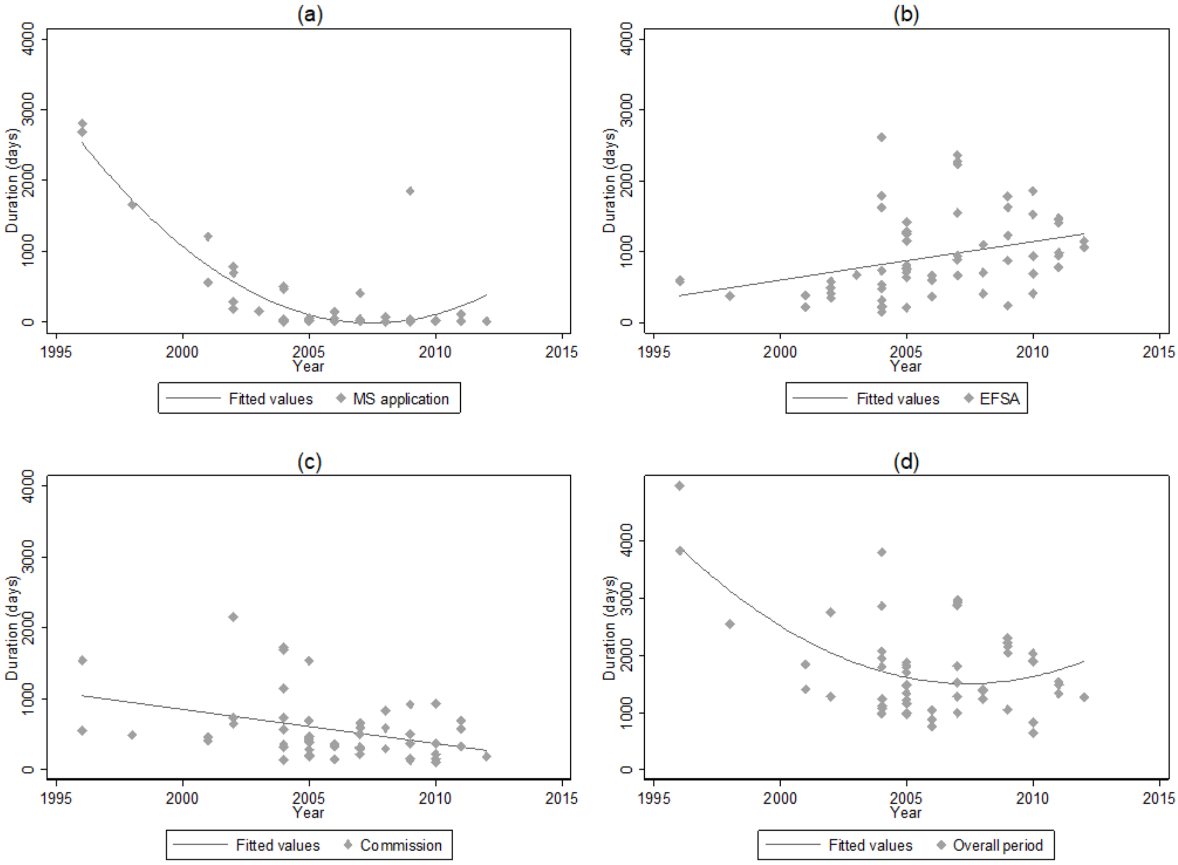

Figure 4-5. Trends in time (days) taken for the authorization, split into the MS-application step (a), the scientific risk assessment step (b), the ‘political’ step at the Commission (c), and overall time taken (d), for all GE crops authorized and those awaiting the outcome of the ‘political’ step in the EU.

took 82% (15 days) longer than those for soy beans, while applications with the trait insect resistance took 150% (88 days) longer than those for herbicide tolerance. Similarly, applications for non-food/feed took 208% (559 days) longer than those for ‘food and feed’ purposes.

Table 4-8. Correlates of time taken for completing MS-application step of the EU’s GE crop approval process, 1996-2012

	(1)	(2)	(3)	(4)	(5)
Variable	Days for MS-application step (natural log)				
Year	-112.25***	-94.94***	-107.16***	-76.39**	-94.63***
	(0.000)	(0.001)	(0.001)	(0.021)	(0.005)
Year^2	0.03***	0.02***	0.03***	0.02**	0.02***
	(0.000)	(0.001)	(0.001)	(0.021)	(0.005)
Domestic		-0.78*	-0.56	-0.54	-0.87*
		(0.060)	(0.112)	(0.126)	(0.051)
Foreign		reference	reference	reference	reference
Single trait		0.94**	0.29	0.54	0.82**
		(0.027)	(0.410)	(0.134)	(0.024)
Multiple trait		reference	reference	reference	reference
Cotton					0.22
					(0.725)
Maize					reference
Soy					-0.82*
					(0.064)
Potato					0.53
					(0.337)
Other crop					0.83
					(0.310)
Herbicide tolerance			-1.50***		
			(0.000)		
Insect resistance			reference		
Other trait			0.34		
			(0.559)		
Food				-2.08***	
				(0.002)	
Non-food				reference	
Constant	112,854.52***	95,502.26***	107,736.87***	76,845.60**	95,133.93***
	(0.000)	(0.001)	(0.001)	(0.020)	(0.004)
Observations	64	64	64	64	64
R-squared	0.39	0.46	0.57	0.56	0.51

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10% levels, respectively. Dependent variable is time taken in days (log) to overcome the scientific process. Reference category refers to a non-EU (foreign) based company, submitting a multiple trait and insect resistant plant (model 3).

For the ‘risk assessment’ step we used a linear-only time variable and found that the corresponding coefficient suggests a statistically significant, positive slope (Table 4-9). This coefficient is robust in models 1-4, but loses robustness when crop type is included (model 5). We used maize as our reference category and found that only applications for cotton, soy beans, and 'other plant' category correlate with the time taken to complete the 'risk assessment' step and that these crops took 53% and 35% longer and 43% less time compared with maize, respectively.

Table 4-9. Correlates of time taken for completing the 'risk assessment' step by the EFSA of the EU's GE crop approval process, 1996-2012

	(1)	(2)	(3)	(4)	(5)
Variables	Days for risk assessment step (natural log)				
Year	0.07***	0.07***	0.07***	0.05***	0.04
	(0.000)	(0.000)	(0.000)	(0.008)	(0.124)
Domestic		0.14	0.07	0.07	0.12
		(0.366)	(0.638)	(0.653)	(0.382)
Foreign		reference	reference	reference	reference
Single trait		-0.18	-0.07	-0.04	-0.06
		(0.254)	(0.668)	(0.788)	(0.690)
Multiple trait		reference	reference	reference	reference
Cotton					0.53*
					(0.071)
Maize					reference
Soy					0.35*
					(0.063)
Potato					-0.52
					(0.338)
Other crops					-0.43*
					(0.090)
Herbicide tolerance			0.20		
			(0.368)		
Insect resistance			reference		
Other trait			-0.24		
			(0.415)		
Food				0.70***	
				(0.007)	
Non-food				reference	
Constant	-136.28***	-139.67***	-139.97***	-100.77**	-65.91
	(0.000)	(0.000)	(0.001)	(0.012)	(0.161)
Observations	65	65	65	65	65
R-squared	0.14	0.17	0.21	0.26	0.32

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10% levels, respectively. Dependent variable is time taken in days (natural log) for passing through the scientific process. Reference category refers to a non-EU (foreign) based company, submitting a multiple trait and insect resistant GE plant (model 3).

Results presented in Table 4-10 indicate a negatively-sloping linear relationship for the 'political' step. We captured this trend with a metric variable measuring the change in approval time by year. The results confirm our observation showing that with every additional year, the approval time decreases by 7-8% (35-48 days): a robust finding for all five models. There is evidence in this model that applications for multiple traits took somewhat longer compared with the single trait category. Coefficients for cotton and potato (model 5) are statistically significantly different to maize, meaning that completing this step took approximately 49% (163 days) and 118% (977 days) longer for these applications, respectively, compared with maize.

Table 4-10. Correlates of time taken for completing the 'political' step at the EC of the EU's GE crop approval process, 1996-2012

	(1)	(2)	(3)	(4)	(5)
Variable	Days for the political step (natural log)				
Year	-0.08***	-0.08***	-0.08***	-0.08***	-0.07***
	(0.001)	(0.001)	(0.000)	(0.002)	(0.003)
Domestic		0.13	0.19	0.13	-0.04
		(0.440)	(0.276)	(0.449)	(0.779)
Foreign		reference	reference	reference	reference
Single trait		-0.39**	-0.49***	-0.39**	-0.40*
		(0.017)	(0.008)	(0.031)	(0.059)
Multiple trait		reference	reference	reference	reference
Cotton					0.49**
					(0.022)
Maize					reference
Soy					0.09
					(0.739)
Potato					1.18***
					(0.001)
Other crop					-0.14
					(0.563)
Herbicide tolerant			-0.06		
			(0.818)		
Insect resistance			reference		
Other trait			0.35		
			(0.185)		
Food				0.01	
				(0.985)	
Non-food				reference	
Constant	165.09***	161.23***	165.47***	161.51***	149.38***
	(0.001)	(0.001)	(0.000)	(0.001)	(0.002)
Observations	59	59	59	59	59
R-squared	0.15	0.22	0.26	0.22	0.36

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10% levels, respectively. Dependent variable is time taken in days (natural log) for passing through period 3.

When analyzing the total time for approving a GE crop, we expect the regression results to conform to the result of the MS-application step. Results presented in Table 4-11 confirm the concave trend in overall approval time; coefficients in all models are statistically significant and all have the expected signs. Comparing these results with those in Table 4-8 - Table 4-10 suggests that the MS-application step drives the reduction in approval time; the 'risk assessment' and 'political' steps contribute to the overall time, but only marginally (if anything) to the observed changes in duration.

Table 4-11. Correlates of time taken for completing the overall approval process for GE crops in the EU, 1996-2012

	(1)	(2)	(3)	(4)	(5)
Variables	Days for the overall authorization process (natural log)				
Year	-29.10***	-35.04***	-33.23***	-33.53***	-30.63***
	(0.001)	(0.000)	(0.000)	(0.000)	(0.001)
Year^2	0.01***	0.01***	0.01***	0.01***	0.01***
	(0.001)	(0.000)	(0.000)	(0.000)	(0.001)
Domestic		-0.08	-0.03	-0.07	-0.17*
		(0.377)	(0.717)	(0.508)	(0.082)
Foreign		reference	reference	reference	reference
Single trait		-0.15	-0.22*	-0.17	-0.19*
		(0.157)	(0.053)	(0.128)	(0.100)
Multiple trait		reference	reference	reference	
Cotton					0.49***
					(0.001)
Maize					reference
Soy					0.13
					(0.453)
Potato					0.54***
					(0.000)
Other crops					0.09
					(0.562)
Herbicide tolerance			-0.06		
			(0.725)		
Insect resistant			reference		
Other trait			0.25		
			(0.160)		
Food				-0.11	
				(0.547)	
Non-food				reference	
Constant	29,218.29***	35,168.60***	33,361.16***	33,656.90***	30,755.96***
	(0.001)	(0.000)	(0.000)	(0.000)	(0.001)
Observations	58	58	58	58	58
R-squared	0.21	0.26	0.32	0.26	0.43

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at the 1, 5, and 10% levels, respectively. Dependent variable is time taken in days (natural log) for passing through the scientific process. Reference category refers to a non-EU (foreign) based company, submitting a multiple trait and insect resistant GE plant (model 3).

Single trait applications required 15-22% less time (206-375 days), confirming earlier findings shown in Table 4-9; applications for potatoes and cotton took about 54% (1,273 days) and 49% (1,021 days) longer, respectively. For the overall time, we find no robust evidence for statistically significant differences between domestic and foreign developers, herbicide tolerant and insecticide resistant crops, or ‘food and feed’ and non-food/feed crops.

4.3.1.3 US-EU Contrasts

The regulatory systems of the US and EU are inherently different (see **Section 4.2**). No applications in our dataset were submitted simultaneously in both jurisdictions. Applications in the US include cultivation as a use in distinct contrast to the EU where only two applications were for this purpose. We avoid drawing direct comparisons of the total time taken for GE crops passing through these regulatory pipelines because it is theoretically flawed due to endogenous inconsistencies. However, because the ‘bureaucratic’ step in the US is similar to the EU’s ‘risk assessment’ step, we computed the mean time taken for the same GE events, a subset of 26, to have completed these steps (all of the events in this subset were approved in the US first; their subsequent applications in the EU were for ‘import’ and or ‘food and feed’ use), yielding 686 days in the US compared with 995 days in the EU, a difference of 309 days.

4.4 Results and Discussion

Generally, the development and commercialization of new GE crops is hampered by slow and costly approval processes (Kalaitzandonakes et al., 2007). A trend towards shorter approval times in a given regulatory system is expected (Pray et al., 2005), as experience with the different steps in the approval process, in scientific research, and the commercialization of GE crops is gained with time, thus allowing efficiencies to develop (Bradford et al., 2005; Giddings et al., 2013). Our analysis of all the approved GE crops in the US to the end of 2015 shows this trend during the period 1988-1997, decreasing by an average of 114 days annually. Surprisingly, from 1998 onwards, the overall trend virtually stagnates with approval periods getting only slightly quicker by an average of approximately five days annually (Table 4-1, Figure 4-4). This break in the trend coincides with a number of disruptive events in the biotechnology arena. Examples from the US include the Prodigene (Federation of American Scientists, 2011) and StarLink (Carter and Smith, 2007) incidents, and the monarch butterfly controversy; and from the EU, which is an important trade destination of GE products from the US: the researcher Pusztai’s work on the health effect of GM potatoes on rats; the de facto moratorium on new GE crop authorizations spawning new legislation (explicitly incorporating the precautionary principle and broadening the criteria for risk assessments) (Devos et al., 2006); “debates over Dolly the sheep and GM crops and food” (Bauer, 2002), and the occurrence of bovine spongiform encephalopathy (The Economist, 2000). Interestingly, a similar phenomenon occurred with the worldwide number of active new GE product quality innovations in the agricultural biotechnology arena, which grew exponentially until 1998 when its declining trend suddenly levelled off (Graff et al., 2009b).

It is surprising that over time, the EU’s approval process has tended to shorten (Figure 4-5), as there is considerable consumer and political resistance to adopting GE crops in this region, which is heterogeneous in terms of attitudes towards GE crops (Devos et al., 2006). In the EU, it is permissible for developers to reference data or “notifications previously submitted by other notifiers” (Council Directive 2001/18/EC) when conducting their scientific investigations—a positive information spill-over effect. The duration of the ‘risk assessment’ step has tended to increase (Figure 4-5 (b)), thus finding ways to shorten this step will reduce the EU’s overall regulatory time.

We found one regulatory change in the US aimed at shortening the approval time of GE crops. An internal inquiry by the APHIS showed “competing priorities for … staff” as a probable cause for the ‘bureaucratic’ step taking longer (Capital Reporting Company, 2011), which subsequently led the APHIS to introduce procedural changes to the US’s petition process in 2012 (compare Figure 4-1 with Figure 4-2). It will be interesting to see if these alterations reach the USDA’s goal of improving customer service (USDA APHIS, 2012), and by implication, regulatory efficiency—one measure of which would be the speeding up of the ‘bureaucratic’ step.

4.5 Conclusion

Repeated calls have been made for the regulatory trigger to be product- rather than process based (e.g., Bradford et al., 2005; House of Commons, 2015), i.e., to regulate the transgenic event and not the plant being altered—an important focus area, as of July 2015, officially mentioned by the US government (Office of Science and Technology Policy, 2015). This change to the ‘scientific’ step has the potential for speeding up the approval of GE plants, since duplicating costly and lengthy scientific inquiries would be eliminated. This can reduce asynchronicity in the approval of GE crops, and therefore positively contribute to the international trade environment, especially as most GE crops are first developed in the US.

An analysis of the EFSA’s ‘risk assessment’ step is required to investigate if its completion-time can be shortened. In principle, the EU’s regulatory path could end at the EFSA. However, a subsequent ‘political’ step exists, which, if shortened or even eliminated would also contribute to speeding up the EU’s regulatory time. The ‘opt-out’ legislation introduced in 2015 allows MSs to restrict or prohibit the cultivation of EU-approved GE crops on their territories (Directive (EU) 215/412), which Dederer (2016) suggests adds nothing to the “additional value” of the existing framework. This policy change can accelerate the ‘political’ step as MSs can approve applications for cultivation at their first voting opportunity at the SCFCAH. However, it seems doubtful if this regulation will impact approval times considering the fairly rigid voting behavior of EU MSs (Smart et al., 2015).

Our results suggest that political decision makers in the EU and the US should consider implementing policies making their regulatory process more affordable. This can be achieved without compromising safety. The increase in approval time seems to have been caused by events in the late 1990s and early 2000s. Human resources handling applications in the US have been reduced, which partially explains an increase in approval time. We offer two additional explanations: (1) staff handling applications may have become more cautious as a result of the events that occurred in the late 1990s and early 2000s; and (2) opening up the approval process for public comments in the mid-2000s slowed down approval time as those comments needed to be addressed and required additional human resources, which had already been identified as a limiting factor. Since the science did not change, such an improvement in shortening approval time would stimulate and encourage investment in agricultural innovation by smaller investors and in a broader spectrum of products—currently restricted to a few, large firms focusing their efforts both on a narrow range of crops and genetic attributes (Bradford et al., 2005) and contribute substantial economic benefits (Zilberman et al., 2015).

The US is the locus for most of these biotech innovations (Graff et al., 2009b), from which they diffuse globally. The US’s rate of commercialization of new GE crops depends not only upon its regulatory system, but also on the compliance requirements of other countries being concurrently addressed by US developers. For society to gain from these innovations earlier in countries adopting this technology, measures for speeding up their regulatory processes need to be found and implemented (Wesseler and Kalaitzandonakes, 2011). Our results support the US government's July 2015 plan for modernizing its regulatory system for biotechnology products, especially its focus on reducing regulatory burdens for small and mid-sized firms (Office of Science and Technology Policy, 2015) and its subsequent announcement to review its regulations to eliminate "unnecessary regulatory burdens" in general (Animal and Plant Health Inspection Service, 2016). If this could be achieved, not only the US but also other countries such as the EU would benefit.

Chapter 5

5 European Union Member States’ Voting for Authorizing Genetically Engineered Crops: A Regulatory Gridlock

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Authors’ contributions: Justus Wesseler provided the concept and guided the theoretical approach, and provided oversight. Richard Smart gathered the data, wrote the section on describing the dataset, prepared the data for empirical analysis, conducted the literature review, formulated the mathematical description of the qualified majority voting (with the guidance of Dr. Maarten Punt), and wrote the bulk of the text. Matthias Blum performed and interpreted the econometric analysis.

Note: The original text was written in British English.

Abstract

Several authors suggest a gridlock of the EU's approval process for GE crops. We analyze the voting behavior of EU MSs for voting results from 2003-2015 on the approval of GE crops to test for a gridlock; no reliable data are available pre-2003—a time which included the EU's moratorium on GE crops. After the EFSA has given a favorable opinion on the safety of a GE crop, the SCFCAH votes on the application. If SCFCAH reaches no decision, the AC (pre the Treaty of Lisbon: the Council) votes on the application; if no decision is reached here, the final decision is left to the EC. All EU MSs are represented on both committees; decisions are made by a QM voting system, the rules of which have changed over time. Our data include 50 events; and 61 ballots at SCFCAH and 57 ballots at Council / AC. A QM has been achieved once only at SCFCAH, but never at Council. At Council / AC level, Austria and Croatia have consistently voted against an approval, while The Netherlands has always supported approvals. All other MSs showed differences in their voting decisions at SCFCAH and Council / AC level at least once. MS fixed effects are the major factor explaining the voting results supporting the gridlock hypothesis, while crop characteristics and crop use play no apparent role in MSs' voting behavior. We postulate a QM is unlikely following the latest directive for MSs to 'opt-out' on GE crop cultivation in their territories.

Key words: EU Member States, qualified majority vote, voting behavior, Standing Committee on the Food Chain and Animal Health, Appeal Committee, Council, genetically engineered crop, political economy, opt-out.

5.1 Introduction

The advancement of scientific discovery gave rise to the development of recombinant DNA technology (genetic engineering), which has been successfully applied, inter alia, in plant breeding for developing GE crops (Wesseler, 2014). Scientists recognized the far-reaching significance of this development, including potential risks and benefits, and consequently initiated steps for the regulation of this type of biotechnology research in the 1970s (McHughen and Smyth, 2008). Regulatory oversight was broadened to include its commercial application for ensuring safety for humans and the environment (Jaffe, 2004). Morris and Spillane (2010) summarize the regulatory history in the EU of this technology up to 2010, commenting that its development has been controversial and difficult. It was interrupted by a de facto moratorium from 1998-2004 (Lieberman and Gray, 2006), and the redrafting of legislation. In April of 2015 a legislative act was introduced whereby MSs can decide whether GE crops authorized for cultivation can be cultivated on their territories (OJEU, 2015), the so-called 'opt-out' directive. Subsequently, a similar proposal for GE crops authorized for 'food and feed' use was made by the Commission (EC, 2015b).

The precautionary principle is the legal instrument used in the EU legislation for preventing and managing risk—connected in the food sector to biotechnology in a multidimensional way via science, ethics, sociology, and religion—thereby treating GE organisms as unique, requiring tailor-made regulations (Cararu, 2009). Thus, in the EU the process of genetic modification is regulated, and not the product (i.e., in the case of GE crops, the new genetic trait introduced to the plant). This means that every GE crop is subjected to regulatory oversight on a case-by-case approach (Cararu, 2009; Twardowski and Małyska, 2015) despite numerous high profile sources in the 1980s advocating that regulations in the EU be "product" rather than "process" based (Morris and Spillane 2010). One has to note, as Beckmann et al. (2011) among others have pointed out, what is considered to be GE, conventional, or organic, is a social construct.

The approval processes for GE crops in the EU and other countries have been criticized for their weak scientific support and welfare losses including health costs, and costs to the environment caused by delays in, or lack of, approval (Falck-Zepeda et al., 2013b). The temporal disparity in regulatory harmony has resulted in asynchronous approval causing disruptions in international trade (Stein and Rodriguez-Cerezo, 2010).

The EU is dependent on the import of food and feed, especially sources of vegetable protein such as soybean, for its livestock industry (Henseler et al., 2013; de Visser et al., 2014; Dunwell, 2014; Kalaitzandonakes et al., 2014). But its stringent rules on the low level (adventitious) presence of unauthorized GE crops in imported shipments of food and or feed have caused the segregation of supply chains with concomitant costs, and disrupted trade (Purnhagen and Wesseler, 2015; Kalaitzandonakes et al., 2014; FAO, 2014). The consequences have been strained relations with its trading partners (in some instances escalating to tribunal action at the World Trade Organization (De Ville, 2014; Punt and Wesseler, 2015), and notable revenue losses to its feed industry (Brookes, 2008). Henseler, et al. (2013) show that a trade disruption of EU soy imports caused by asynchronous approvals could compromise the competitiveness of its livestock sector and jeopardize agricultural incomes and employment with bidirectional knock-on effects within affected value chains. The EU's relatively unfavorable regulatory environment has led to innovators in the field of green biotechnology to relocate their R&D activities to countries with more accommodating regulatory oversight where the prospect of commercializing innovations is better. The result is a loss in human capital, expertise, investment and employment opportunities, and potential benefits from the commercialization of these products (Trager, 2012; Dunwell, 2014; Malyska and Twardowski, 2014).

Taking a closer look at the EU's GE crop regulations reveals that authorization is required for one or more of the following purposes: use as food and or feed; import for processing; and cultivation. Authorization is governed by Directive 2001/18/EC (OJEU, 2001) and Regulation (EC) No 1829/2003 (OJEU, 2003), is valid for 10 years after which a renewal is required, and follows a consecutive two-tier process starting with a risk assessment followed by risk management. The former comprises scientific investigations conducted by the EFSA for determining a crop's safety for humans and animals (applications for use as food and or feed, and or import for processing), and the environment (additionally for applications for cultivation). If EFSA's opinion is favorable, the next step is risk management—a political decision-making process (EFSA, 2013) during which MSs' representatives vote at the EU for authorization (OJEU, 2001).

After the EFSA completes its involvement in the risk assessment (which is criticized for ignoring any potential benefits (Morris and Spillane, 2010)) of a given GE crop's application, its overall opinion of the crop’s safety is published in the EFSA Journal. Risk management is triggered when EFSA passes its favorable opinions on to the EC for adoption, which the latter uses for preparing a proposal called a draft decision. A body comprising representatives (national experts) from all MSs, the SCFCAH, then assesses the draft decision. Approval of the draft decision is put to the vote via a QM voting system (for an explanation of QM voting, see **Section 5.4** below: **Empirical Analysis of the Voting Data**) under Regulation 1829/2003 (if submitted under Directive 2001/18, then by the Regulatory Committee) (EC, 2015c). If the SCFCAH agrees with the EC’s draft decision (i.e., a QM is achieved), then the GE crop is authorized for the specific use/s applied for. However, if the SCFCAH rejects the draft decision (via a qualified minority) or expresses no opinion (a QM is not reached), the EC either amends its draft decision and resubmits it to the SCFCAH or submits the original draft decision to the AC for a decision. The AC affords MSs the opportunity for “a second discussion at a higher level of representation” (EC, 2015d); comprises representatives from MSs; is chaired by the Commission; and uses QM voting. If the AC rejects the EC’s draft decision, authorization is declined. If the AC expresses no opinion, the authorization will be granted as the EC may then adopt the decision (Figure 4-3).

The time taken for a GE crop’s application successfully passing through the political step of the overall authorization process is of socio-economic importance as the less time it takes, the sooner society can benefit from using it, i.e., the loss of foregone benefits will be reduced. Those losses can be substantial (Wesseler and Zilberman, 2014; Zilberman et al., 2015). A full consensus (unanimity) within the EU at MS level for authorizing GE crops has never been reached—an unusual result considering a high and stable level of consensus over time at Council level on other topics (Jensen, 2010). So far, one GE crop has approval for cultivation in the EU and 61 GE crops for import and processing, while in the US, 115 crops have been approved for cultivation as of 2014.

While a number of scholars have assessed consumer, farmer, and farm-level, coexistence and labelling issues for GE crops, the literature assessing the EU’s policy on approving these crops is limited. Graff et al. (2009a) explain the low number of approvals by political economy factors whereby the political economy forces opposing the approval of GE crops are stronger in the EU than in other countries. It would be expected that these forces would have weakened with time here, tempered by the positive experiences of the technology in other regions and the catching-up of the European plant breeding and chemical industry on the technology. As Swinnen and Vandemoortele (2010) argue, a change in voting behavior, not to mention a change in regulation, will become more difficult once a regulation has been in place. The forces establishing a policy gridlock (Vogel, 2003) are further strengthened if the uncertainty about the political outcome of a change in policy is strengthened (Wesseler and Zilberman, 2014).

In this contribution, we report and analyze the voting results for approving GE crops from 2003-2015 at the SCFCAH, and the Council and the AC (C/AC), respectively. Reliable voting data pre-2003 (also a time during which the moratorium also occurred) were unavailable.

We use the voting results to test whether or not individual MS characteristics are more relevant for explaining the voting behavior supporting the aforementioned argument of a policy gridlock (Vogel, 2003; Swinnen and Vandemoortele, 2010) than other factors such as the crop type, e.g., maize or oilseed rape, or the transgenic trait, e.g., insect resistance or herbicide tolerance. Our investigation does not, however, attempt at identifying and testing which MS characteristics, if any, can be used to explain voting behavior as Mühlböck and Tosun (2015) have done. Further, we use the results to identify possibilities for achieving a QM in favor of approval, i.e., which MSs would need to change their voting behavior, and discuss the results in light of the Directive (EU) 215/412 for MSs to restrict or prohibit the cultivation of GE crops in their territories—the ‘opt-out’ directive (OJEU, 2015)[6]—as a change in regulation to overcome the policy gridlock.

Our analysis shows that a MS’s identity (i.e., endogenous factors) and not specific characteristics of the GE crop is statistically the most significant factor driving voting behavior, putting into question the success of the ‘opt-out’ proposal to overcome the policy gridlock.

Our paper continues with section 5.2 where we describe the voting process in the EU for authorizing GE plants. We describe our dataset in section 5.3, and in section 5.4 we present our empirical analysis of the voting data. Our paper ends in section 5.5 with our discussion and conclusion.

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[6] We concentrate on achieving a QM in favour of approval as this has been the objective for revising the legal framework.

5.2 The Voting Process in the EU for Authorizing GE Plants

5.2.1 QM Voting

The number of MSs comprising the EU has increased since its inception (originally known as the European Economic Community: EEC) from six core states to 15—when GE crops first appeared in the mid-1990s—to the current 28. Each MS's vote is weighted according to its population (with the less-populous states having a proportionally larger weighting). A QM is achieved when the number of votes cast ('for' or 'against') equal or exceed a threshold value calculated as a percentage of the maximum possible number of votes. Threshold values and the vote weights for individual MSs have changed over time (see Table 5-1 and its footnotes) (EC, 2013).

We give our mathematical description of the QM voting as follows:
At any given time, the EU MSs comprise a set *N* denoted i.
We denote the votes of MS i as V_i:

(5-1) $$V_i = \begin{cases} 1 & if\ MS_i\ votes\ 'for' \\ 0 & if\ MS_i\ votes\ anything\ but\ 'for' as\ described\ below \end{cases}$$

$V_i = 0$ if a MS i votes 'against' including any form of 'against' (i.e., an abstention, or absent from the ballot).
Each MS i, has a vote weight, w_i.
For each ballot, the total number of 'for' votes, Q is calculated as follows:

(5-2) $$Q = \sum_{i \epsilon N} w_i V_i.$$

A positive decision (i.e., approval) is reached if $Q \geq t$, where t is the QM threshold value of 'for' votes for a given decision (ballot). For the period December 01, 2007-June 30, 2013, for example, a decision required at least 255 votes (73.91%) out of the 345 total, for adoption (Table 5-1). The weighting arrangements are the result of a compromise reached between MSs in a "degressively proportional system" where smaller and larger MSs are over- and under-represented, respectively—a compromise reached between federalist and intergovernmental elements within the EU of the "one man, one vote" and "one country, one vote" principles, respectively (Moberg, 1998). The current weighting of votes, enshrined in The Treaty of Nice, came into force on November 01, 2004. Subsequently, The Treaty of Lisbon (Article 16 of the Treaty on EU) introduced a new definition for the rule of QM with a three-stage implementation (for details, see Table 5-2).

Table 5-1. MSs of the EU, year joined, and their vote weights for the QM voting system from 1995-2015

MS[1] with official abbreviation	Year joined[1]	EU-15 (01.01.1995 - 30.04.2004)[1]	EU-25 (01.05.2004 – 31.10.2004)[1]	EU-25 (01.11.2004 - 31.12.2006)[1]	EU-27 (01.12.2007 – 30.06.2013)[1]	EU-28 (01.07.2013 – 31.10.2013)[1]	EU-28 (from 01.11.2014) (%)
Austria (AT)	1995	4	4	10	10	10	1.67
Belgium (BE)	1952	5	5	12	12	12	2.21
Bulgaria (BG)	2007				10	10	1.44
Croatia (HR)	2013					7	0.84
Cyprus (CY)	2004		2	4	4	4	0.17
Czech Rep. (CZ)	2004		5	12	12	12	2.08
Denmark (DK)	1973	3	3	7	7	7	1.11
Estonia (EE)	2004		3	4	4	4	0.26
Finland (FI)	1995	3	3	7	7	7	1.07
France (FR)	1952	10	10	29	29	29	12.98
Germany (DE)	1952	10	10	29	29	29	15.93
Greece (EL)	1981	5	5	12	12	12	2.19
Hungary HU)	2004		5	12	12	12	1.96
Ireland (Rep) (IE)	1973	3	3	7	7	7	0.91
Italy (IT)	1952	10	10	29	29	29	11.81
Latvia (LV)	2004		3	4	4	4	0.40
Lithuania (LT)	2004		3	7	7	7	0.59
Luxembourg (LU)	1952	2	2	4	4	4	0.11
Malta (MT)	2004		2	3	3	3	0.08
Netherlands (NL)	1952	5	5	13	13	13	3.32
Poland (PL)	2004		8	27	27	27	7.62
Portugal (PT)	1986	5	5	12	12	12	2.07
Romania (RO)	2007				14	14	3.97
Slovakia (SK)	2004		3	7	7	7	1.07
Slovenia (SI)	2004		3	4	4	4	0.41
Spain (ES)	1986	8	8	27	27	27	9.24
Sweden (SE)	1995	4	4	10	10	10	1.89
United Kingdom (UK)	1973	10	10	29	29	29	12.61
Total		87	124	321	345	352	100.01
QM[2]		62 (71.26%)	88 (70.97%)	232 (72.27%)	255 (73.91%)	260 (73.91%)	65% ≥16 MSs[3]
QM[2]		26	37	90	91	93	35% ≥ 4 MSs[4]

[1] EC, 2004

[2] A majority of the MSs must vote in favor when a proposal has been presented by the Commission, or two thirds of the MSs must vote in favor in all other cases. The QM shall cover at least 62% of the EU's population (EC, 2004).

[3] A QM is reached when 55% of MSs vote in favor (16 out of 28) and MSs representing at least 65% of the EU's population (Poptcheva and Devaney, 2014; European Council, 2015).

[4] A blocking minority must include at least four Council members representing more than 35% of the EU population (European Council, 2015).

Table 5-2. Descriptive statistics for voting results at SCFCAH and C/AC for authorizing GE crops in the EU (referring to models 8 and 16 from Tables 5-3 and 5-4, respectively)

Parameter	Voting Body							
	SCFCAH				C/AC			
	Mean	SD	Min	Max	Mean	SD	Min	Max
Vote 'for'	0.44	0.5	0	1	0.43	0.50	0	1
Year	2009.63	3.22	2003	2014	2009.8	3.26	2004	2015
Import	0.65	0.48	0	1	0.79	0.41	0	1
Food, feed	0.82	0.38	0	1	0.69	0.46	0	1
Cultivation	0.08	0.27	0	1	0.02	0.13	0	1
Multiple trait	0.34	0.47	0	1	0.34	0.47	0	1
Single trait	0.66	0.47	0	1	0.66	0.47	0	1
Herbicide tolerance	0.71	0.45	0	1	0.69	0.46	0	1
Insect resistance	0.45	0.5	0	1	0.45	0.50	0	1
Other	0.15	0.36	0	1	0.14	0.35	0	1
Foreign (ex-European) [1]	0.62	0.48	0	1	0.65	0.48	0	1
Domestic (European) [1]	0.38	0.48	0	1	0.35	0.48	0	1
Cotton	0.07	0.25	0	1	0.09	0.29	0	1
Flower	0.02	0.12	0	1	0.02	0.13	0	1
Maize	0.53	0.50	0	1	0.54	0.50	0	1
Oilseed rape	0.11	0.32	0	1	0.10	0.30	0	1
Potato	0.03	0.18	0	1	0.04	0.19	0	1
Rice	0.02	0.13	0	1	.	.	.	.
Soybean	0.21	0.40	0	1	0.22	0.41	0	1
Sugarbeet	0.02	0.13	0	1	.	.	.	.

[1] Applicant's domicile

MS voting is a continuous process involving strategy and "a stream of interconnected decisions" where synergies and opportunities are sought for initiating so-called package deals. MSs practice vote trading and log-rolling (exchange of political favors) while they simultaneously defend national interests and promote common European ones. Occasionally domestic pressure is too high for sustaining this balancing strategy (Trzaskowski, 2009). Thus decision-making is a bargaining act (Moberg, 2007) where reciprocity is likely (Jensen, 2010). It is therefore evident that voting takes place in a complex environment in which many interactions play a role in each ballot's result, including MSs bargaining with lobbyists (e.g., the GE crop and nuclear energy trade-off between France and ecologists (Ficek, 2013)).

Scholars have assessed the ramifications of various voting arrangements for, inter alia, ‘balance’ or fairness and tactical arrangements amongst voters such as forming coalitions (Penrose, 1946; Banzhaf III, 1964; Coleman, 1971; Felsenthal and Machover, 2000; Leech, 2002; Alonso-Meijide, et al., 2009; Plechanovová, 2011). Slomczynski and Zyczkowski (2006) comment that analyzing coalition formations is highly complex for the EU—demonstrated by the high number (134 M) of possible coalitions for the EU-27—and show that the difficulty of forming winning coalitions is positively correlated with membership number.

5.3 Description of the Dataset

We sourced our data from two publications: AgraFacts and AgraFocus (see http://www.agrafacts.com/Home.html), which published most of the voting results for the SCFCAH and the Council and AC for the period December 2003-January 2015; no reliable data were available for earlier ballots, and little voting took place during the moratorium. We captured the ballot results in the following categories for the aforementioned voting bodies: ‘for’; ‘against’; ‘abstain’; and pooled the results for ‘absent’, ‘no representative’, and ‘no position taken due to “parliamentary reserve”, and ‘no result published’ as ‘no vote cast’ because of their infrequent occurrence and their failure to contribute to a QM.

The EU’s membership has grown over time. Therefore, the number of voting opportunities per MS is a function of: (1) how long it has been a member of the EU, and (2) the number of ballots during its membership. Generally, the longer a MS has been a member, the higher the number of voting opportunities. The Netherlands, Sweden, Finland, the UK, the Czech Republic, Estonia, Romania, and Spain; and Austria, Luxembourg, Greece, Hungary, Cyprus, and Lithuania voted ‘for’ and ‘against’, respectively, with a frequency of at least 80%; Italy, France, Bulgaria, and Ireland abstained at least 40% of the time at the SCFCAH. Finland and The Netherlands always voted ‘for’, and Austria always ‘against’, at both the SCFCAH and the C/AC. Croatia, Luxembourg, and Latvia never voted ‘for’ at the C/AC (Figures 5-1 and 5-2).

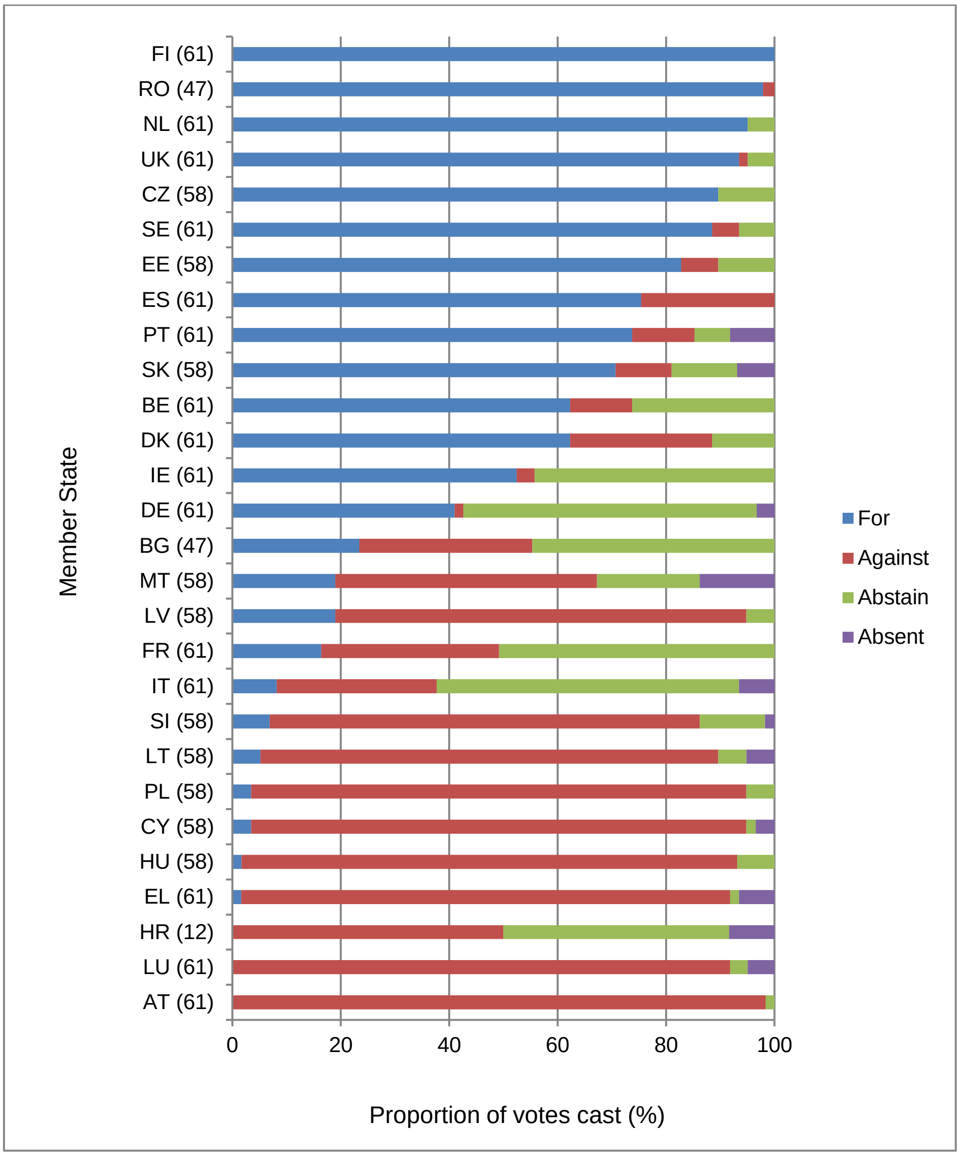

Figure 5-1. The relative frequency of votes cast by MSs at the SCFCAH from December 2003-December 2014 (MS abbreviations are listed in Table 5-1). On the vertical axis, the numbers in parentheses are the number of voting opportunities per MS. Note: 'Absent' included no position taken due to parliamentary reserve.

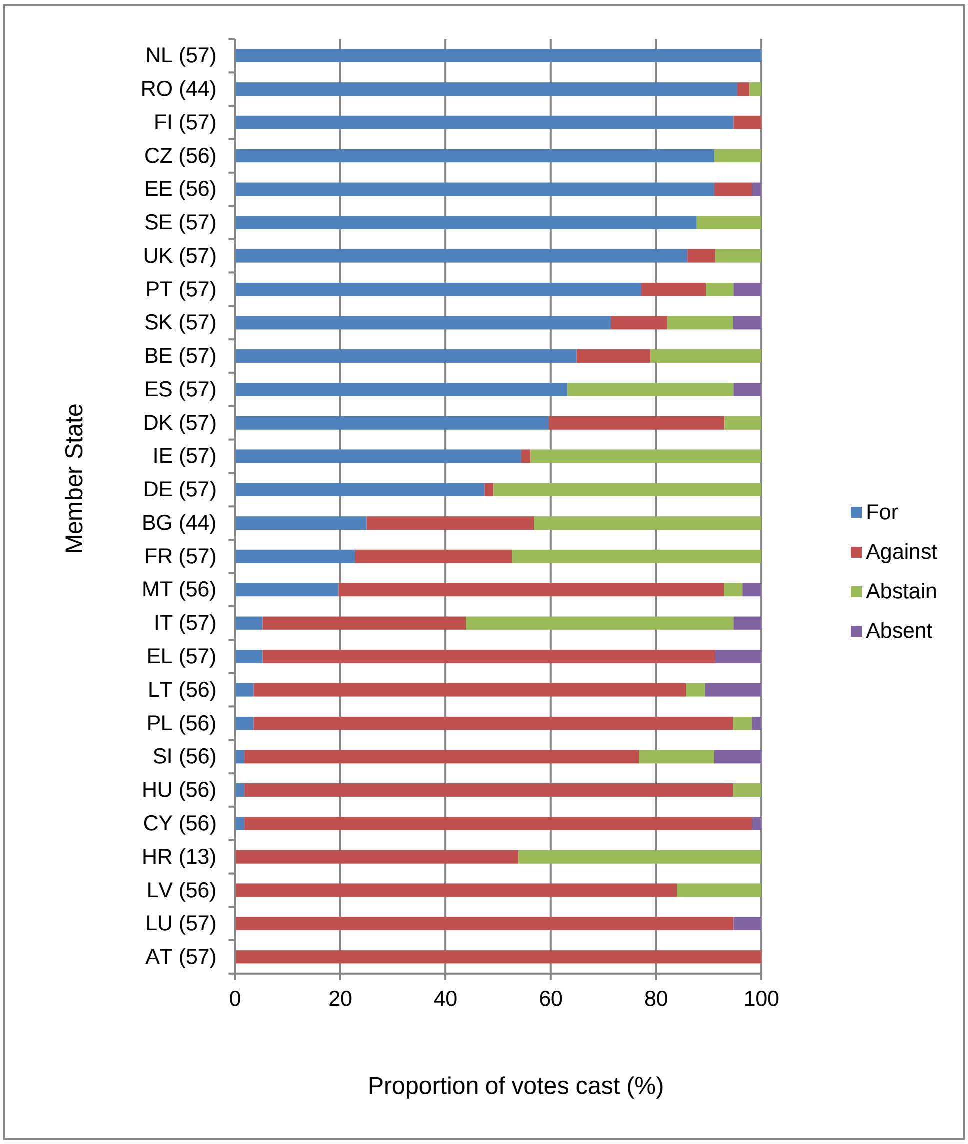

Figure 5-2. The relative frequency of votes cast by MSs at the C/AC from May 2004-February 2015 (MS abbreviations are listed in see Table 5-1). On the vertical axis, the numbers in parentheses are the number of voting opportunities per MS. Note: ‘Absent’ included no position taken due to parliamentary reserve. Because voting on the same GE crop takes place at the C/AC after the SCFCAH, our start and end date of 2004 and 2015, respectively, are each a year later than that for SCFCAH in Figure 5-1.

The data summarized in Figures 5-3 and 5-4 essentially represent the binary outcome of each ballot. However, the weighted outcome is the important result of each voting event as this determines whether or not a QM vote is achieved. We applied the weights given in Table 5-1 to each successive ballot at the SCFCAH and the C/AC, and calculated the minimum number of additional ‘for’ votes needed for a QM (last column in Tables A5-1 and A5-2).

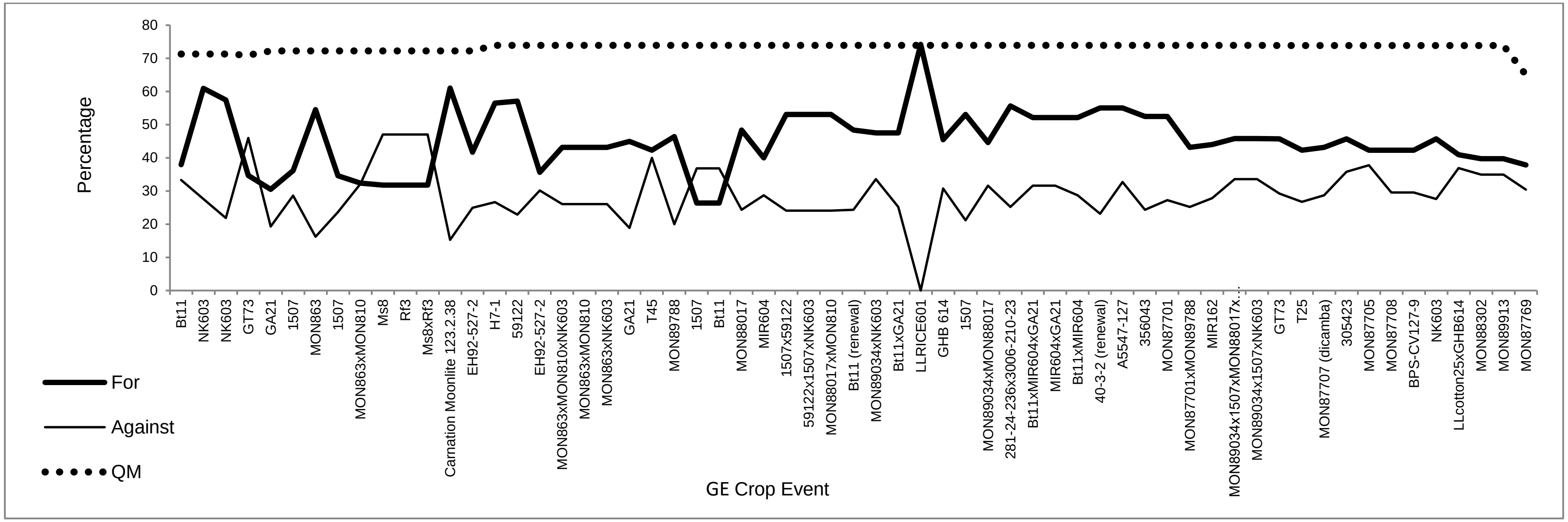

Figure 5-3. The total number of ‘for’ and ‘against’ votes cast at the SCFCAH expressed as a percentage of the maximum possible number of votes, according to each EU MS’s weight for ballots authorizing GE crops from December 2003-December 2014 versus the QM threshold.

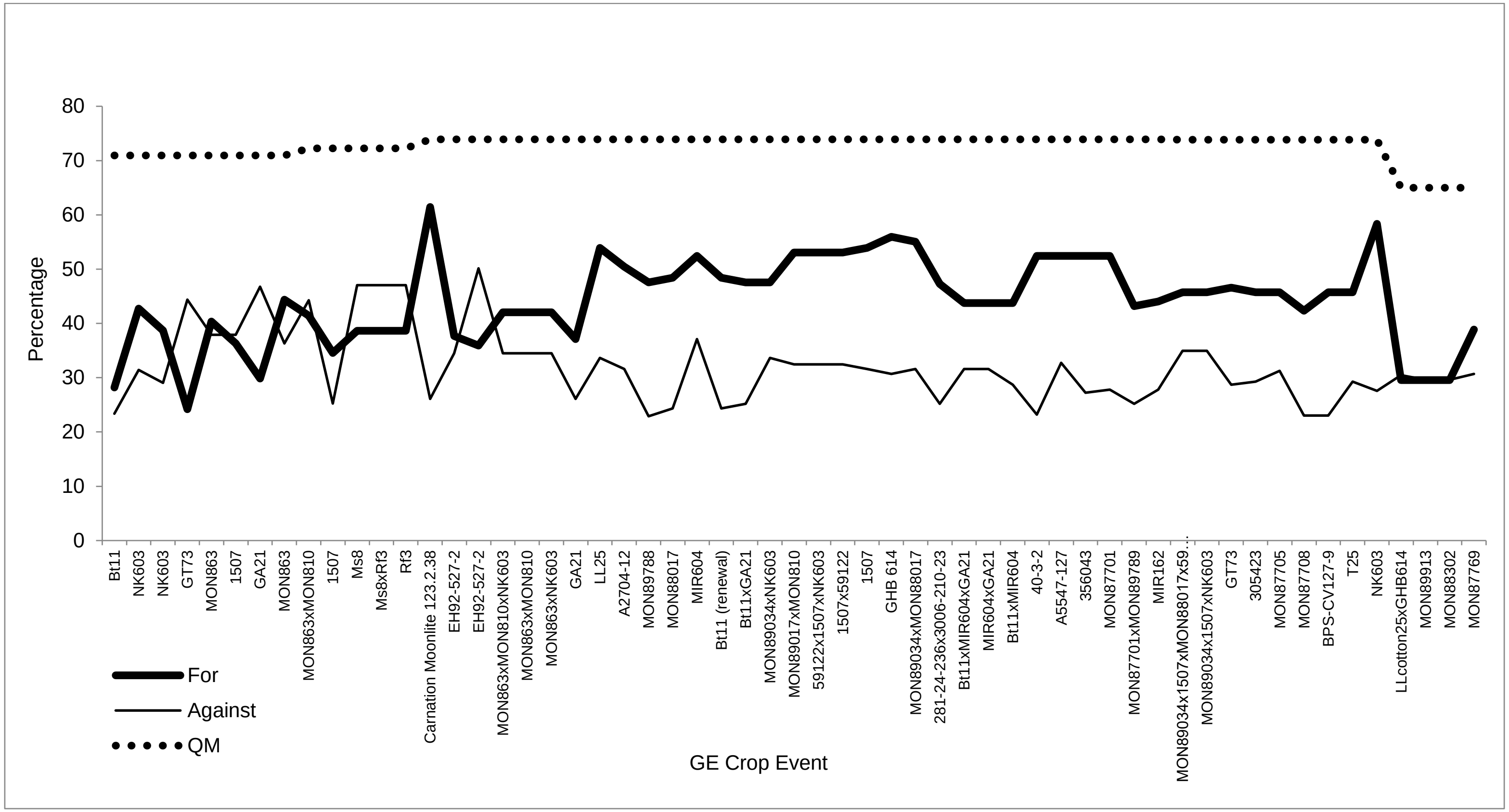

Figure 5-4. The total number of ‘for’ and ‘against’ votes cast at the C/AC expressed as a percentage of the maximum possible number of votes, according to each EU MS’s weight for ballots authorizing GE crops from 2004-2015 versus the QM threshold.

5.4 Empirical Analysis of the Voting Data

The SCFACH represents the first step in the political decision-making process. Should MSs not vote in favor of an application here, the political process continues with the Commission becoming involved as shown in Figure 4-1. Descriptive statistics presented in Table 5-2 indicate that the voting behavior of the SCFCAH and the C/AC is similar (see also Figures 5-3 and 5-4).

We treated every ‘for’ vote as a positive statement for supporting a GE crop’s authorization. The ‘against’ and ‘abstain’ votes, and several forms of absenteeism were interpreted as negative statements opposing authorization as they prevented a QM (Jensen, 2010).

We used odds ratios in a set of logistic regressions for testing whether a MS’s identity, an applicant’s domicile, and a crop plant’s genetic trait are suitable explanatory variables for explaining a MS’s voting decision. This was done by first testing a MS’s identity, and then stepwise adding additional explanatory variables. The rationale for using this method is to assess whether voting decisions can be explained by factors associated with a MS’s characteristics (i.e., endogenous factors), or whether MS-specific effects prevail if explanatory variables based on qualitative information (e.g., crop type, or the crop’s intended use) are added to the model. Theoretically, what appears to be a MS-specific effect may in fact reflect a MS-specific concern or opportunity leading respectively to a negative or positive vote. For example, Scandinavian MSs tend to accept (vote ‘for’) GE crops, but it is unknown whether these MSs’ voting behavior is related to liberal and open-minded societies, or whether their positive votes are associated with, for example, factors favoring these MSs’ bio-economies (agricultural and biotech sectors). We use a set of logistic regression models for disentangling these factors and for testing if they can be used for explaining the variation in voting behavior.

The equation below illustrates our estimation strategy for testing the relationship between a positive vote and a set of explanatory factors, where μ represents a binary variable that is one for a positive vote of MS i, at time t, for crop j, and zero otherwise. The dependent variable is assumed to be a function of MS fixed effects (C) that are included to reflect MS-specific voting patterns. The vector X includes controls for plant-related features such as type of trait, plant type, intended crop use, and the developer's (applicant) domicile. We aim at capturing a time trend (*T*) to observe any temporal changes in voting pattern; α and ε represent a constant and the error term, respectively.

(5.3) $$\mu_{ijt} = \alpha + \beta_1 * \mathrm{C} + \beta_2 * \mathrm{X} + \beta_3 * \mathrm{T} + \varepsilon$$

Regression models 1-8 in Table 5-3 analyze MSs' voting at the C/AC, which is politically more important than the SCFCAH (Table 5-4) (EC, 2015d). Model 1 only controls for MS fixed effects, reflecting general voting behavior. For example, the coefficient for the voting behavior of Finland and Sweden reflects an accepting (positive) attitude towards GE crops contrasted by Cyprus' voting indicating the opposite sentiment. Italy was chosen as a reference category because its voting behavior was the most dynamic (i.e., changed its position the most) of the 'heavy-weight' MSs. In subsequent models we added explanatory variables, which may: (1) help explain results represented in model 1, (2) add more statistical explanatory power, and (3) test the robustness of initial results. For example, in model 2, we added a metric variable capturing a time trend; results indicate that with time EU MSs have become more likely to vote positively. In model 3 we added controls for a GE crop's intended use (import; or food or feed; or cultivation), which turned out to be statistically unimportant. However, this finding needs to be contextualized: the number of applications for cultivation is very low. Similarly, we found no robust evidence for differences between multiple- and single trait crops, or crops engineered for herbicide tolerance or insect resistance, respectively (models 4 and 5). In models 7 and 8 we tested the influence of plant type on voting behavior. Our results suggest that MSs were most in favor of GE flowers (a flower's petal color was altered) and least in favor of GE oilseed rape.

Table 5-3. Correlates of positive (‘for’) votes at the EU’s C/AC for authorizing GE crops from 2004-2015

Parameter		Model							
		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Dependent variable: likelihood of ‘for’ vote at C/AC							
MS	AT	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
	BE	3.51***	3.60***	3.60***	3.61***	3.61***	3.62***	3.74***	3.75***
		(5.35)	(5.46)	(5.46)	(5.47)	(5.47)	(5.48)	(5.57)	(5.57)
	BG	1.79***	1.67**	1.67**	1.67**	1.67**	1.68**	1.70**	1.69**
		(2.61)	(2.42)	(2.42)	(2.41)	(2.42)	(2.43)	(2.42)	(2.41)
	CP	-1.12	-1.13	-1.13	-1.13	-1.13	-1.13	-1.15	-1.15
		(-0.95)	(-0.97)	(-0.97)	(-0.96)	(-0.96)	(-0.97)	(-0.97)	(-0.98)
	CZ	5.01***	5.14***	5.14***	5.15***	5.16***	5.17***	5.35***	5.37***
		(6.83)	(6.94)	(6.95)	(6.96)	(6.96)	(6.97)	(7.10)	(7.10)
	DE	2.79***	2.85***	2.85***	2.86***	2.86***	2.87***	2.96***	2.96***
		(4.29)	(4.36)	(4.36)	(4.36)	(4.37)	(4.37)	(4.44)	(4.44)
	DK	3.28***	3.37***	3.37***	3.38***	3.38***	3.39***	3.50***	3.50***
		(5.03)	(5.13)	(5.13)	(5.14)	(5.14)	(5.15)	(5.23)	(5.23)
	ES	3.43***	3.52***	3.53***	3.53***	3.53***	3.54***	3.66***	3.66***
		(5.25)	(5.35)	(5.35)	(5.36)	(5.36)	(5.37)	(5.46)	(5.46)
	EE	5.21***	5.34***	5.34***	5.36***	5.36***	5.37***	5.57***	5.58***
		(6.90)	(7.01)	(7.01)	(7.03)	(7.03)	(7.04)	(7.17)	(7.17)
	FI	5.78***	5.93***	5.93***	5.95***	5.95***	5.96***	6.16***	6.19***
		(6.89)	(7.02)	(7.02)	(7.04)	(7.04)	(7.05)	(7.18)	(7.19)
	FR	1.67**	1.70**	1.70**	1.70**	1.70**	1.71**	1.76**	1.76**
		(2.49)	(2.51)	(2.51)	(2.51)	(2.52)	(2.52)	(2.56)	(2.56)
	EL	-0.00	-0.00	0.00	0.00	-0.00	0.00	0.00	-0.00
		(-0.00)	(-0.00)	(0.00)	(0.00)	(-0.00)	(0.00)	(0.00)	(-0.00)
	HU	-1.12	-1.13	-1.13	-1.13	-1.13	-1.13	-1.15	-1.15
		(-0.95)	(-0.97)	(-0.97)	(-0.96)	(-0.96)	(-0.97)	(-0.97)	(-0.98)
	IE	3.07***	3.15***	3.15***	3.15***	3.15***	3.16***	3.27***	3.27***
		(4.72)	(4.80)	(4.80)	(4.81)	(4.81)	(4.82)	(4.90)	(4.90)
	IT	reference	reference	reference	reference	reference	reference	reference	reference
	LV	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
	LT	-0.41	-0.42	-0.42	-0.42	-0.42	-0.42	-0.43	-0.43
		(-0.43)	(-0.45)	(-0.45)	(-0.45)	(-0.45)	(-0.45)	(-0.45)	(-0.45)
	LU	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
	MT	1.48**	1.49**	1.49**	1.50**	1.50**	1.50**	1.55**	1.54**
		(2.17)	(2.18)	(2.18)	(2.18)	(2.18)	(2.18)	(2.22)	(2.22)
	NL	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
	PL	-0.41	-0.42	-0.42	-0.42	-0.42	-0.42	-0.43	-0.43
		(-0.43)	(-0.45)	(-0.45)	(-0.45)	(-0.45)	(-0.45)	(-0.45)	(-0.45)
	PT	4.11***	4.23***	4.23***	4.24***	4.24***	4.25***	4.40***	4.41***
		(6.12)	(6.24)	(6.24)	(6.25)	(6.25)	(6.26)	(6.37)	(6.37)
	RO	5.93***	5.87***	5.88***	5.89***	5.89***	5.91***	5.99***	5.97***
		(6.34)	(6.26)	(6.26)	(6.27)	(6.28)	(6.29)	(6.32)	(6.31)
	SI	-1.12	-1.13	-1.13	-1.13	-1.13	-1.13	-1.15	-1.15

		(-0.95)	(-0.97)	(-0.97)	(-0.96)	(-0.96)	(-0.97)	(-0.97)	(-0.98)
	SK	3.81***	3.90***	3.90***	3.91***	3.92***	3.92***	4.06***	4.07***
		(5.74)	(5.84)	(5.84)	(5.85)	(5.85)	(5.86)	(5.97)	(5.97)
	SE	4.86***	4.99***	5.00***	5.01***	5.01***	5.02***	5.20***	5.21***
		(6.77)	(6.90)	(6.90)	(6.92)	(6.92)	(6.93)	(7.05)	(7.05)
	UK	4.70***	4.84***	4.84***	4.85***	4.85***	4.86***	5.04***	5.05***
		(6.67)	(6.80)	(6.80)	(6.81)	(6.82)	(6.83)	(6.94)	(6.95)
	HR	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
Time trend	Year		0.13***	0.13***	0.13***	0.13***	0.13***	0.12***	0.12***
			(4.90)	(4.66)	(4.70)	(4.72)	(4.57)	(4.00)	(3.94)
GE crop’s use	Import			-0.05	0.02	0.01	0.07	0.16	0.15
				(-0.22)	(0.10)	(0.06)	(0.29)	(0.65)	(0.61)
	Food, feed			reference	reference	reference	reference	reference	reference
	Cultivation			-0.32	0.00	-0.02	0.15	0.64	0.63
				(-0.51)	(0.00)	(-0.04)	(0.23)	(0.73)	(0.71)
Trait multiple	multiple					-0.10	-0.10	-0.22	-0.20
						(-0.53)	(-0.56)	(-1.11)	(-0.91)
	single					reference	reference	reference	reference
Type of GE trait	Herbicide tolerance				-0.16	-0.13	-0.13		0.10
					(-0.84)	(-0.64)	(-0.61)		(0.45)
	Insect resistance				reference	reference	reference		reference
	Other				-0.42	-0.41	-0.39		-0.49
					(-1.56)	(-1.51)	(-1.45)		(-1.31)
Developer's domicile	Foreign (ex-Europe)						0.24	0.06	0.05
							(1.37)	(0.34)	(0.27)
	Domestic (European)						reference	reference	reference
Plant type	Cotton							-0.17	-0.30
								(-0.50)	(-0.86)
	Flower							2.37***	2.81***
								(3.22)	(3.59)
	Maize							0.08	-0.05
								(0.31)	(-0.17)
	Oilseed rape							-1.10***	-1.09***
								(-3.29)	(-3.20)
	Potato							-0.91	-0.49
								(-1.40)	(-0.70)
	Rice								omitted
	Soybean								omitted
	Sugarbeet								omitted
	Constant	-2.89***	-254.57***	-255.52***	-262.33***	-264.35***	-257.60***	-252.48***	-250.19***
		(-4.87)	(-4.95)	(-4.72)	(-4.76)	(-4.78)	(-4.63)	(-4.05)	(-3.99)
	Pseudo R²	0.44	0.45	0.45	0.45	0.45	0.46	0.47	0.47

	Observations	1,276	1,276	1,276	1,276	1,276	1,276	1,276	1,276

Note: Robust z-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10% levels.
Dependent variable is the likelihood of ‘for’ vote at C/AC.
Some MSs’ voting behavior cannot be assessed in the chosen framework since there is no ‘variation’ in their votes, i.e., they consistently voted either ‘for’ or ‘against’.

Table 5-4. Correlates of positive (‘for’) votes at SCFCAH for authorizing GE crops in the EU from 2003-2014

Parameter		Model							
		(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)
		Dependent variable: Likelihood of ‘for’ vote at SCOFCAH							
MS	AT	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
	BE	2.85***	2.88***	2.91***	2.92***	2.92***	2.92***	3.16***	3.17***
		(5.32)	(5.36)	(5.40)	(5.40)	(5.41)	(5.41)	(5.57)	(5.58)
	BG	1.23**	1.15**	1.15**	1.15**	1.16**	1.16**	1.29**	1.29**
		(2.12)	(1.97)	(1.97)	(1.97)	(1.99)	(1.99)	(2.11)	(2.11)
	CY	-0.92	-0.94	-0.94	-0.94	-0.94	-0.94	-1.03	-1.02
		(-1.07)	(-1.09)	(-1.09)	(-1.09)	(-1.09)	(-1.09)	(-1.15)	(-1.14)
	CZ	4.58***	4.60***	4.69***	4.69***	4.70***	4.70***	5.06***	5.08***
		(7.20)	(7.22)	(7.30)	(7.30)	(7.31)	(7.31)	(7.53)	(7.54)
	DE	2.05***	2.07***	2.09***	2.09***	2.09***	2.09***	2.28***	2.29***
		(3.84)	(3.86)	(3.88)	(3.88)	(3.89)	(3.89)	(4.03)	(4.04)
	DK	2.92***	2.95***	2.99***	2.99***	2.99***	2.99***	3.24***	3.25***
		(5.44)	(5.48)	(5.52)	(5.52)	(5.53)	(5.53)	(5.69)	(5.70)
	ES	3.54***	3.57***	3.63***	3.63***	3.64***	3.64***	3.93***	3.94***
		(6.39)	(6.43)	(6.49)	(6.50)	(6.50)	(6.50)	(6.68)	(6.69)
	EE	3.98***	4.00***	4.08***	4.08***	4.09***	4.09***	4.42***	4.43***
		(6.85)	(6.86)	(6.93)	(6.93)	(6.95)	(6.95)	(7.14)	(7.16)
	FI	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
	FR	0.79	0.79	0.79	0.80	0.80	0.80	0.88	0.88
		(1.35)	(1.36)	(1.36)	(1.36)	(1.36)	(1.36)	(1.43)	(1.43)
	EL	-1.68	-1.68	-1.68	-1.68	-1.69	-1.69	-1.81	-1.81
		(-1.51)	(-1.51)	(-1.51)	(-1.51)	(-1.51)	(-1.51)	(-1.58)	(-1.58)
	HU	-1.63	-1.65	-1.65	-1.65	-1.65	-1.65	-1.78	-1.78
		(-1.46)	(-1.48)	(-1.48)	(-1.48)	(-1.48)	(-1.48)	(-1.55)	(-1.55)
	IE	2.51***	2.54***	2.57***	2.57***	2.57***	2.57***	2.79***	2.80***
		(4.72)	(4.75)	(4.78)	(4.79)	(4.79)	(4.79)	(4.95)	(4.96)
	IT	reference	reference	reference	reference	reference	reference	reference	reference
	LV	0.96*	0.95*	0.96*	0.96*	0.96*	0.96*	1.06*	1.06*
		(1.68)	(1.65)	(1.66)	(1.66)	(1.66)	(1.66)	(1.74)	(1.74)
	LT	-0.49	-0.51	-0.51	-0.51	-0.51	-0.51	-0.57	-0.57
		(-0.65)	(-0.68)	(-0.68)	(-0.68)	(-0.68)	(-0.68)	(-0.72)	(-0.71)
	LU	omitted	omitted	omitted	omitted	omitted	omitted	omitted	omitted
	MT	0.96*	0.95*	0.96*	0.96*	0.96*	0.96*	1.06*	1.06*
		(1.68)	(1.65)	(1.66)	(1.66)	(1.66)	(1.66)	(1.74)	(1.74)
	NL	5.38***	5.43***	5.52***	5.53***	5.53***	5.53***	5.91***	5.93***
		(7.13)	(7.18)	(7.26)	(7.26)	(7.27)	(7.27)	(7.51)	(7.52)
	PL	-0.92	-0.94	-0.94	-0.94	-0.94	-0.94	-1.03	-1.02
		(-1.07)	(-1.09)	(-1.09)	(-1.09)	(-1.09)	(-1.09)	(-1.15)	(-1.14)
	PT	3.45***	3.49***	3.54***	3.54***	3.55***	3.55***	3.83***	3.84***

		(6.27)	(6.31)	(6.37)	(6.38)	(6.38)	(6.38)	(6.56)	(6.57)
	RO	6.24***	6.18***	6.27***	6.28***	6.30***	6.30***	6.60***	6.62***
		(5.61)	(5.55)	(5.61)	(5.62)	(5.63)	(5.63)	(5.80)	(5.81)
	SI	-0.19	-0.21	-0.20	-0.21	-0.20	-0.20	-0.23	-0.23
		(-0.27)	(-0.30)	(-0.29)	(-0.29)	(-0.29)	(-0.29)	(-0.31)	(-0.31)
	SK	3.30***	3.31***	3.36***	3.36***	3.37***	3.37***	3.65***	3.66***
		(6.01)	(6.01)	(6.07)	(6.07)	(6.08)	(6.09)	(6.26)	(6.28)
	SE	4.46***	4.51***	4.58***	4.59***	4.59***	4.60***	4.94***	4.95***
		(7.24)	(7.29)	(7.36)	(7.37)	(7.37)	(7.38)	(7.57)	(7.59)
	UK	5.07***	5.12***	5.21***	5.22***	5.22***	5.22***	5.59***	5.61***
		(7.28)	(7.33)	(7.41)	(7.41)	(7.42)	(7.42)	(7.64)	(7.66)
	HR	4.81***	4.50***	4.59***	4.57***	4.54***	4.53***	4.89***	4.90***
		(4.21)	(3.92)	(3.99)	(3.97)	(3.94)	(3.94)	(4.18)	(4.19)
Time trend	Year		0.07***	0.06**	0.06**	0.06**	0.06**	0.07**	0.07**
			(3.03)	(2.33)	(2.25)	(2.25)	(2.22)	(2.24)	(2.13)
GE crop’s use	Import			-0.28	-0.30*	-0.35*	-0.34*	-0.05	-0.05
				(-1.54)	(-1.65)	(-1.87)	(-1.81)	(-0.27)	(-0.26)
	Food, feed			reference	reference	reference	reference	reference	reference
	Cultivation			-1.31***	-1.33***	-1.41***	-1.39***	-1.93***	-1.85***
				(-4.15)	(-3.94)	(-4.11)	(-4.02)	(-4.50)	(-4.30)
Trait multiple	multiple					-0.22	-0.23	-0.12	-0.19
						(-1.27)	(-1.28)	(-0.63)	(-0.90)
	single					reference	reference	reference	reference
Type of GE trait	Herbicide tolerance				0.09	0.15	0.15		0.29
					(0.47)	(0.78)	(0.78)		(1.31)
	Insect resistance				reference	reference	reference		reference
	Other				0.16	0.18	0.18		-0.15
					(0.65)	(0.74)	(0.73)		(-0.44)
Developer's domicile	Foreign (ex-Europe)						0.05	0.22	0.20
							(0.34)	(1.18)	(1.10)
	Domestic (European)						reference	reference	reference
Plant type	Cotton							-1.98***	-1.87**
								(-2.71)	(-2.54)
	Flower							0.96	1.42
								(1.03)	(1.43)
	Maize							-1.73***	-1.60**
								(-2.59)	(-2.37)
	Oilseed rape							-2.71***	-2.60***
								(-3.96)	(-3.73)
	Potato							0.02	0.38
								(0.02)	(0.41)
	Rice							0.94	0.95
								(1.01)	(1.02)
	Soybean							-1.79**	-1.64**
								(-2.56)	(-2.34)
	Sugar beet							omitted	omitted

	Constant	-2.42***	-148.34***	-119.00**	-115.72**	-116.11**	-114.99**	-139.27**	-135.02**
		(-5.18)	(-3.07)	(-2.38)	(-2.29)	(-2.30)	(-2.27)	(-2.26)	(-2.16)
	Pseudo R²	0.45	0.45	0.45	0.45	0.45	0.45	0.48	0.49
	Observations	1,418	1,418	1,418	1,418	1,418	1,418	1,418	1,418

Note: Robust z-n parentheses. ***, **, * indicate statistical significance at 1, 5, and 10% levels. Dependent variable is the likelihood of ‘for’ vote at SCOFCAH.

Most importantly however, we observed no substantial changes in the coefficients reflecting MS-fixed effects. MSs’ voting decisions can neither be explained by crop type nor a developers’ domicile. Foreign-based developers were involved with 62% and 65% of the votes at SCFCAH and the C/AC, respectively. It seems that the factors influencing voting decisions are related to a MS’s endogenous characteristics, which is supported by the explanatory power of our models: controlling for MS-fixed effects only, gave a pseudo-R² of 0.44. By adding the full set of explanatory variables available increases this metric marginally to 0.47, an unimportant difference (Table 5-2). Mühlböck and Tosun (2015) found that voting patterns on GE crops at Council are influenced by: (1) national interests: expressed via a combination of public opinion (public fear of GMOs); “issue salience” (agriculture’s share of total employment); and lobbying against GMOs (share of organic farming); and (2) ideology (i.e., the political party family the responsible minister voting belonged to).

We repeated the above analysis for votes cast at the SCFCAH. Our results (Table 5-3) confirmed earlier findings regarding the importance of a MS’s identity for explaining vote polarity. Coefficients reflecting MS-fixed effects are similar in magnitude to the corresponding models in Table 5-2, and they are very robust (including additional explanatory variables had a negligible effect in terms of effect size and pseudo-R^2 values). MS-fixed effects alone account for 45% of the explanatory power of the basic model; all additional qualitative models add a mere four percentage points (pseudo-R² of 0.49 in model 16, Table 5-3). We found a positive and statistically significant time trend in the likelihood for positive votes. GE crops intended for cultivation appear to have gained less support for authorization at the SCFCAH than at the C/AC. This is supported by the fact that only one GE crop has been approved for cultivation, but very few applications have been submitted for this use category (i.e., statistically a low number of observations).

There is marginal evidence for supporting imported GE crops, but this observation is neither robust nor consistently statistically significant. We also found evidence that at the SCFCAH caution was exercised for authorizing the following crops: oilseed rape, cotton, maize, and soybean.

We ran a set of robustness tests addressing the changes in the EU's growing membership over time. During the period under observation (2003-2015), the EU's membership grew by 13, potentially giving rise to a systematic change in voting outcomes. We addressed this issue by using a set of regressions that were identical to the aforementioned ones using 15 'core' MSs instead of the full panel of 28[7]. The results confirmed earlier findings: MS-fixed effects are virtually identical and pseudo-R^2 computations indicate that these MS-fixed effects explain 29% of votes alone. Additional explanatory variables increase this metric by nine percentage points. For the 15 'core' members, we found a positive time trend for the C/AC and the SCFCAH, as well as negative sentiments towards approvals for the cultivation of GE crops (SCFCAH only) and generally weaker support for GE oilseed rape.

Therefore, the current voting mechanism, despite the voting gridlock, allows for the importation of certain GE crops as food and or feed. Its slowness contributes to approval asynchrony. Developers avoid applying for authorization to cultivate GE crops in the EU. Unity in the EU concerning the approval of GE crops for their various uses, is lacking. Research is required for finding possible mechanisms for breaking the gridlock so that those MSs wishing to gain from using these innovations earlier, can do so.

5.4.1 Voting Gridlock on GE Crops

A decision by QM vote for the authorization of GE crops in the EU has been reached once; for all other ballots there was a consistent 'no opinion', i.e., a QM was not reached (Figures 5-3 and 5-4). This relentless deadlock has contributed to the slowness of the authorization process, and hence approval asynchronicity. We are interested to know if there are any MSs who have persistently contributed to this trend. Is a there a way out of this regulatory gridlock?

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[7] These results are not reported, but available on request from the authors.

We assume that each MS cast its ballot independently—uninfluenced by exogenous factors[8].

The following MSs comprised subset A (i.e., all MSs who did not vote ‘for’), in descending order (vote weight in parenthesis): France (29); Germany (29); Italy (29); Poland (27); Greece (12); Hungary (12); Austria (10); Bulgaria (10); Sweden (10); Croatia (7); Cyprus (7); Denmark (7); Lithuania (7); Slovakia (7); Latvia (4); Slovenia (4); Luxembourg (4); and Malta (3) (Agrafacts, 2014). The sum of the votes for the first four voters is 114. A minimum of six more votes is needed for a QM, i.e., for t to be reached. The next candidate in alphabetical order is Greece with 12 votes, but Hungary has the same weight, therefore both MSs are chosen as potential contributors for reaching a QM. We computed the frequency with which MSs’ negative votes could have contributed to achieving a QM for the six periods shown in Table 5-4. The results reported includes a bias towards larger EU MSs, but can be justified as coalitions are easier to achieve with a lower number of participants.

Table 5-5 shows six voting periods according to the number of EU MSs and EU voting rules. Columns 3 to 6 show the relation between the number of ‘against’ votes in relation to the total number of votes. The MSs listed are those that would be needed for a QM. Germany for example, had a weight of 11.49% (10 votes) in the first period, voting three times at the SCFCAH, always ‘against’. Germany was needed each time for achieving a QM. Italy voted ‘against’ twice in the same period and would have also been needed for getting a QM. On the other occasion, Italy voted ‘for’.

Three of the four ‘heavy-weight’ MSs, namely, France, Germany, and Italy (UK is the fourth) feature prominently in preventing a QM. Since its accession to the EU in May 2004, Poland has become an important and consistent opponent (contributor to the ‘against’ vote) due to its sizable vote weight, while Spain (Poland’s equal in vote weight (see Table 5-1)) switched to being a consistent supporter from 2007 onwards. Although the number of ballots with the latest double majority voting rule is low, early evidence reveals that the influence of Germany, France, and Italy—in this order—on achieving a QM has strengthened due to their new, larger vote weights (Table 5-4).

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[8] Note: the formation of coalitions and other tactics influencing a ballot’s outcome do not form part of this study and are investigated in on-going research on the topic.

Table 5-5. The absolute and relative frequency (%) with which MSs opposed (voted ‘against’, ‘abstain’, or were absent) the authorization of a GE crop at the SCFCAH and the C/AC from 2003-2014

Period	MS (relative vote weight (%))	Voting Body			
		SCFCAH (2003-2014)		C/AC (2004-2015)	
		MS’s Vote/No. of Ballots	Frequency (%)	MS’s Vote/No. of Ballots	Frequency (%)
1. EU15: 01.01.1995 - 30.04. 2004	Germany (11.49)	3/3	100,0	No voting took place	
	France (11.49)	1/3	33,3		
	Italy (11.49)	2/3	66,7		
	Spain (9.20)	1/3	33,3		
2. EU25: 01.05.2004 - 31.10.2004	Germany (8.06)	1/1	100,0	6/8	75,0
	France (8.06)			2/8	25,0
	Italy (8.06)	1/1	100,0	7/8	87,5
	UK (8.06)	1/1	100,0	1/8	12,5
	Poland (6.45)			4/8	50,0
	Spain (6.45)	1/1	100,0	8/8	100,0
	Belgium (4.03)			4/8	50,0
	Czech Rep. (4.03)			2/8	25,0
	Greece (4.03)	1/1	100,0	8/8	100,0
	Hungary (4.03)	1/1	100,0	4/8	50,0
	Portugal (4.03)	1/1	100,0	6/8	75,0
	Austria (3.23)			2/8	25,0
	Denmark (2.42)			1/8	12,5
	Luxemburg (1.61)			1/8	12,5
3. EU25: 01.11.2004 - 31.12.2006	Germany (9,03)	5/10	50,0	1/5	20,0
	France (9,03)	2/10	20,0		
	Italy (9,03)	10/10	100,0	5/5	100,0
	UK (9,03)			3/5	60,0
	Poland (8,41)	8/10	80,0	5/5	100,0
	Spain (8,41)	9/10	90,0	5/5	100,0
	Belgium (3,74)	1/10	10,0	1/5	20,0
	Czech Rep. (3,74)	4/10	40,0	1/5	20,0
	Greece (3,74)	7/10	70,0	2/5	40,0
	Hungary (3,74)	7/10	70,0	2/5	40,0
	Portugal (3,74)	4/10	40,0	2/5	40,0
	Austria (3,12)	3/10	30,0		
	Sweden (3,12)	3/10	30,0		
4. EU27: 01.01.2007 - 30.06.2013	Germany (8,41)	17/36	47,2	10/31	32,3
	France (8,41)	35/36	97,2	29/31	93,5
	Italy (8,41)	32/36	88,9	29/31	93,5
	UK (8,41)	3/36	8,3	3/31	9,7
	Poland (7,83)	35/36	97,2	30/31	96,8
	Spain (7,83)			5/31	16,1
	Romania (4,06)	1/36	2,8	2/31	6,5
	Netherlands (3,77)	2/36	5,6		
	Belgium (3,48)	4/36	11,1		
	Czech Rep. (3,48)	2/36	5,6		
	Greece (3,48)	6/36	16,7	5/31	16,1
	Hungary (3,48)	6/36	16,7	5/31	16,1
	Portugal (3,48)	5/36	13,9	5/31	16,1
5. EU28: 01.07.2013 – 31.10.2013	Germany (8,24)	9/9	100,0	9/9	100,0
	France (8,24)	9/9	100,0	9/9	100,0
	Italy (8,24)	9/9	100,0	9/9	100,0
	Poland (7,67)	9/9	100,0	9/9	100,0
	Greece (3,41)	3/9	33,3		
	Hungary (3,41)	3/9	33,3		
6. EU28[1]: From 01.11.2013	Germany (15,93)	1/1	100,0	4/4	100,0
	France (12,98)	1/1	100,0	4/4	100,0
	Italy (11,81)			3/4	75,0

[1] Vote weights in this category are percentages.

5.5 Discussion and Conclusion

Our statistical analysis shows that a MS’s identity (i.e., endogenous factors) is statistically the most significant factor driving voting behavior. Other factors like a GE crop’s characteristics play an unimportant role (i.e., do not influence the voting outcome—all GE crops are seen in the same light) in explaining MS voting behavior in the context of our study and assumptions. The country fixed effects are in the majority of the cases statistically significantly the most important factors explaining voting behavior. This empirical finding supports the gridlock hypotheses. We also found an overall positive time trend suggesting a persistent, but slightly weakening, gridlock. We postulate that it is unlikely in the foreseeable future for this trend to persist to the point where a QM is reached.

Results indicate that reaching a QM vote is unlikely due to the strong blocking effect of a few ‘heavy weight’ voters like France, Germany, Italy (Leech, 2002), and more recently, Poland. The latest changes to the voting rules (double majority) mean that Germany has the strongest blocking power in the EU conferring it with significant leverage for concessions with other voters (Moberg, 2007).

The status quo of not reaching a QM is likely to persist unless the likes of Germany, France, and Italy collectively change their positions to a ‘for’ vote for supporting GE crops. The 2015 proposal by the EC for MSs to ‘opt-out’ from approvals for cultivation is designed in part to “improve the process of authori[z]ations” (OJEU, 2015), i.e., facilitate an increase the number of GE crops authorized for cultivation in the Union. According to our results, this outcome is unlikely as it would require more MSs to vote in favor of approval. This would require at least two of the three heavy weights in France, Germany, or Italy to change their latest voting behavior. Importantly, it would require them to vote in favor of the most sensitive use category, namely cultivation. The strong policy signals from Germany and France against the cultivation of GE crops further supports our doubt that their voting behavior will change in the foreseeable future. Italy might be the only ‘heavy weight’ most likely to change—this is based on its historical voting behavior and the demand by some of its “pro-biotech” farmers to access the technology (Flak et al., 2013). Even if the ‘opt-out’ proposal does not result in a QM for approval, the time the EC takes after the voting at the AC might shorten as the EC might be under less pressure from MSs to delay a final decision, and can therefore justify accepting EFSA’s favorable opinions by indicating that MSs who had voted against cultivating GE crops in their countries had in fact ‘opted-out’ anyway.

The voting behavior of the EU MSs for GE plants is well established and therefore unlikely to change much because green biotechnology is such a “controversial and value-loaded” issue (Mühlbock and Tosun, 2015). Why is it so controversial and value-loaded? More in-depth research is required to understand the MS endogenous factors driving voting behavior such as: (1) the core reasons for each MS’s stance on GE plants, (2) the factors driving politicians’ voting behavior, and (3) at MS-level, the link between the public’s stance on genetic engineering and the voting behavior of its representatives at the Union. A reductionist approach is one avenue for future research to follow for revealing the underlying reasons for this voting gridlock. An improved understanding of the root causes of the gridlock has the potential for finding ways of alleviating the gridlock so that the costs caused by the current approval system will be reduced.

Finally, political-economy factors of each MS that may play a role in their voting behavior need to be investigated more deeply for providing an improved understanding of their voting behavior. We suggest that further research test the hypothesis that in the EU the political-economic benefit-cost ratio is too low for politicians to vote in favor of approving GE crops.

5.6 Appendix

Table A5-1. SCFCAH’s voting results (‘for’, ‘against’) according to each MS’s weight, and the minimum additional number of votes required for reaching a QM for authorizing GE crops for votes from December 2003-September 2014 in the EU

Plant	Event	Votes ‘For’			Votes ‘Against’	Additional votes required for a QM
		Number	Percent of maximum possible	Percent of QM		
Results for EU-15 until April 2004, maximum possible votes = 87						
Maize	Bt11	33	37.9	53.2	25	29
Maize	NK603	53	60.9	85.5	20	9
Maize	NK603	50	57.5	80.6	15	12
Results for EU-25 from May-November 2004, maximum possible votes = 124						
Rapeseed	GT73	43	34.7	48.9	57	45
Results for EU-25 from November 2004–December 2006, maximum possible votes = 321						
Maize	GA21	98	30.5	42.2	62	134
Maize	1507	116	36.1	50.0	92	116
Maize	MON863	175	54.5	75.4	52	57
Maize	1507	111	34.6	47.8	76	121
Maize	MON863xMON810	94	29.3	40.5	45	138
Rapeseed	Ms8	102	31.8	44.0	151	130
Rapeseed	Rf3	102	31.8	44.0	151	130
Rapeseed	Ms8xRf3	102	31.8	44.0	151	130
Flowers	Carnation Moonlite 123.2.38	196	61.1	84.5	49	36
Potato	EH92-527-2	134	41.7	57.8	80	98
Results for EU-27 from January 2007–June 2013, maximum possible votes = 345						
Sugar beet	H7-1	195	56.5	76.5	92	60
Maize	59122	197	57.1	77.3	79	58
Potato	EH92-527-2	123	35.7	48.2	104	132
Maize	MON863xMON810xNK603	149	43.2	58.4	90	106
Maize	MON863xMON810	149	43.2	58.4	90	106
Maize	MON863xNK603	149	43.2	58.4	90	106
Maize	GA21	155	44.9	60.8	65	100
Rapeseed	T45	146	42.3	57.3	138	109
Soybean	MON89788	160	46.4	62.7	69	95
Maize	1507	91	26.4	35.7	127	164
Maize	Bt11	91	26.4	35.7	127	164
Maize	MON88017	167	48.4	65.5	84	88
Maize	MIR604	138	40.0	54.1	99	117
Maize	1507x59122	183	53.0	71.8	83	72
Maize	59122x1507xNK603	183	53.0	71.8	83	72
Maize	MON88017xMON810	183	53.0	71.8	83	72
Maize	Bt11 (renewal)	167	48.4	65.5	84	88

Maize	MON89034xNK603	164	47.5	64.3	116	91
Maize	Bt11xGA21	164	47.5	64.3	87	91
Rice	LLRICE601	256	74.2	100.4	0	-1
Cotton	GHB 614	157	45.5	61.6	106	98
Maize	1507	183	53.0	71.8	73	72
Maize	MON89034xMON88017	154	44.6	60.4	109	101
Cotton	281-24-236x3006-210-23	192	55.7	75.3	87	63
Maize	Bt11xMIR604xGA21	180	52.2	70.6	109	75
Maize	MIR604xGA21	180	52.2	70.6	109	75
Maize	Bt11xMIR604	180	52.2	70.6	99	75
Soybean	40-3-2 (renewal)	190	55.1	74.5	80	65
Soybean	A5547-127	190	55.1	74.5	113	65
Soybean	356043	181	52.5	71.0	84	74
Soybean	MON87701	181	52.5	71.0	94	74
Soybean	MON87701xMON89788	149	43.2	58.4	87	106
Maize	MIR162	152	44.1	59.6	96	103
Maize	MON89034x1507xMON88017x59122	158	45,8	62,0	116	97
Maize	MON89034x1507xNK603	158	45,8	62,0	116	97
Results for EU-28 from July 2013-October 2014, maximum possible votes = 352						
Oilseed rape	GT73	161	45,7	61,9	103	99
Maize	T25	149	42,3	57,3	94	111
Soybean	MON87707 (dicamba)	152	43,2	58,5	101	108
Soybean	305423	161	45,7	61,9	126	99
Soybean	MON87705	149	42,3	57,3	133	111
Soybean	MON87708	149	42,3	57,3	104	111
Soybean	BPS-CV127-9	149	42,3	57,3	104	111
Maize	NK603	161	45,7	61,9	97	99
Cotton	LLcotton25xGHB614	144	40,9	55,4	130	116
Oilseed rape	MON88302	140	39,8	53,8	123	120
Cotton	MON89913	140	39,8	53,8	123	120
Results for EU-28 from November 2014, double majority voting; maximum possible votes = 100						
Soybean	MON87769	37,9	37,8	58,2	30,5	27,15

Table A5-2. C/AC’s voting results (‘for’, ‘against’) according to each EU MS’s weight, and the minimum additional number of votes required for reaching a QM for authorizing GE crops for votes from 2004-2015

Plant	Event	Votes ‘For’			Votes ‘Against’	Votes required for a QM
		Number	Percent of maximum possible	Percent of QM		
Results for EU-25 from May-November 2004, maximum possible votes = 124						
Maize	Bt11	35	28.2	39.8	29	53
Maize	NK603	53	42.7	60.2	39	35
Maize	NK603	48	38.7	54.5	36	40
Oilseed rape	GT73	30	24.2	34.1	55	58
Maize	MON863	50	40.3	56.8	47	38
Maize	1507	45	36.3	51.1	47	43
Maize	GA21	37	29.8	42.0	58	51
Maize	MON863	55	44.4	62.5	45	33
Results for EU-25 from November 2004–December 2006, maximum possible votes = 321						
Maize	MON863xMON810	133	41.4	57.3	142	99
Maize	1507	111	34.6	47.8	81	121
Oilseed rape	Ms8	124	38.6	53.4	151	108
Oilseed rape	Ms8xRf3	124	38.6	53.4	151	108
Oilseed rape	Rf3	124	38.6	53.4	151	108
Results for EU-27 from January 2007–June 2013, maximum possible votes = 345						
Flower	Carnation Moonlite 123.2.38	212	61.4	83.1	90	43
Potato	EH92-527-2	130	37.7	51.0	119	125
Potato	EH92-527-2	114	33.0	44.7	173	141
Maize	MON863xMON810xNK603	145	42.0	56.9	119	110
Maize	MON863xMON810	145	42.0	56.9	119	110
Maize	MON863xNK603	145	42.0	56.9	119	110
Maize	GA21	128	37.1	50.2	90	127
Cotton	LL25	186	53.9	72.9	109	69
Soybean	A2704-12	174	50.4	68.2	109	81
Soybean	MON89788	164	47.5	64.3	79	91
Maize	MON88017	167	48.4	65.5	84	88
Maize	MIR604	181	52.5	71.0	128	74
Maize	Bt11 (renewal)	167	48.4	65.5	84	88
Maize	Bt11xGA21	164	47.5	64.3	87	91
Maize	MON89034xNK603	164	47.5	64.3	116	91
Maize	MON89017xMON810	183	53.0	71.8	112	72
Maize	59122x1507xNK603	183	53.0	71.8	112	72
Maize	1507x59122	183	53.0	71.8	112	72
Maize	1507	186	53.9	72.9	109	69
Cotton	GHB 614	193	55.9	75.7	106	62
Maize	MON89034xMON88017	190	55.1	74.5	109	65

Cotton	281-24-236x3006-210-23	163	47.2	63.9	87	92
Maize	Bt11xMIR604xGA21	151	43.8	59.2	109	104
Maize	MIR604xGA21	151	43.8	59.2	109	104
Maize	Bt11xMIR604	151	43.8	59.2	99	104
Soybean	40-3-2	181	52.5	71.0	80	74
Soybean	A5547-127	181	52.5	71.0	113	74
Soybean	356043	181	52.5	71.0	94	74
Soybean	MON87701	181	52.5	71.0	96	74
Soybean	MON87701xMON89789	149	43.2	58.4	87	106
Maize	MIR162	152	44.1	59.6	96	103
Results for EU-28 from July 2013-October 2014, maximum possible votes = 352						
Maize	MON89034x1507xMON88017x59122	161	45,7	61,9	123	99
Maize	MON89034x1507xNK603	161	45,7	61,9	123	99
Oilseed rape	GT73	164	46,6	63,1	101	96
Soybean	305423	161	45,7	61,9	103	99
Soybean	MON87705	161	45,7	61,9	110	99
Soybean	MON87708	149	42,3	57,3	81	111
Soybean	BPS-CV127-9	161	45,7	61,9	81	99
Maize	T25	161	45,7	61,9	103	99
Maize	NK603	161	45,7	61,9	97	99
Results for EU-28 from November 2014, double majority voting; maximum possible votes = 100						
Cotton	LLcotton25xGHB614	29,6	29,6	45,5	61,2	35,4
Cotton	MON89913	29,6	29,6	45,5	61,2	35,4
Oilseed rape	MON88302	29,6	29,6	45,5	61,2	35,4
Soybean	MON87769	38,9	38,9	59,8	61,2	26,1

Chapter 6

6 Foregone Benefits of Important Food Crop Improvements in Sub-Saharan Africa

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Abstract

A number of new crops have been developed that address important traits of particular relevance for smallholder farmers in Africa. Scientists, policy makers, and other stakeholders have raised concerns that the approval process for these new crops causes delays that are often scientifically unjustified. This article develops a real option model for the optimal regulation of a risky technology that enhances economic welfare and reduces malnutrition. We consider gradual adoption of the technology and show that delaying approval delays adoption and hence benefits, while reducing uncertainty about perceived risks of the technology. Optimal conditions for approval incorporate parameters of the stochastic processes governing the dynamics of risk. The model is applied to three cases of improved crops, which either are, or are expected to be, delayed by the regulatory process.

The benefits and costs of the crops are presented in a partial equilibrium that considers changes in adoption over time and the foregone benefits caused by a delay in approval under irreversibility and uncertainty. We derive the equilibrium conditions where the net-benefits of the technology equal the costs that would justify a delay. The sooner information about the safety of the technology arrives, the lower the costs for justifying a delay need to be, i.e., it pays more to delay. The costs of a delay can be substantial: for example, a 1-year delay in approval of the pod-borer resistant cowpea in Nigeria will cost the country about 33 M USD-46 M USD and between 100 and 3,000 lives.

Keywords: real option, foregone benefits, biotechnology, regulation, Africa, malnutrition, genetically modified organisms (GMOs), genetically engineered (GE) crops.

6.1 Introduction

> *"There is uncertainty and confusion in many of the African governments' responses to a wide range of social, ethical, environmental, trade and economic issues associated with the development and application of modern genetic engineering. The absence of an African consensus and strategic approaches to address these emerging biotechnology issues has allowed different interest groups to exploit uncertainty in policymaking, regardless of what may be the objective situation for Africa."* [African Union, 2006]

A number of new crops have been developed that address important traits of relevance to smallholder farmers in Africa (Qaim, 2016). A sizeable body of literature (see survey by Bennett et al., 2013) argues that flows in the regulatory system, partially caused by political economic considerations (Paarlberg, 2008), caused scientifically unjustified delays in the approval process for these new crops. Such delays often result in the bizarre situation where technologies that both increase consumer and producer surplus, also have the potential for meaningfully decreasing malnutrition, fail to reach the market. The objective of this paper is to assess the costs caused by those delays under uncertainty and irreversibility.

In this article we investigate three GE crops for Africa in more detail, namely disease resistant cooking banana (matoke), insect resistant cowpea, and insect resistant corn. A yield increase for those crops can improve the dietary energy supply and have a positive impact on malnutrition (Smith and Haddad, 2015).

The disease resistant banana (Kikulwe et al., 2014) and insect resistant corn (De Groote et al., 2011) have been available for field trials since the mid- to late 2000s, while the insect resistant cowpea has recently received approval for field trials in Nigeria (Addae, 2014). Although delays for the corn and banana have already been observed, further delays can be expected, including for cowpea.

Despite the clear link between agricultural productivity and malnourishment, many countries in Africa are reluctant to approve GE crops. African governments find themselves juxtaposed between the opponents and proponents of the technology.

Here, we develop a theoretical model assessing the benefits and costs of approval processes using a real option framework calling upon the “Santaniello Theorem of Irreversible Benefits” (Wesseler, 2009). The model explicitly considers the standard welfare measures of changes in producer and consumer surplus. Many studies on GE crops have focused on the economic surplus at farm, regional, or sector levels. We contribute to the literature by also considering the effects of GE crops on malnutrition, which is an effect often acknowledged (for example, Santaniello, 2005), but has received scant attention in the economic literature (notable exceptions: Vitamin A enriched rice (Stein et al. 2008; Wesseler and Zilberman, 2014), and bio-fortified cassava (Nguema et al., 2011)).

We calculate the foregone benefits caused by a delay in approval under irreversibility and uncertainty, and threshold values that would justify a delay. We consider differences in the approval time of a new crop, and derive the equilibrium conditions (where the net-benefits of the technology equal potential costs) that would justify a delay. We calibrate the model for the three crops considered to indicate the magnitude of the effects, and crucially, the economic and humanitarian consequences of delaying approvals.

The results show that about two thirds of uncertainty is sufficient to compensate for three thirds of certainty. This lowers the costs for opponents to delay the approval than for proponents to speed-up the approval process. Delays are costly and the effects on malnutrition can sometimes exceed the effects on producer and consumer surplus, and may even be much larger, especially for the case of cowpea (a protein-rich crop) as we only consider the crops’ energy content.

Our paper is structured as follows. We proceed with section 6.2 where we describe delays in the approval of GE crops in Africa. Section 6.3 outlines the benefits and costs of delaying the approval of GE crops. Section 6.4 presents our results, namely, the cost of regulatory policy, and section 6.5 is our discussion and conclusion.

6.2 Approval Delays of GE Crops in Africa

Bt cotton was the first GE crop approved for cultivation in Africa and was introduced into South Africa in 1997, followed by yellow and white corn in 1998 and 2001, respectively

(Gouse, 2014). The first field trials of GE crops in South Africa started in 1989. It took seed companies about 9 years to identify and multiply the appropriate corn varieties, a time frame that is usual in plant breeding. If the private sector had approached Kenya or other African countries simultaneously, it is reasonable to expect that local corn varieties with insect- and herbicide resistance would have also been available shortly after the year 2000. In Kenya, the first varieties for release were recommended in 1998 (KARI and CIMMYT, 2003). According to Wafula and Clark (2005), the National Agricultural Research Organisation of Uganda (NARO) submitted applications to the Uganda National Council for Science and Technology (UNCST) in 2000 to introduce Bt cotton and Bt corn, but their approval for confined field trials was denied. One of the reasons the UNCST gave was that Uganda was unprepared to handle GE crops because it lacked a national biotechnology and biosafety policy. The progress of the Insect Resistant Maize for Africa Project (IRMA) was similarly delayed by regulatory issues (KARI and CYMMIT, 2007).

In Kenya, under the IRMA (started in 1999) (KARI and CYMMIT, 2005) and the Water Efficient Maize for Africa (WEMA) (started in 2008) projects for insect and drought resistant corn varieties are under development with field trials at different stages. Kenya banned the import and cultivation of GE crops in 2012 due to health concerns (Snipes and Kamau, 2012), but is currently considering removing the ban (Gebre, 2016). If the development of this crop under the IRMA project had proceeded as planned, the first varieties would have appeared on farmers’ fields in 2006 (KARl and CIMMYT, 2005).

In Uganda, field trials with black sigatoka (also known as black leaf streak) resistant matoke started in 2007 (Falck-Zapeda et al., 2013b). A bacterial wilt resistant matoke is under development. Field trials have been in place since 2011 (Meldolesi, 2011), and its release to farmers is expected in 2020.

Research in Benin, Niger, and Nigeria (under the coordination of the AATF) to develop cowpea resistant to pod borers started in 2008. Confined field trials commenced in 2010, and it is expected that seeds will be available for farmers by 2017, subject to approval from regulatory agencies (AATF, 2012). An overview about the regulatory status of the three crops considered is presented in Table 6-1.

Table 6-1. An overview about the regulatory status of cowpea, white corn, and matoke in selected African countries

Country	Benin, Niger, Nigeria [1]	Kenya [2,3]	Uganda [4]
Crop	Cowpea (*Vigna unguiculata*)	White corn	Matoke
Trait	Insect resistance	Insect resistance, stress tolerance	Black sigatoka resistance, bacterial wilt resistance
Genetic Event/Genes Introduced	Cry1Ab	Examples: MON810, Event 176, Event 5207	Chitinase gene (black sigatoka), hypersensitivity response-assisting protein (Hrap) gene from sweet pepper (bacterial wilt).
Partners Involved	AATF, CSIRO, IAR, IITA, INERA, Monsanto Company, NARS, NGICA, The Kirkhouse Trust	AATF, KALRO (former KARI), CIMMYT, Monsanto Company, University of Ottawa, NARS, Syngenta Foundation, Rockefeller Foundation, USAID	Academia Sinica, NARO, IRAZ, IITA, Public and private tissue culture laboratories in the Great Lakes region of Africa including Burundi, Democratic Republic of Congo, Kenya, Rwanda, Tanzania and Uganda
Regulatory Status	Confined field trials since 2011	National Performance Trials (NPT) since 2004	Confined field trials since 2007
Expected Release [a]	2017 [b]	Since 2006 [c]	Since 2007 [d] 2020
Country Policy	Cartagena Protocol signed in 2000	Cartagena Protocol signed in 2000 National cultivation and import ban since 2012	Cartagena Protocol signed in 2000

Sources: references 1-4 below and project websites: http://aatf-africa.org/

[1] AATF (2016)

[2] KARI and CIMMYT (2007)

[3] KARl and CIMMYT (2005)

[4] Falck-Zepeda et al. (2013b)

[a] Expected release refers to reports. As none has been released so far early dates indicate regulator delays.

[b] Expected by 2017 depending on regulatory approval.

[c] According to KARI and CIMMYT, first varieties should have reached farmers field by 2006, while first recommendations for release have been submitted in 1998.

[d] The status of the black sigatoka resistant banana is unknown. Several experts involved in the research as well as the deregulation had been contacted.

For the bacterial wilt resistant banana confined field trials are undertaken and release to farmers is expected for 2020.

Acronyms:

AATF: African Agricultural Technology Foundation
CIMMYT: International Maize and Wheat Improvement Center
CSIRO: Commonwealth Scientific and Industrial Research Organisation
IAR Institute of Agricultural Research, Zaria, Nigeria
IITA: International Institute of Tropical Agriculture
INERA: Institut de l'Environnement et de Recherches Agricoles, Burkina Faso
IRAZ: Institut de recherche agronomique et zootechnique
KALRO: Kenya Agricultural and Livestock Research Organisation
NARO: National Agricultural Research Organisation of Uganda
NGICA: Network for the Genetic Improvement of Cowpea for Africa
NARS: National Agricultural Research Systems in target countries of west Africa

Table 6-2. Benefits and costs of GE crops considered

Crop	Banana	Cowpea	Corn
Country	Uganda [1]	Benin, Niger, Nigeria [2]	Kenya [3]
Traits	Disease resistance (black sigatoka, bacterial wilt)	Pest resistance (maruca pod borer)	Pest resistance (stem borers)
Benefits	Reduced damage loss, better quality	Reduced damage loss, less mycotoxins	Reduced damage loss, less mycotoxins
Δ Yield/ha	2.0t (20%)	12.5%	0.06-0.3t
Δ Rev/ha	280-450 USD		10-55 USD
Δ PS/a	280-360 M USD	-61-186 M USD	2.0-16.1 M USD
Δ CS/a		-31-77 M USD	4.0-32.2 M USD
Δ TS/a	280-360 M USD	90-154 M USD	6.0-48.3 M USD
K-Shift	0.16 (19.8%)	0.10 (12.5%)	0.11 (13.4%)

Note: Results derived from the studies mentioned for each country in the superscript.
[1] Kikulwe et al. (2014)
[2] Gbègbèlègbè et al. (2015)
[3] De Groote et al. (2011)

Further, Benin, Kenya, Niger, Nigeria, and Uganda signed the Cartagena Protocol in 2000 (Secretariat of the Convention on Biological Diversity, 2016). The interpretation at national level is that they must first have a biosafety law in place before approving GE crops for cultivation. The protocol does, however, provide exemptions under Article 11 in cases where countries have not yet passed a biosafety law (Falck-Zepeda et al., 2013c). In Africa, the development of a biosafety law is used as an instrument in the political process to delay the introduction of GE crops. As long as a national biosafety law has not been passed, a GE crop will not be approved for cultivation in a given country. This has been well documented for Kenya and Uganda (see above). It is reasonable to expect that similar issues will arise in Benin, Niger, and Nigeria.

6.3 Benefits and Costs of Delay

We are interested in the minimum additional costs that policy makers implicitly perceive would justify postponing the introduction of the crops considered. The model used is explained in detail in **Chapter 2.5.2**: The General Analytical Model. In particular, we assume that the policy makers know with certainty the benefits of the crops in terms of consumer and producer surplus, and malnourishment, but are uncertain about the wider impact. Those uncertainties are modelled as a random shock. Thus, to account for this uncertainty there is a threshold of the benefit from the use of the technology one period earlier that has to be exceeded at each moment in order to approve the technology for use—otherwise the regulator should delay the decision by one or more periods to gain more information. We computed that this threshold of benefits is the expected cost of earlier adoption multiplied by a coefficient that is decreasing as the variability of the cost affecting the random shock is increasing (see **Chapter 2.5.2**, eq. 2-19). Our analysis shows that for a delay in approval, the increase in benefit by one dollar requires only an increase in the cost of adoption about two thirds of a dollar. Thus, the tendency to over-regulate the technology may be explained by the low cost of regulation relative to the benefit of adopting the technology.

The expected economic benefits of cultivating Bt corn (De Groote et al., 2011), Bt cowpea (Gbègbèlègbè et al., 2015), and disease resistant bananas (Kikulwe et al., 2014) are expected to be substantial. The total surplus reported by studies using partial equilibrium models range from 280-360 M USD, 90-154 M USD, and 6-48 M USD, for bananas, cowpea, and corn, respectively. We use this information and apply the linear supply and demand model with a logistic adoption function (see **Chapter 2.5.2**) to calculate the expected average annual consumer and producer surplus. We report the results for a range of supply and demand elasticities commonly found in the literature for these crops (Magrini et al., 2016; Kumar et al., 2011) (Table A6-3). If not mentioned otherwise, results are reported for short-run own demand and supply elasticity of -0.3 and 0.6, respectively.

6.3.1 The Country-level Cost of Stunting and Benefits of Crop Improvement

The changes in consumer and producer surplus exclude additional benefits that might arise due to changes in malnutrition. Assessing those benefits requires information about malnutrition and related costs. We measure effects on malnutrition by using changes in stunting, as those are well documented. Stunting reflects a failure of the human body to reach linear growth potential because of suboptimal health and or nutritional conditions. Stunting at national level represents the percentage of children below the age of 5 years with more than minus two standard deviations below the median height-for-age of the World Health Organization (WHO) Child Growth Standards (UNICEF, 2013).

Table 6-3 gives an overview of malnutrition in the five countries we consider, and forms part of the data we use for calculating changes in malnutrition. More than 10% of stunted children worldwide live in these countries. Nigeria has the worst situation with more than 11 M stunted children, followed by Kenya and Uganda. The situation is worse in rural than in urban areas, except in Niger.

Table 6-3. Status of malnourishment in Benin, Niger, Nigeria, Kenya, and Uganda for the year 2011 (UNICEF, 2013)

Country →	Benin	Niger	Nigeria	Kenya	Uganda
Crop →	Cowpea			Corn	Matoke
Children below six (thousand)	1,546	3,196	27,195	6,805	6,638
Stunting [a] (percent of children below 5 years of age)	43 (<1)	51 (1.0)	41 (6.8)	35 (1.5)	33 (1.4)
Children stunted (thousand)	572	1,585	10,029	1,839	2,318
Children stunted rural areas (thousand)	337	763	5,938	1,015	1,405
Consumption (kg / head and year of crop)	9 [b]	1.5 [b]	18 [b]	98 [c]	300 [d]
Consumption increase (kg / year)	2.25	0.375	4.5	14	60
Calories supplied by yield increase / year	2,610	435	5,220	51,100	53,400
Percent of demand ≅ effect on stunting in percent [e]	0.51	0.09	1.02	10.00	10.48
Current costs of stunting (M USD / year)	572	1,585	10,029	1,839	2,318
Current costs of stunting in rural areas (M USD / year)	337	763	5,938	1,015	1,405
Cost reduction (M USD / year)	1.72	0.65	60.66	101.54	146.83
Cost reduction (M USD / year) [f]	0.48	0.18	16.85	10.53	15.23

Note: Current costs per country estimated by 1,000 USD per stunted child.

[a] Number in brackets indicate world share.

[b] Mamiro et al. (2011). Grams per day per household multiplied by 365 and divided by five members per household, providing a range between 2.99 and 14.60 kg per year. A value of 10 kg per year was chosen.

[c] ACDI/VOCA (2016)

[d] Englberger et al (2003)

[e] Gómez (2004)

[f] Based on estimations by Smith and Haddad (2015).

Calculating the costs related to stunting is not a trivial exercise. The costs include those related to early childhood death and losses in labor productivity. We use the number provided by The World Bank (Shekar, 2013) on productivity losses caused by stunting for Africa and Asia of 1,000 USD per child below the age of 5 years (present value). The details of our calculations are provided in **Section 6.6.1** of the **Appendix: Calculating the Costs of Stunting.** The current costs of stunting in rural areas (M USD per year) are very much on the low side. Other estimations show much higher costs (World Food Programme, 2014).

6.4 Results: The Cost of Regulatory Policy

A delay in approval results in welfare losses due to foregone benefits. In our analysis, the foregone benefits include: foregone consumer and producer surplus, and foregone reductions in malnutrition (measured as reduced stunting among children). The results shown in Figure 6-1 and in Table A6-1, assume an immediate introduction of the GE crops and report the resultant consumer and producer surplus, plus the benefits of reduced stunting. In general, the consumer surplus is twice as large as the producer surplus due to the following assumptions: η (elasticity of demand) is -0.3 and ε (elasticity of supply) is 0.6. The total surplus (NPV) is the largest for GE matoke in Uganda with about 1,300 M USD, followed in descending order by: cowpea in Nigeria with about 710 M USD; corn in Kenya with about 475 M USD; and cowpea in Niger and in Benin with about 375 M USD and about 47 M USD, respectively. The average annual consumer and producer surplus is reported in Table 6-4.

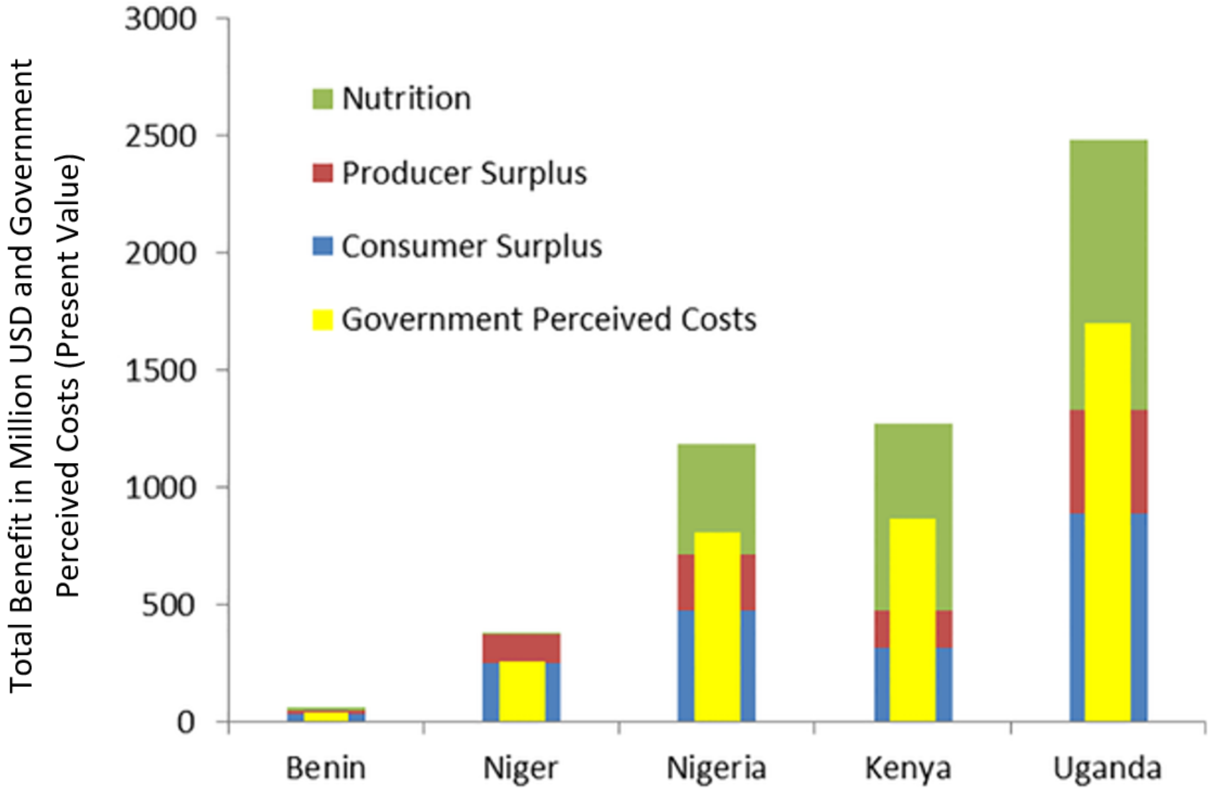

Figure 6-1. Consumer and producer surplus, benefits of reduced malnutrition, minimum amount of government perceived costs for a 1-year delay in approval (M USD).
Note. Parameter values: adoption ceiling of 40% after 20 years; discount rate r = 0.04; d = 0.5; elasticity of supply ε = 0.6, elasticity of demand η = -0.3.

Table 6-4. Foregone benefits (consumer and producer surplus, benefits of reduced malnutrition) for a 1- and 10-year delay in approval (M USD)

Country →	Benin		Niger		Nigeria		Kenya		Uganda	
Crop →	Cowpea						Corn		Matoke	
Delay →	1-year	10-year	1-year	10-year	1-year	10-year	1-year	10-year	1-year	10-year
Foregone: - consumer surplus	1.23	10.33	9.82	82.60	18.65	156.80	12.42	104.46	34.87	293.16
- producer surplus	0.61	5.17	4.91	41.30	9.32	78.40	6.21	52.23	17.43	146.58
- total surplus	1.84	15.50	14.74	123.91	27.97	235.19	18.64	156.69	52.30	439.74
- reduced stunting	0.53	4.44	0.20	1.68	18.61	156.49	31.16	261.96	45.05	378.78
- reduced stunting ^{SH}	0.15	1.23	0.06	0.47	5.17	43.47	3.23	27.17	4.67	39.28
Total	2.37	19.93	14.94	125.58	46.58	391.68	49.79	418.65	97.35	818.52
Total ^{SH}	1.99	16.73	14.79	124.37	33.14	278.66	21.87	183.86	56.97	479.02

Note: Parameter values: adoption ceiling of 40% after 20 years; discount rate r = 0.04; d = 0.5; elasticity of supply ε = 0.6, elasticity of demand η = -0.3.
The superscript SH denotes calculation for malnutrition based on Smith and Haddad (2015).

The effect of alleviating malnutrition by using GE crops can be substantial. In Kenya, the benefits from reduced malnutrition can be larger than the total economic surplus, which may be exaggerated as a result of using the results of Smith and Haddad (2015) (refer earlier about the worst-case-scenario). The benefits from reduced malnutrition can be up to about 1,150 M USD for matoke in Uganda, followed by about 795 M USD for corn in Kenya. The effects are also substantial for cowpea in Nigeria with about 475 M USD, while they are smaller for Benin with about 13 M USD and Nigeria with about 5 M USD. The average annual benefits of reduced stunting reported in Figure 6-1 are lower than those in Table 6-3 as adoption over time has been taken into consideration (40% ceiling reached after 20 years) for the former.

The minimum perceived costs by national governments that would justify a delay from a welfare economic viewpoint are lower than the welfare benefits. They are about 68% (based on the following: discount rate of 0.04, value of d = 0.5, demand elasticity of -0.3, supply elasticity of 0.6, and an adoption ceiling of 40% reached after 20 years) (see Figure 6-1). Outcomes by crop, country, and method used to calculate the effect on malnutrition, vary substantially. The methodology for calculating the effects on malnutrition has a strong impact on the results for Kenya (GE corn) and Uganda (GE matoke). The minimum perceived costs are the lowest for Benin (about 40-48 M USD), and the highest for Uganda (ca. 1,160-1,983 M USD). The perceived costs increase with an increase in the time of delay, for example, an increase in delay from 1-10 years increases the perceived costs, c.p., by about 17% (Table A6-

1). Placing these numbers in perspective (Figure 6-2) shows their importance: they are similar to Niger's health budget and more than three times Uganda's health budget.

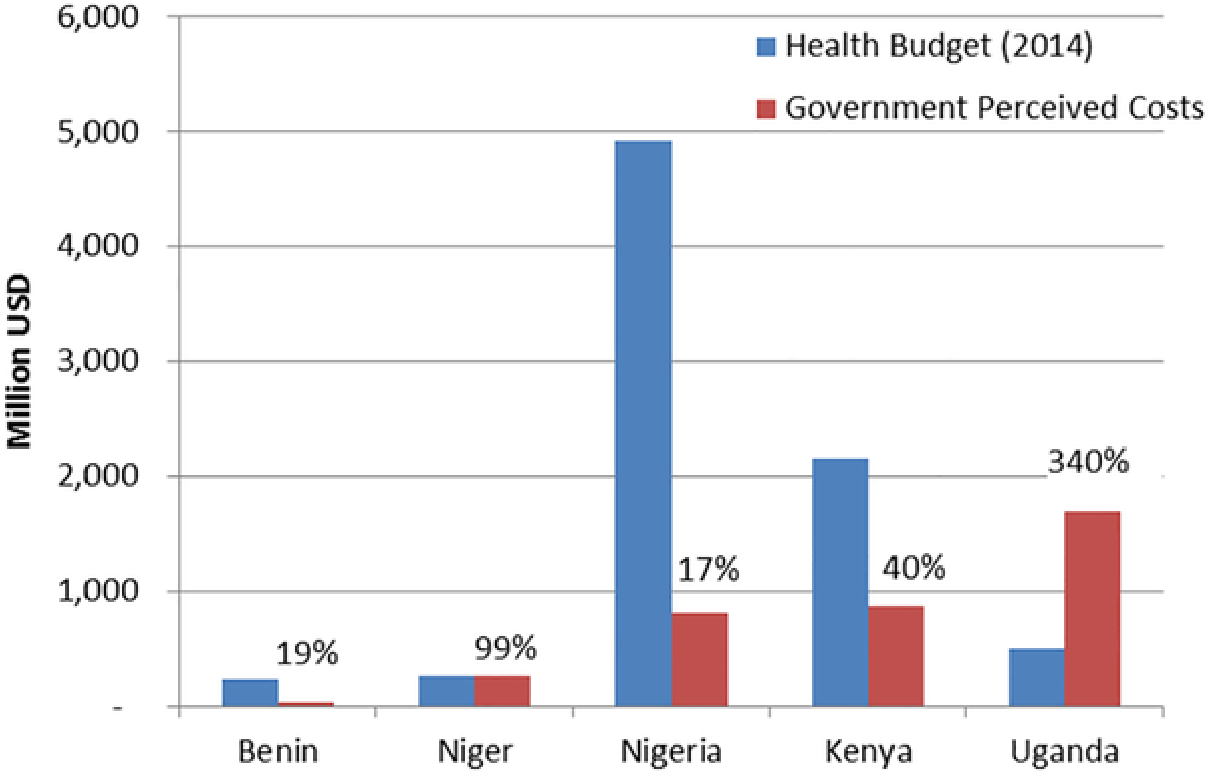

Figure 6-2. Comparing government perceived costs with health budget of 2014 (The World Bank, 2017a). Note. Parameter values: adoption ceiling of 40% after 20 years; discount rate r = 0.04; d = 0.5; elasticity of supply ε = 0.6, elasticity of demand η = -0.3.

Table 6-4 reports the forgone benefits caused by delays in approval, which range between ca. 2 M USD and 97 M USD, and ca. 17 M USD and 818 M USD for a 1- and 10-year delay, respectively. As with the share of benefits from reduced malnutrition, the share of foregone benefits of reduced malnutrition can be substantial. In Kenya (similar to the results reported above), these benefits can be larger than the foregone economic surplus.

Figure 6-3 and Table A6-2 report the results of changes in the adoption ceiling, as well as the speed of adoption expressed in lives lost, which illustrate the effects of the GE crops on food deficient households. We report results for 40, 80, and 100% adoption ceilings and two rates of adoption: ceiling reached after 20 and 10 years, respectively. The number of lives lost by delaying the introduction range between about 200 and 5,500, depending on the speed of adoption, adoption ceiling, and the method used for calculating malnourishment. The results illustrate that a higher adoption ceiling has a much stronger effect on the death toll than a higher adoption rate (Figure 6-2).

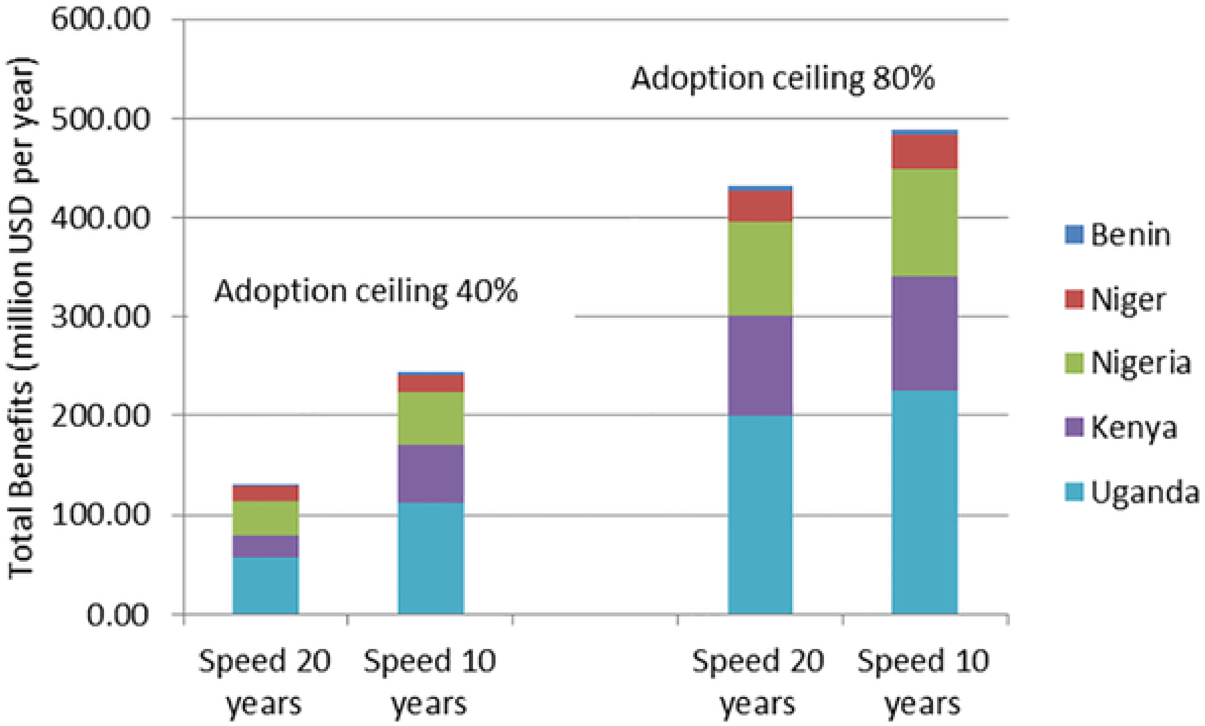

Figure 6-3. Comparison of doubling the speed of adoption and the ceiling of adoption. Note. Parameter values: discount rate $r = 0.04$; $d = 0.5$; elasticity of supply $\varepsilon = 0.6$, elasticity of demand $\eta = -0.3$. See Table A6-3 for different elasticities.

The effect of the length in delay, as well as changes in the discount rate for different levels of d on the perceived government costs, are displayed in Figure 6-4. The share of perceived costs needed to compensate one unit of welfare benefits decreases with an increase in d at a decreasing rate. The effect of a marginal change in the discount rate is the same as a marginal change in the length of the delay (see **Chapter 2.5.2**, eq. 2-19). The lower the value of d, the larger the effect of marginal changes in d (i.e., a relatively high elasticity) on changes in the perceived costs of the government.

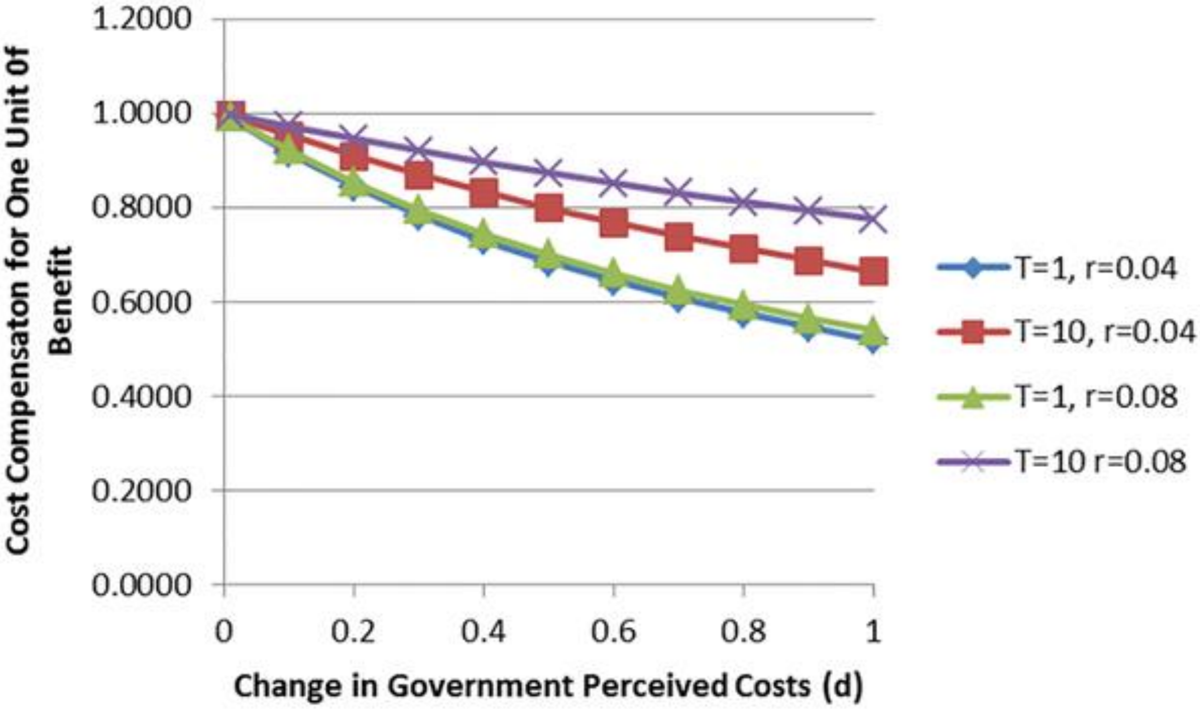

Figure 6-4. Effect of changes in government perceived costs (d) on cost needed to compensate for one unit of benefit for different discount rates, r, and length in delay, T.

The effects of delaying the introduction of a GE crop on foregone benefits also depend on the demand- and supply elasticities. The results reported so far were based on a demand elasticity of -0.3 and a supply elasticity of 0.6. Foregone benefits have also been calculated for lower and higher elasticity values (Table A6-3). In general, we observe that a change in the demand elasticity has a less pronounced effect than a change in the supply elasticities. Overall, the effect of changes in the elasticities on foregone benefits are less pronounced than changes in adoption ceiling.

6.5 Discussion and Conclusion

For opponents of the technology, announcing uncertainty about the GE crops shortly before decisions are to be made about them can be an effective tool for delaying their introduction. High uncertainty reduces the perceived costs needed (about two thirds) to compensate for one unit of welfare benefits. This eases the opponents' success in delaying approval compared to the proponents' efforts at speeding up the approval process. This finding also applies to cases not discussed by us and to the approval process for GE crops in general. Delays in approval have been observed for countries outside of Africa too (Smart et al., 2017; Herring 2015). The results further support the findings by Tosun et al. (2016) that show opponents compared with proponents of GE crops time their activities better, have much larger networks, and are more active.

Few studies have investigated the costs of a delay. Most ex-ante studies identify the benefits and costs of the introduction of a new GE crop, which are different to those of a delay. Nevertheless, estimating producer and consumers surplus is an important step. The producer and consumer surplus we report for the three crops are somewhat lower than those reported by others (De Groote et al., 2011; Kikulwe et al., 2014; Gbègbèlègbè et al., 2015) because of the specification we chose. In comparison to previous studies on the benefits and costs of GE crops, we include their effect on malnutrition, which we show can be substantial. For Kenya, the effect on malnutrition can even be larger than the effect on producer and consumer surplus. This illustrates that in countries where malnutrition is of importance the effect should be considered in the analysis of welfare effects. This further illustrates that the effect on malnutrition of GE crops and other yield increasing strategies deserve attention, so that their economic and humanitarian effects are not underestimated.

Kenya and Uganda (and many other African countries) had the chance to follow South Africa's example of adopting GE crops. If Kenya had adopted GE corn in 2006—according to the reports of the IRMA project this was possible—between 440 and 4,000 lives could theoretically have been saved. Similarly, Uganda had the possibility in 2007 to introduce the black sigatoka resistant banana, thereby potentially saving between 500 and 5,500 lives over the past decade. The introduction of Bt cowpea was expected to have been in 2017 in Benin, Niger, and Nigeria. The AATF had already [in 2016] indirectly expressed concerns about reaching this goal by explicitly mentioning the phrase: "depending on approvals" (AATF, 2017). A 1-year delay in approval would especially harm Nigeria, as malnourishment is widespread there. The consumption of cowpea per capita is higher than in both Benin and Niger. A 1-year delay is estimated to cost Nigeria about 33-46 M USD and between 100 and 3,000 lives.

Our results might have underestimated the cost of delay, especially in evaluating the benefit of adopting insect resistant cowpea, as we only consider the energy content of this crop. Further, environmental and health benefits from reduced pesticide use for pest and disease control are not explicitly included—an important area for future research.

Nevertheless, our results show that delaying the approval of GE crops not only reduces consumer and producer surplus of households (mainly in rural areas), but importantly, it also costs human lives. We have expressed the effects of a 1-year delay on lives lost. The death toll can be substantial. Reducing the approval time of GE crops results in generating economic gains, potentially contributing to reducing malnutrition and saving lives, and can be an inexpensive strategy for reaching the Sustainable Development Goal of eradicating malnutrition by 2030.

Unfortunately, the use of GE crops has been very controversial. African governments are in the dilemma as they face contradicting statements from international organizations. While those organizations (for example, the United Nations (FAO, 2013)) stress the importance of addressing malnutrition and urge countries to use modern biotechnology, they concurrently warn about the environmental risks of using the technologies (Sekanjako, 2016). Unsurprisingly, governments are uncertain about which is the right strategy to follow. We have calculated the economic value of this uncertainty, which is substantial and costs lives. As already mentioned, about two thirds of uncertainty are sufficient to compensate for three thirds of certainty.

6.6 Appendix

6.6.1 Calculating the Costs of Stunting

Step one is to compute the contribution of crop improvements to reducing stunting. This is done by adding the percentage increase in yield (by assuming a linear relationship between yield increase and consumption increase at household level) to the average annual consumption in kg per head and country of the respective crops. The average annual consumption per head of matoke bananas in Uganda is about 300 kg (Englberger et al., 2003), while that of corn is about 98 kg in Kenya (ACDI/VOCA, 2016), and that of cowpea covers a wide range from a low of 1.5 kg in Niger followed by 9 kg in Benin to a high of 18 kg in Nigeria (Gómez, 2004). These data are used to compute the increase in consumption per head and year, which range for cowpea from 0.38 kg in Niger, 2.25 kg in Benin, and 4.50 kg in Nigeria to 60 kg for matoke in Uganda, and 98 kg for corn in Kenya.

Step two involves multiplying the number of calories per kg by the average increase in kg per head, which provides the additional calories per year added, ranging from a low of 435 calories for Niger to a high of 53,400 calories for Uganda. The percentage of those additional calories on average calorie demand by children below 5 years of age and year of 511,000 calories is used as the indicator of the percentage reduction in stunting. The annual proportional effect on stunting in ascending order is: 0.09, 0.51, 1.02, 10.00, and 10.48% for Niger, Benin, Nigeria, Kenya, and Uganda, respectively.

We weigh the percentage reduction in stunting by the share of rural stunted population on total population by country. The current costs of stunting using a value of 1,000 USD per year and child stunted (Shekar, 2013) are about 572 M USD for Benin and up to 10,029 M USD for Nigeria, where in the rural areas it ranges between 337 M USD and 5,938 M USD. The annual reduction in the costs of stunting, assuming full adoption, using the increase in calorie supplies mentioned earlier are about 0.54, 0.20, 18.99, 57.55, and 45.96 M USD for Benin, Niger, Nigeria, Kenya, and Uganda, respectively.

The procedure for calculating the costs of stunting may create biases as the contribution from banana and corn might be overestimated, as calories are but one component of a healthy diet. Further, cowpea is poor in calories, but rich in protein, thus contributing to increasing dietary diversity. As an alternative to assess the contribution to reduce stunting, we use the results provided by Smith and Haddad (2015) (SH), who estimate the strength of six underlying determinants on child stunting per capita dietary energy supply from what they call staple and non-staple foods, using unbalanced panel data. They find that on average, an increase of 135 calories from staple foods and a 3.5% increase in calories from non-staple foods would reduce stunting by 1%. Using these results, the effects of an increase in the supply of cowpea was considered as a non-staple food, and an increase in the supply of banana and corn was valued as a staple food (see Table A6-3, last row). Based on this approach, the contribution to reduce stunting is lower by a factor of 10 for banana and corn, and a factor of about four for cowpea. Hence, the relative importance of cowpea has increased. Based on this approach, Nigeria would gain the most, followed by Uganda and Kenya. The substantially lower effect on stunting can partially be explained by the fact that the results by SH were based on the total population, while our approach only considers children, which require a substantially lower (about a half) relative energy intake than adults. Further, SH consider changes in total food supply to be distributed among malnourished and other persons. Finally, the estimations are based on more than a hundred countries and are reported as averages. The five countries we consider have an above average share of malnourished children—covering more than 10% of the world’s total number of malnourished children. Hence, using SH’s results is somewhat of a worst-case scenario.

Table A6-1. Consumer and producer surplus, benefits of reduced malnutrition, minimum amount of government perceived costs for a 1- and 10-year delay in approval (M USD) (note: numbers in brackets show average annual values)

<table>
<tr><th>Country →</th><th></th><th colspan="2">Benin</th><th colspan="2">Niger</th><th colspan="2">Nigeria</th><th colspan="2">Kenya</th><th colspan="2">Uganda</th></tr>
<tr><td>Crop →</td><td></td><td colspan="6">Cowpea</td><td colspan="2">Corn</td><td colspan="2">Matoke</td></tr>
<tr><td>Benefits:</td><td>- consumer surplus</td><td colspan="2">31.33 (1.25)</td><td colspan="2">250.56 (10.02)</td><td colspan="2">475.60 (19.02)</td><td colspan="2">316.86 (12.67)</td><td colspan="2">889.23 (35.57)</td></tr>
<tr><td></td><td>- producer surplus</td><td colspan="2">15.67 (0.63)</td><td colspan="2">125.28 (5.01)</td><td colspan="2">237.80 (9.51)</td><td colspan="2">158.43 (6.34)</td><td colspan="2">444.61 (17.78)</td></tr>
<tr><td></td><td>- total surplus</td><td colspan="2">47.00 (1.88)</td><td colspan="2">375.84 (15.03)</td><td colspan="2">713.40 (28.54)</td><td colspan="2">475.29 (19.01)</td><td colspan="2">1,333.84 (53.35)</td></tr>
<tr><td></td><td>- reduced stunting</td><td colspan="2">13.46 (0.54)</td><td colspan="2">5.08 (0.20)</td><td colspan="2">474.66 (18.99)</td><td colspan="2">794.58 (31.78)</td><td colspan="2">1,148.94 (45.96)</td></tr>
<tr><td></td><td>- reduced stunting ^{SH}</td><td colspan="2">3.74 (0.15)</td><td colspan="2">1.41 (0.06)</td><td colspan="2">131.85 (5.27)</td><td colspan="2">82.40 (3.30)</td><td colspan="2">119.15 (4.77)</td></tr>
<tr><td colspan="2">Total</td><td colspan="2">60.46 (2.42)</td><td colspan="2">380.92 (15.24)</td><td colspan="2">1,188.06 (47.52)</td><td colspan="2">1,269.87 (50.79)</td><td colspan="2">2,482.78 (99.31)</td></tr>
<tr><td colspan="2">Total ^{SH}</td><td colspan="2">50.74 (2.03)</td><td colspan="2">377.25 (15.09)</td><td colspan="2">845.25 (33.81)</td><td colspan="2">557.69 (22.31)</td><td colspan="2">1,452.99 (58.12)</td></tr>
<tr><td colspan="2">Perceived Government Costs (1- and 10-year delay)</td><td>41.34</td><td>48.29</td><td>260.50</td><td>304.23</td><td>812.48</td><td>948.89</td><td>868.43</td><td>1,014.23</td><td>1,697.89</td><td>1,982.95</td></tr>
<tr><td colspan="2">Government Perceived Costs (1- and 10-year delay) ^{SH}</td><td>34.70</td><td>40.52</td><td>257.99</td><td>301.30</td><td>578.04</td><td>675.09</td><td>381.39</td><td>445.42</td><td>993.65</td><td>1,160.48</td></tr>
</table>

Parameter values: adoption ceiling of 40% after 20 years; discount rate r=0.04; d=0.5; elasticity of supply ε=0.6, elasticity of demand η=-0.3.
Superscript SH denotes calculation for malnutrition based on Smith and Haddad (2015).

Table A6-2. Costs of stunting from a 1- and 10-year delay in relation to adoption ceilings and speed of adoption

Country →	Benin			Niger			Nigeria				Kenya			Uganda			Total	
Crop →	Cowpea										Corn			Matoke				
Adoption Ceiling (%)	40	80	100	40	80	100	40	80	100	40	80	100	40	80	100	40	80	100
Adoption Ceiling after 20 Years (1-year delay)																		
Lives lost	9	18	22	3	7	9	355	709	886	505	1,010	1,262	761	1,522	1,902	1,633	3,266	4,082
Lives lost ^{SH}	2	5	6	1	2	2	98	197	246	52	105	131	79	158	197	233	466	583
Adoption Ceiling after 10 Years (1-year delay)																		
Lives lost	10	20	25	4	8	10	401	803	1,003	572	1,143	1,429	862	1,723	2,154	1,849	3,697	4,621
Lives lost ^{SH}	3	6	7	1	2	3	111	223	279	59	119	148	89	179	223	264	528	660
Adoption Ceiling after 20 years (10-year delay)																		
Lives lost	75	150	187	29	57	72	2,981	5,961	7,452	4,246	8,491	10,614	6,398	12,767	15,996	13,728	27,456	34,320
Lives lost ^{SH}	21	42	52	8	16	20	828	1,656	2,010	440	881	1,101	664	1,327	1,659	1,961	3,921	4,901
Adoption Ceiling after 10 Years (10-year delay)																		
Lives lost	85	169	212	32	65	81	3,375	6,749	8,437	4,807	9,614	12,017	7,244	14,488	18,110	15,543	31,085	38,857
Lives lost ^{SH}	24	47	59	9	18	23	937	1,875	2,344	498	997	1,246	751	1,502	1,878	2,220	4,439	5,549

Parameter values: discount rate r=0.04; d=0.5.

Lives lost calculated by dividing reduced stunting costs by the life-expectancy per country in years (Benin: 59.3; Niger: 58.4; Nigeria: 52.5; Kenia: 61.7; Uganda: 59.2 (The World Bank, 2017b) times 1,000 USD for the value of a disability-adjusted-life-year (DAILY).

Superscript SH denotes calculation for malnutrition based on Smith and Haddad (2015).

Table A6-3. Costs of a 1-year delay (M USD) per year for different elasticities

Country →	Benin			Niger			Nigeria			Kenya			Uganda		
Crop →	Cowpea									Corn			Matoke		
Demand elasticity	-0.1	-0.3	-0.5	-0.1	-0.3	-0.5	-0.1	-0.3	-0.5	-0.1	-0.3	-0.5	-0.1	-0.3	-0.5
Supply elasticity	0.4	0.6	0.8	0.4	0.6	0.8	0.4	0.6	0.8	0.4	0.6	0.8	0.4	0.6	0.8
Benefits: - consumer surplus	0.98	1.23	1.52	7.84	9.82	12.13	14.89	18.65	23.02	9.92	12.42	15.34	27.80	34.87	43.11
- producer surplus	0.25	0.61	0.95	1.96	4.91	7.58	3.72	9.32	14.39	2.48	6.21	9.59	6.95	17.43	26.95
- total surplus	1.23	1.84	2.46	9.80	14.74	19.71	18.61	27.97	37.41	12.40	18.64	24.93	34.75	52.30	70.06
- reduced stunting	0.53	0.53	0.53	0.20	0.20	0.20	18.61	18.61	18.61	31.16	31.16	31.16	45.05	45.05	45.05
- reduced stunting ^{SH}	0.15	0.15	0.15	0.06	0.06	0.06	5.17	5.17	5.17	3.23	3.23	3.23	4.67	4.67	4.67
Total	1.75	2.37	2.99	10.00	14.94	19.91	37.22	46.58	56.02	43.55	49.79	56.08	79.80	97.35	115.11
Total ^{SH}	1.37	1.99	2.61	9.86	14.79	19.76	23.78	33.14	42.58	15.63	21.87	28.16	39.42	56.97	74.73
Government perceived costs	30.59	41.34	52.19	174.47	260.50	347.19	649.18	812.48	977.04	759.60	868.43	978.15	1391.84	1697.89	2007.67
Government perceived costs ^{SH}	23.94	34.70	45.54	171.96	257.99	344.68	414.74	578.04	742.60	272.56	381.39	491.11	687.60	993.65	1303.43

Calculations based on a discount rate of r= 0.04, a change in perceived costs of d=0.5; and a delay of T=1 year.
Superscript SH denotes calculation for malnutrition based on Smith and Haddad (2015).

Chapter 7

7 Decomposition of Efficiency in the Global Seed Industry: A Nonparametric Approach

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Authors' contributions: Amer Ait Sidhoum and Johannes Sauer are the co-authors. Johannes Sauer provided the concept and guided the theoretical approach, and provided technical oversight. Amer Ait Sidhoum contributed material for the literature review, suggested the empirical method, oversaw and reviewed the empirical analysis, and reviewed and contributed to the final script. Richard Smart did the literature review, collected the data, conducted and interpreted the empirical analysis, and wrote the bulk of the text.

Abstract

We analyzed the efficiency levels of nine of the largest commercial seed producing firms globally for the period 2008-2015 and assessed if there is a relationship between firm size and efficiency. We employed the non-parametric technique of data envelopment analysis (DEA) using an input-oriented model with balanced panel data. We accounted for the assumption of time invariance of the frontier by using the DEA windows analysis technique. Aggregate mean overall technical efficiency increased by 0.8%. We decomposed these results to pure technical efficiency and scale efficiency, and found no meaningful relationship between firm size (assets) and efficiency.

Keywords: Data envelopment analysis (DEA); overall technical efficiency (OTE); pure technical efficiency (PTE); scale efficiency (SE); genetically engineered (GE) crop; seed firm.

7.1 Introduction

The seed industry is an integral component of the first link in the agri-food value chain, which also comprises, amongst others, the fertilizer and crop protection industries (FAO, 2019). The seed industry makes an important contribution to the sustainability of the global agri-food system and to food security. Within this food chain, the seed sector, and food processing and large-scale distribution sector, are the smallest and most important sectors (measured by sales), respectively (Bonny, 2017).

Seeds acquired by farmers for planting generally fall into two broad categories, namely commercial- (produced by seed firms) and noncommercial seed (Federico, 2005). Seeds in the former category are two to three times more expensive because of a technology fee (Bonny, 2014) as they typically have superior genetic traits, which afford their users the potential for increased productivity. The latter category comprises seeds from the plant breeding efforts of farmers (i.e., farmers' seed systems), seeds saved from conventional seeds (farm-saved seeds), and seeds from public research (scarcely sold to farmers).

The commercial seed industry comprises around 7,500 firms globally, ranging in size from very small enterprises (specialists in local, specific crops) to SMEs, to several large firms with origins in the chemical sector (exceptions are KWS and Limagrain) (Bonny, 2017).

Firms develop seeds primarily by conventional plant breeding techniques, but some firms also employ technology intensive methods, specifically transgenesis, for developing GE crops. The aforementioned comprise the formal seed sector, while the "informal seed sector comprises farmer-saved seeds … [and] seeds exchanged in local markets" (Bonny, 2014). Commercial seed firms are vertically integrated (Howard, 2009) "managing the entire production, distribution and marketing phases" (Fernandez-Cornejo and Spielman, 2002). Furthermore, the diversity of seed types and their pricing (dependent on both the crop and method of seed development), and firm profile (firm origin; offer of product mix: seeds and agrochemicals; and involvement in agricultural inputs) make the seed sector highly heterogeneous (Bonny, 2017).

In the 1990s, many developing economies, especially in South America and Africa, initiated structural reform programs to rectify macro-economic imbalances that developed in the preceding two decades. Reducing the state's role in the agricultural sector was an important feature of these reforms. Consequently, these economies' seed sectors were opened to the private sector (Cromwell et al., 1992). For example, the privatization of the seed sector in Ghana took place in 1990 "because it [was] generally accepted that the private sector would be more efficient in the production and supply of seed relative to the public sector" (Konja et al., 2019).

Since the 1980s, consolidation in the global seed sector increased through corporate activity (takeovers, M&As, cooperation agreements, and demergers), often also involving the crop protection (herbicides and pesticides) industry. The result is market concentration in this sector (Mammana, 2014; Lianos et al., 2016), which has, and continues to accord these few, large firms with perceived power and influence on global food production at the start of the agro-food chain (Bonny, 2014). The negative impacts of the increasing power of the agro-chemical-seed industry include increased seed prices and the reduced ability of farmers to save seeds (Howard, 2015). In the late 1990s, patent applications in the plant biotechnology and seed industries—mainly by these few, large firms—increased exponentially (Pray et. al., 2005b). Bonny (2014) predicted that market concentration would continue and that the focus would sharpen "on the most profitable or widely cultivated crops". Her prediction is vindicated by the merger of Dow AgroSciences and DuPont Pioneer (Dow DuPont, 2017) and the takeover of Syngenta by ChemChina (Syngenta website, 2020) in 2017, and the acquisition of Monsanto by Bayer in 2018 (Bayer website, 2020).

The market concentration of the seed industry arose from "the dynamic interplay between business strategies, scientific breakthroughs, and government policies" (Schenkelaars et al. (2011) cited by Bonny (2017)). Fernandez-Cornejo and Spielman (2002) examined the effects of industry concentration on market power and costs in the US corn seed industry. They found that the overall effect of concentration for this industry appears to be economically beneficial (during their study period), and that a strong processing-cost-reducing effect overpowers the market-power enhancing effect of concentration.

Pray et al. (2005b) point out that "concentration brings to the foreground the economic tradeoff between static efficiency and dynamic efficiency that is inherent in any R&D-based

industry. Static efficiency—the maximization of social welfare in the market (for agricultural biotechnology products such as seeds) at a specified point in time—occurs when the market structure is competitive and no firm has market power. However, the absence of market power prevents firms from recovering investments necessary to enter the market …. M&As by larger firms have increased the concentration of patent ownership much more than R&D alone.” Moreover, Brennan et al. (2005) report that the seed industry is highly concentrated. Mobility indices indicate that this concentration is persistent as the same few firms dominate the innovation market from year to year. Their concern is that the leading plant biotechnology firms have the potential to reduce the seed industry’s level of R&D activity.

Disquiet expressed by a broad spectrum from society, ranging from farmers to NGOs (see Shand, 2012), that market concentration in the seed sector devolve asymmetric power on these firms, thus giving them strong influence on the world’s food production (Bonny, 2014), supports the need for further scientific inquiry to empirically validate these concerns. According to Bonny (2014), there is “a lack of precise appraisals and analyses” for the seed sector. In 2017, she states that an “analysis of the seed sector is a particularly difficult task given the extent of partial or biased analyses, as well as a lack of data on certain aspects … the economic data are heterogeneous and sometimes non-concordant.” Additionally, she notes that representatives of seed companies involved in M&A activities justified their intentions by emphasizing that “their assets and activities were complementary, and how consolidation would lead to better efficiency and to an enhanced capacity for innovation, which in turn would benefit all stakeholders.” Separately, KWS improved efficiency throughout its seed production cycle by introducing a data integration system to streamline its order, delivery and logistics processes for better inventory management (Proagrica website, 2021). In the two preceding examples, and the notion of the private sector being more efficient than the public sector (see our earlier reference to Konja et al. (2019)), no empirical evidence is presented to support how efficiency was, or would be, improved. This lack of evidence is a gap in the literature. However, we found two reports analyzing the efficiency of seed firms in China (Liu and Huang, 2010; Hu and Dou, 2015) (the abstracts are in English, but the remainder of the texts are in Chinese). To the best of our knowledge, the efficiency of non-Chinese seed firms has not been formally analyzed, and that generally, there is a dearth of scientific literature in this domain.

Our research contributes to the small pool of formal knowledge by analyzing the efficiency levels of nine of the largest commercial seed producing firms globally for the period 2008-2015 and assessing if there is a relationship between firm size and efficiency. Firms criticized for contributing to the concentration of the global seed market are included in our study. Thus, we add empirical evidence (efficiency scores) to: (1) the debate about whether market concentration (through M&As, for example) compromises firm efficiency, and (2) whether managerial tactics like demergers or consolidating R&D activities impact firm efficiency positively.

We employ the non-parametric technique of DEA using an input-oriented model with balanced panel data spanning this period[9]. DEA windows analysis technique is used to account for the assumption of time invariance of the frontier. This method has been used to study the efficiency of, amongst others, the biotech industry (Kim et al., 2009), banks (Drake, 2001; Webb, 2003; Sufian and Majid, 2007; Řepková, 2014), hospitals (Kazley and Ozcan, 2009; Jia and Yuan, 2017), pharmaceutical firms (Al-Refaie et al., 2019), and environmental management (Zhou et al., 2020).

This chapter is organized as follows. In section 7.2 we cover the methodology that we employed and describe our dataset. In section 7.3 we present and discuss our empirical results. The paper ends with our concluding remarks in section 7.4.

7.2 Testing for Efficiency in the Seed Sector

7.2.1 Methodology

7.2.1.1 Data Envelopment Analysis

Fundamentally, efficiency is the ratio of inputs to outputs. Resources (inputs) are used by a firm in ways that minimize waste and maximize outputs for quality, cost, and production (Cooper et al., 2000). Two widely applied techniques for measuring efficiency are: (1) the econometric approach (the parametric SFA), and (2) the mathematical programming approach

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[9] An input-oriented model is used as the firms have little control over their outputs, but they have better possibilities to reduce their input use.

(non-parametric DEA) (Berger and Humphrey, 1997). The important difference between the two approaches is the way in which each method treats the random noise (Fried et al., 2008). The calculation of efficiency in SFA is based on the choice of a particular functional form, and on specific distributional assumptions of the statistical noise and the inefficiency term. Since empirical findings from a stochastic frontier are susceptible to parametric assumptions, modeling biases and incorrect inferences may arise.

The DEA framework allows for overcoming the limitation of SFA. In this study, we employ the nonparametric DEA method proposed by Charnes et al. (1978), which is known as the CCR model. Essentially, the CCR model measures the efficiency of each DMU, which is obtained as a maximum of a ratio of weighted outputs to weighted inputs. The CCR model has a precondition, namely, that there is no significant relationship between the scale of operations and efficiency. This precondition is met by assuming CRS. The CRS precondition is only reasonable when all DMUs are operating at an optimal scale (Sufian and Majid, 2007; Řepková, 2014). The model’s outcome is OTE, which indicates a DMU’s ability to maximize output from a given set of inputs (Ma et al., 2002).

In reality, it is unlikely that all DMUs operate at optimal scale, i.e., DMUs may face either economies- or diseconomies of scale. In such a scenario where CRS is assumed, the OTE scores are tainted with SEs (Sufian and Majid, 2007). This restriction is overcome in the BCC model, which assumes VRS (Banker et al., 1984). If a change in inputs results in a disproportional change in outputs, the DMU operates under VRS. The BCC model measures PTE by ignoring the impact of scale size, which is achieved by comparing DMUs of similar scale (Ma et al., 2002). According to Al-Refaie et al. (2019), PTE is an indication of how a DMU uses resources under exogenous (non-discretionary resources or products (Bogetoft and Otto, 2011)) environments: the higher the score, the greater the efficiency with which the DMU manages its resources. In short, PTE measures OTE without SE effects.

The DEA efficiency model of DMU_n can be computed from the following programming problem. Following Řepková (2014), let us consider N DMUs (n = 1, 2, ..., N) observed in T (t = 1, 2, ... , T) periods using r inputs to produce s outputs. Let DMU_n^t represent a DMU_n in period t with an r input dimensional vector x_n^t = (x_n^{1t}, x_n^{2t}, … , x_n^{rt})' and an s dimensional output vector y = (y_n^{1t}, y_n^{2t}, … , y_n^{st})'. If a window starts at time k ($1 \leq k \leq \mathrm{T}$) with window width w ($1 \leq w \leq \mathrm{t} - k$), then the inputs metric is given by:

(7-1) $x_{kw} = (x_1^k , x_2^k , \dots , x_N^k , x_1^{k+1} , x_2^{k+1} , \dots , x_N^{k+1} , x_1^{k+w} , x_2^{k+w} , \dots , x_N^{k+w})'$,

and the outputs metric is given by:

(7-2) $y_{kw} = (y_1^k , y_2^k , \dots , y_N^k , y_1^{k+1} , y_2^{k+1} , \dots , y_N^{k+1} , y_1^{k+w} , y_2^{k+w} , \dots , y_N^{k+w})'$,

The CCR model of the DEA window problem for DMU_t^k is given by solving the following linear program:

(7-3)
$$\begin{aligned} &\min \theta, \\ &\text{subject to} \\ &\theta' X_t - \lambda' X_{kw} \ \geq\ 0, \\ &\lambda' Y_{kw} - Y_t \ \geq\ 0, \\ &\lambda_n \ \geq\ 0\ (n \ =\ 1, 2, \dots, N \ \times\ w). \end{aligned}$$

where θ is a measure of efficiency and λ' is the vector of intensity variables representing the weight of each DMU in the efficient frontier. By adding the restriction: $\sum_{n=1}^{n} \lambda_n = 1$, the BCC model formulation can be obtained (Banker et al. (1984) cited by Řepková (2014)). The objective values of the CCR model and the BCC model are designated OTE and PTE, respectively.

The BCC model is shown as:

(7-4)
$$\begin{aligned} &\min \theta, \\ &\text{subject to} \\ &\theta' X_t - \lambda' X_{kw} \ \geq\ 0, \\ &\lambda' Y_{kw} - Y_t \ \geq\ 0, \\ &\sum_{n=1}^{n} \lambda_n = 1 \\ &\lambda_n \ \geq\ 0\ (n \ =\ 1, 2, \dots, N \ \times\ w). \end{aligned}$$

The BCC model allows for the OTE score to be decomposed to PTE and SE scores as follows:

(7-5) $$SE = \frac{OTE}{PTE}$$

SE is a measure of how scale size affects efficiency (Al-Refaie et al., 2019). Furthermore, a difference between the OTE and PTE scores for a given DMU indicates scale inefficiency (Sufian and Majid, 2007).

7.2.1.2 Window Analysis

We used the DEA windows analysis method to allow for the assumption of time invariance of the frontier. Windows analysis repeats the DEA model in time segments, called windows, across the time continuum of a panel dataset that comprises both time series and cross-section samples (Table 7-1) (Al-Refaie et al., 2019). Windows analysis works on the principle of moving averages (Řepková, 2014). This method facilitates the capturing of temporal variations in efficiency, which is achieved by treating each DMU (firm) as a different entity in each time period (Sufian and Majid, 2007).

Our dataset has nine seed-producing firms, thus n = 9. The number of outputs is one and inputs is three. The period under investigation is: 2008-2015, yielding eight annual periods, so let P = 8. We increased the number of observations by choosing a window width of 4 years, so let w = 4. Although there is no theoretical basis for determining the width of a window (Tulkens and Vanden Eeckaut, 1995), Asmild et al. (2004) remark about the following tradeoff. A window should be small enough to minimize the temporal unfairness comparison, but large enough to have sufficient sample size. We found that 4 years proved to be the optimal window width for our relatively small sample size and study period spanning 8 years. In her study on the banking sector, Řepková (2014), makes a case for a window width of 3 years.

Each firm is placed in a window as if it was a different firm for each of the 4 years within that window. Thus, for window 1 (W1): years 2008, 2009, 2010, and 2011. This assumption increases the number of firms to 36 ($= n \times \mathrm{w} = 36$), and the analysis is performed on these 36 firms. W2 shifts the yearly period out by one to 2012 and simultaneously excludes the first year, 2008. Thus, W2 is 2009, 2010, 2011, and 2012. This pattern is repeated until the final window, W5, analyzes 2012-2015 (Table 7-1).

Table 7-1. Width of each window

Window	Width (Year)							
1	2008	2009	2010	2011				
2		2009	2010	2011	2012			
3			2010	2011	2012	2013		
4				2011	2012	2013	2014	
5					2012	2013	2014	2015

A model of seed production by a commercial seed firm is the outset for testing its efficiency. One such model is that a seed firm combines capital with scientific knowledge (born from its R&D efforts, intellectual property, and know-how), human resources (labor) (Pray et al., 2005b), and marketing-advertising-sales effort to produce improved seed (i.e., with superior genetic traits).

Our model uses a single-output (seed sales) production technology. From the data we collected, the following inputs are used to compute the efficiency scores: capital (assets), variable costs (a combination of: sales, marketing, and advertising costs; R&D expenditure; and cost-of-goods), and labor (headcount). Typically, seed firms produce improved seeds comprising a unique range of plant species. Thus, the single output, namely seeds, is in effect heterogeneous in terms of plant species composition and method of genetic improvement (Bonny, 2017). In terms of the latter, GE seeds could be considered to be a second category of output—with conventionally bred seeds the first—due to their high costs of development (Kalaitzandonakes et al., 2007; Phillips McDougall, 2011b), the lengthy period it takes for them to overcome regulatory hurdles for commercialization (Smart et al., 2016), and their market protection from competition through their patents, which "protect a marketed product for about 15 to 20 years after … product development" (Zhou, 2015). For simplicity, our model assumes that all seeds, irrespective of plant species and method of development, are a single homogenous output. Thus, seed sales—our single 'homogenous' output variable—overcomes the aggregate problem of dealing with what is essentially a heterogenous output (multiple seed types (plant species) with two possible development methods (conventional plant breeding or genetic engineering), each with a different unit price per sales region).

7.2.2 Data

We derived the data for our output and inputs for the firms studied (Table 7-2) by scrutinizing the content of two sources: (1) publicly available corporate documents such as annual reports and financial reports[10], and (2) annual reports obtained from a data analysis firm called Phillips McDougall (Phillips McDougall 2008, 2010, 2011a, 2012, 2013, 2014, 2015, 2016), which specializes in “providing detailed analysis of the agrochemical and seed industries” (Phillips McDougall website, 2016). Documents of this type are commonly used in empirical benchmarking studies to examine firms’ performance (for example: Li et al., 2015; Yuan and Wen 2018; Mooneeapen et al., 2021). Of importance, is that our data collection effort proved fruitless for sourcing annual productivity data (for example: tons of seed produced, area used for producing seed, tons of fertilizer used, and so on) either directly from firms or from annual financial statements, because some firms are not publicly listed. Our experience supports the claim by Bonny (2014) that accessible data on this sector are scarce. The data of our finite sample comprise a balanced panel of eight consecutive years, with nine firms, one output variable, and five input variables.

Table 7-2 provides summary statistics for 2015, the final year in our dataset, for the output (Y) and inputs (X) considered in this study. In the production frontier specification, output is represented by gross seed sales measured in USD, which is about 25,130 M USD for the whole sample. Five input variables are used, namely: (1) assets (we used equity and non-current liabilities as a proxy for fixed assets), (2) cost-of-goods, (3) R&D expenditure, (4) sales-marketing-advertising costs (all the aforementioned are measured in USD), and (5) staff compliment (measured as headcount). For simplicity, we reduced the number of input variables from five to three by combining the input cost variables (2, 3, and 4 above). In summary, our single output (gross seed sales) is a function of the following three inputs: assets, variables costs (cost-of-goods, R&D, sales-marketing-advertising), and staff compliment.

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[10] See for example: https://www.annualreports.com/HostedData/AnnualReportArchive/b/OTC_BAYZF_2008.pdf

Table 7-2. The expanded dataset of our sample for 2015 the final year in our study

Firm	Output	Inputs				
	Gross Seed Sales	Assets	Cost-of-goods	R&D	Sales-marketing-advertising	Staff
	(M USD nominal)					(Headcount)
Monsanto	10,021	21,920,000	3,957	1,482	2,144	22,400
DuPont Pioneer	6,787	41,166,000	3,381	783	1,469	12,300
Syngenta	2,828	18,977,000	1,386	640	588	4,500
Dow	1,453	68,026,000	668	285	304	700
Bayer	1,417	80,473,000	508	551	165	2,100
KWS	1,179	1,517,000	542	209	292	4,816
DLF	617	328,000	425	32	131	816
Takii	429	1,153,000	237	34	108	750
Sakata	399	851,000	197	43	120	1,998
Sample Total	25,130	234,411,000	11,301	4,059	5,321	50,380

"The total size of the seed market is not well known due to the difficulty of assessing the value of seeds saved by farmers and the total value of the commercial seed market. The latter was approximately 48.5 billion USD in 2015" (Bonny, 2017). Thus, our sample covers about half of the estimated global seed market in terms of sales for the final year in our sample (Table 7-2).

Each variable's total is reported for each firm's financial year[11]. For most firms, the financial- and calendar year are asynchronous. As this feature remains constant in the panel, we avoided statistical manipulations to adjust asynchronous temporal data to align with the calendar- rather than financial year. An anomaly of the dataset for the firm Bayer is that its headcount

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[11] The financial data reported were in USD (firms operating in other currencies had their financial data converted to USD by Phillips McDougall). As most economic behavior is assumed to be influenced by real- rather than nominal variables (Wooldridge, 2013), we deflated these data from nominal- to real values as follows. The OECD's producer price indices were used (OECD website, 2016). We used the country index for each firm's head office. The exception was Japan as it was not listed on the OECD's database. Here, we used the Bank of Japan's data (Bank of Japan website, 2016). This index was set to unity as the base value for 2008 by dividing all indices by the 2008 index value. The new indices were used to deflate all the variables (except headcount) by dividing each year's data by its index value.
$newindex_t = (oldindex_t / oldindex_{newbase})$
The deflating exercise is the only adjustment that we made to our data.

remained unchanged for all years reported, which we consider unrealistic especially as it acquired 13 firms, inclusive of their personnel, during our study period (Table 7-3).

All firms grew inorganically through corporate activity, which contributed to the concentration of the global seed market. The total number of acquisitions made across all firms was 86. Syngenta (19) and Takii (one) made the most and fewest acquisitions, respectively (Table 7-3). The most and least active years for corporate activity were jointly 2008 and 2013 (15 acquisitions each), and 2015 (four acquisitions), respectively. Noteworthy, is that GE crop-producing firms made the most acquisitions (in descending order: Syngenta (19), Dow (15), Bayer (13), Monsanto (13), and DuPont Pioneer (11) (Table A7-1)). These firms expanded their seed production and distribution bases, and developed their technology platforms. This business strategy was followed because the GE seed market was in a growth phase, while the commercial seed market was considered mature (Phillips McDougall, 2016).

During our study period, Monsanto had the highest seed sales (nominal USD). Dow had the greatest growth in sales of around 209% and Vilmorin (excluded from our analysis together with AgRelaint Genetics because of incomplete data) the lowest growth of less than 2%. GE seed sales represented about 22.5% and 32% of global commercial seed sales in 2008 and 2012, respectively (Bonny, 2014). The sale of GE seeds contributes appreciably to the gross seed sales of firms producing these seeds (Phillips McDougall, 2016). Of the total number of GE crops approved for sale in the US (i.e., petitions of events[12] granted non-regulatory status) during our study period, 37 were approved (extensions were granted to five events that were previously approved) by firms in our study. Monsanto was the leader in event approvals (14), and the year with the most event approvals was 2013 with eight (Table 7-3).

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[12] In the US's regulatory terminology, each genetic transformation (i.e., a GE crop) is called an event (Animal and Plant Health Inspection Service, 2020).

Table 7-3. Top 11 firms globally ranked by seed and trait sales for 2008 and 2015 (nominal USD), and acquisitions made and events approved in the US (2008-2015)

Rank	Firm	Seed Sales			Firms Acquired 2008-2015 [d]	Events Approved in the US 2008-2015 [e]
		2008 (USD M) [a]	2015 (USD M) [b]	Increase 2008-2015 (%)		
1	Monsanto	6,632	10,021	51.10	13	14
2	DuPont Pioneer	3,992	6,787	70.02	11	7
3	Syngenta	2,442	2,838	16.22	19	6
4	Vilmorin [c]	1,495	1,518	1.54	NA	NA
5	Dow	470	1,453	209.15	15	5
6	Bayer	662	1,417	114.05	13	4
7	KWS	880	1,179	33.98	8	1
8	AgReliant Genetics [c]	344	630	83.14	NA	NA
9	DLF	442	617	39.59	2	0
10	Takii	400	429	7.25	1	0
11	Sakata	304	399	31.25	4	0

[a] Source: Phillips McDougall, 2008
[b] Source: Phillips McDougall, 2016
[c] Excluded from our study due to insufficient data
[d] Refer Table A7-1
[e] Refer Table A7-3

7.3 Empirical Results and Discussion

The body of scientific literature is lean on studies reporting on the economic efficiency of commercial seed-producing firms. This study provides new information on the efficiency of nine of the largest of these firms worldwide. The DEA model is applied in five 4-year windows for the period 2008-2015. The results are reported for the general trend in OTE for each window followed by decomposing them into PTE and SE. Trends in efficiency are described and discussed.

7.3.1 Overall Technical Efficiency

We used the CCR model to compute the OTE scores for each firm. The OTE score indicates a seed firm's ability to maximize seed sales from the defined set of inputs (see **Section 7.2.1 Methodology**) under conditions of CRS.

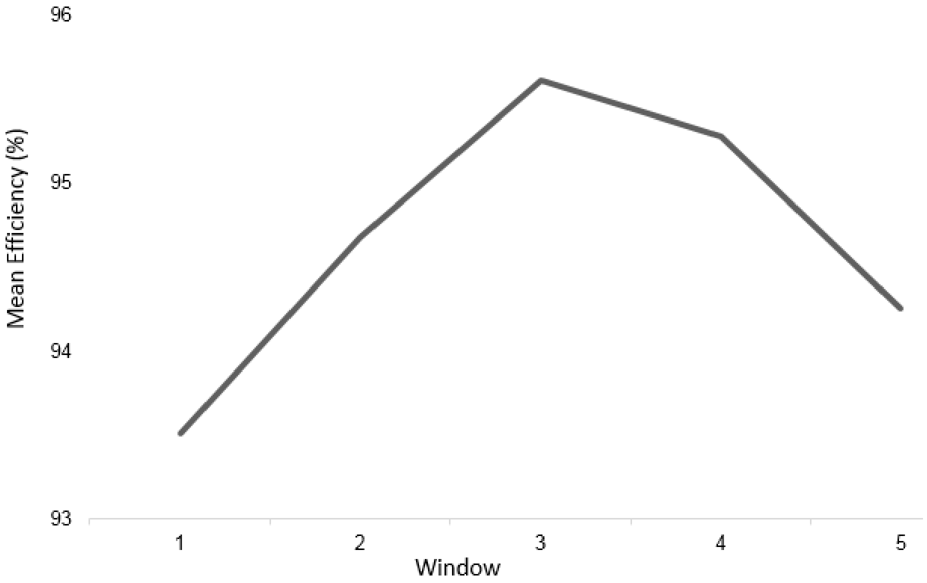

Figure 7-1. Mean aggregate OTE score (%) for all firms for windows 1-5.

The trend for the temporal mean aggregate OTE score is convex-shaped. Efficiency increased steadily from 93.5% in W1 to peak at 95.6% in W3, followed by a small decrease to W4 with a slightly steeper descent to W5 (94.3%). Overall, there was a slight increase in mean efficiency (W5 > W1) of 0.8% (Figure 7-1; note that the y-axis is rescaled to the mean efficiency range 93-96%). This observation reflects the overall trend of managerial ability to maximize seed sales from inputs.

The following firms contributed most to the upward trend (W1-W3) in efficiency: Dow, Sakata, and Takii. The latter two contributed most to the subsequent downward trend, possibly as a result of declining sales revenue coupled with unfavorable exchange rates (Phillips McDougall, 2016). The overall change in the mean aggregate OTE is positive, but minuscule. Of the nine firms analyzed, a meagre increase and decrease (less than ±2%) in OTE is displayed by two and six firms, respectively. This result indicates a relatively stable temporal OTE. The exception is Dow with an overall positive change in efficiency of 7.75% (Table 7-4). Dow's five GE crops that were approved in the US and its phenomenal growth in seed sales (209%) (Table 7-3) contributed to this improvement in efficiency.

Table 7-4. Mean OTE scores for each firm in each window, and overall difference

Firm	Mean Efficiency (%)					Difference W1-W5 (%)
	Window 1	Window 2	Window 3	Window 4	Window 5	
Bayer	90.03	89.79	90.25	90.34	89.96	-0.08
DLF Trifolium	99.77	99.30	99.63	98.89	99.06	-0.71
Dow	91.42	97.10	98.88	99.73	99.10	7.75
DuPont Pioneer	95.72	96.07	96.83	97.32	95.67	-0.05
KWS	98.74	97.99	98.54	98.81	97.81	-0.95
Monsanto	99.10	98.69	98.76	98.08	97.93	-1.19
Sakata	87.20	91.33	91.09	88.43	85.80	-1.64
Syngenta	84.83	85.19	87.32	87.85	86.32	1.73
Takii	94.78	96.71	99.26	98.12	96.67	1.96

Table 7-5 reports the means and variances across all windows and the greatest differences by window and by year of OTE. The relative stability of each firm's performance is evident from these results, especially their low variances. DLF Trifolium is the strongest, most consistent performer (highest mean OTE score, lowest overall variance) with Sakata the weakest, most inconsistent performer (lowest mean OTE score, greatest overall variance). DLF Trifolium's stability is reinforced by two of its greatest difference scores (within a window and across the entire period) being the lowest (GDW = GDY = 2.97%). DLF Trifolium's performance was probably the result of its management having executed prudent decisions that resulted in consistent growth in seed sales, while simultaneously having managed inputs carefully. For example: following the acquisition of the Advanta grass seed business from Vilmorin in 2007, it reduced its excess research capability by divesting ASP Research in Oregon, US. In 2010, it established a subsidiary in Moscow to grow its forage grass business there. In 2015, it expanded into Ireland by forming a joint venture with the local firm Seedtech (Phillips McDougall, 2016).

Dow had the lowest score for the greatest difference in the same year, but a different window. Monsanto and KWS were both strong, consistent performers with remarkably similar results, but Monsanto performed better within a window and across the entire period. Monsanto's strategy of regularly bringing new GE crops to this growing market segment (2009 and 2010 are the only exceptions: see Table A7-3) probably contributed to its consistent performance. The bulk of KWS's seed sales (>80%) was from maize (sales in Brazil rose by 25.6% in 2015, for example) and sugar beet (Phillips McDougall, 2016). KWS's strategy of maintaining this strong, but narrow focus probably contributed to its consistently strong performance.

Table 7-5. Mean, variance, and difference statistics (highest mean first) for OTE for all firms

Firm	Overall Mean (%)	Overall Variance (%)	GDW [a] (%)	GDY [b] (%)	TGD [c] (%)	Performance Rating
DLF Trifolium	99.33	0.01	2.97	2.97	2.97	α [d]
Monsanto	98.51	0.02	3.00	2.67	3.00	α
KWS	98.38	0.02	5.54	2.26	5.54	α
Bayer	90.07	0.03	5.30	2.24	5.45	α
DuPont Pioneer	96.32	0.08	8.85	2.25	8.85	Ω [e]
Takii	97.11	0.10	9.15	2.73	9.15	Ω
Syngenta	86.30	0.14	12.94	4.09	12.94	Ω
Dow	97.25	0.30	24.06	0.62	24.06	Π [f]
Sakata	88.77	0.35	15.41	3.19	17.95	Π

[a] GDW: greatest difference within a window
[b] GDY: greatest difference in the same year, but different window
[c] TGD: total difference for the entire period
[d] α: strong, consistent performers
[e] Ω: average, inconsistent performers
[f] Π: weak, inconsistent performers

DuPont Pioneer’s average, inconsistent performance might be ascribed in part to its high level of corporate activity (Tables 7-3, A7-1, A7-2) and the associated managerial challenges of incorporating new businesses into the mother company (Bogetoft and Wang, 2005). Seed sales declined in 2015 due to declining maize and soybean seed volumes and prices in North and Latin America. Efforts to improve efficiency included the following. In 2008, it implemented a strategy “to improve and develop business agreements with independent seed companies separate from the Pioneer brand” to improve its access to markets. In 2014, it launched its precision agriculture service and entered into research and information-sharing agreements. Farmers are able to use these services to make financially-driven decisions (Phillips McDougall, 2016), and presumably purchase ‘appropriate’ seeds and matching agrochemicals from the company.

Although Bayer has the seventh lowest OTE score, it was the fourth best performer (Table 7-5). The acquisition of Stoneville in mid-2007 (the year before the start of our study period) made a significant contribution to sales growth in 2008 and 2009. Bayer’s slight drop in performance from W4-W5 was probably due to a 3.3% decline in seed sales (in USD terms) in 2015 “… due in part to a significant fall in global sales of cotton seed and sales of seed in Europe where currency conversion affected growth in dollar terms.” Also playing a role in this decline in seed sales might have been Bayer's divestment in 2013 of its hybrid maize seed business in India (Phillips McDougall, 2016).

Takii is primarily involved in producing seeds of vegetables and flowers, which is largely "a consumer end-use driven market". Japan represents ca. two-thirds of Takii's market, followed by Europe and the US (ca. 11% each). To improve its market presence in Europe, Takii made acquisitions in 2007 and 2008 there. However, its average, inconsistent performance (Table 7-5) was mainly impacted by unfavorable currency effects (Yen vs. USD) (Phillips McDougall, 2016).

Despite Syngenta ranking third in terms of seed sales (Table 7-3), it was an average, inconsistent performer with the lowest overall mean OTE (Table 7-5) that was consistently below 88% (Table 7-4). Syngenta made the most acquisitions (Table 7-3), which were temporarily evenly distributed across windows (Table A7-2). Thus, it is possible that the managerial challenges associated with incorporating these new firms into Syngenta's corporate structure and business culture kept its OTE from improving (Bogetoft and Wang, 2005). Syngenta's relative inefficiency might also have been impacted by its lawn and garden products being excluded from its seed business from 2011, and that its key seed brands, despite being consolidated within its overall organization, operated relatively autonomously (Phillips McDougall, 2016). A possible downside of this autonomy is the loss of potential synergies arising from operating cooperatively.

Table 7-5 shows that Sakata was the weakest, most inconsistent performer with the second lowest overall mean OTE score. This performance might be ascribed to the following three factors: (1) Sakata made two divestments in 2009, (2) during the 2005 fiscal year (ending in May), it restructured the company's organization to make it more cost efficient, and (3) unfavorable currency fluctuations (Yen vs. USD) (Phillips McDougall, 2016).

In summary, the aggregate mean OTE (a measure of managerial ability) increased marginally by 0.8%. OTE displayed a convex-shaped trend that peaked in W3 at 95.6%. Dow, Sakata, and Takii contributed most to its upward trend with the latter two contributing most to its subsequent decline. The three strongest, most consistent performers were DLF Trifolium, Monsanto, and KWS, and the three weakest, most inconsistent performers were Syngenta, Dow, and Sakata. As it is likely that one or more of these firms operated under either economies- or diseconomies of scale (the CCR model presuppose CRS, which is only justifiable when all firms are operating at optimal scale), the results for OTE are tainted with scale efficiencies (Sufian and Majid, 2007). The next section relaxes the CCR assumption of firms operating under CRS by analyzing VRS efficiency—also known as PTE.

7.3.2 Pure Technical Efficiency

In this section, we analyze PTE using the BCC model, which assumes VRS. PTE measures OTE without SE effects (see **Section 7.2.1 Methodology**). In theory, when one moves along the frontier from smaller- to larger inputs in a VRS model, returns to scale display the following trend: increase, remain constant, and decrease. In economic terms, the equivalent trend is true for average product. The input level at which CRS is achieved is the most productive scale size and is where all firms would like to operate (Bogetoft and Otto, 2011). Increasing returns to scale (IRS) and decreasing returns to scale (DRS) are achieved before and after this input level, respectively. When a firm operates under either IRS or DRS, expanding or contracting its operations (i.e., scale size), respectively, are prudent management considerations.

Figure 7-2 (note that its y-axis is rescaled to start at an efficiency score of 80%) displays the results of the relationship between PTE and scale (in terms of assets) for all firms across all windows. Four clusters are apparent: (1) with efficiency scores ranging from >94.5-100% with relatively low capital (≤1,454 M USD); (2) with efficiency scores fluctuating in the range 80.8-100% with moderately low capital (a narrow band: 14,584-20,769 M USD); (3) with efficiency ratings in the range >91-100% with medium capital (36,209-46,694 M USD), and (4) firms that have efficiency scores in the range >90-100% with relatively high capital (61,872-81,637 M USD).

Therefore, within each cluster, firms differ in their ability to convert inputs into outputs under the assumption of VRS.

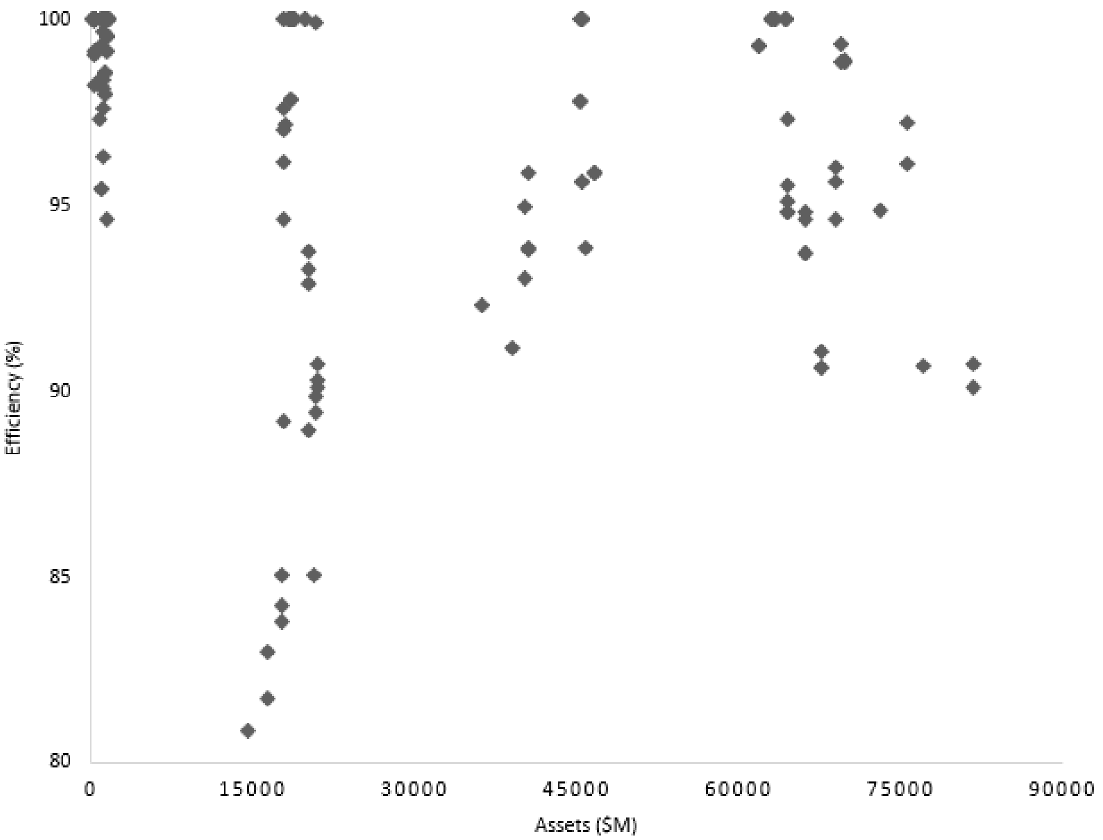

Figure 7-2. PTE versus assets of firms for all years and all windows.

As there is no clear relationship between PTE and asset size (Figure 7-2), we examined each firm’s behavior. Due to the large range in the asset values across firms, we rescaled the axes of each firm’s graph to reveal any trends and to assess if the firm operates under IRS, CRS, or DRS (Figure 7-3).

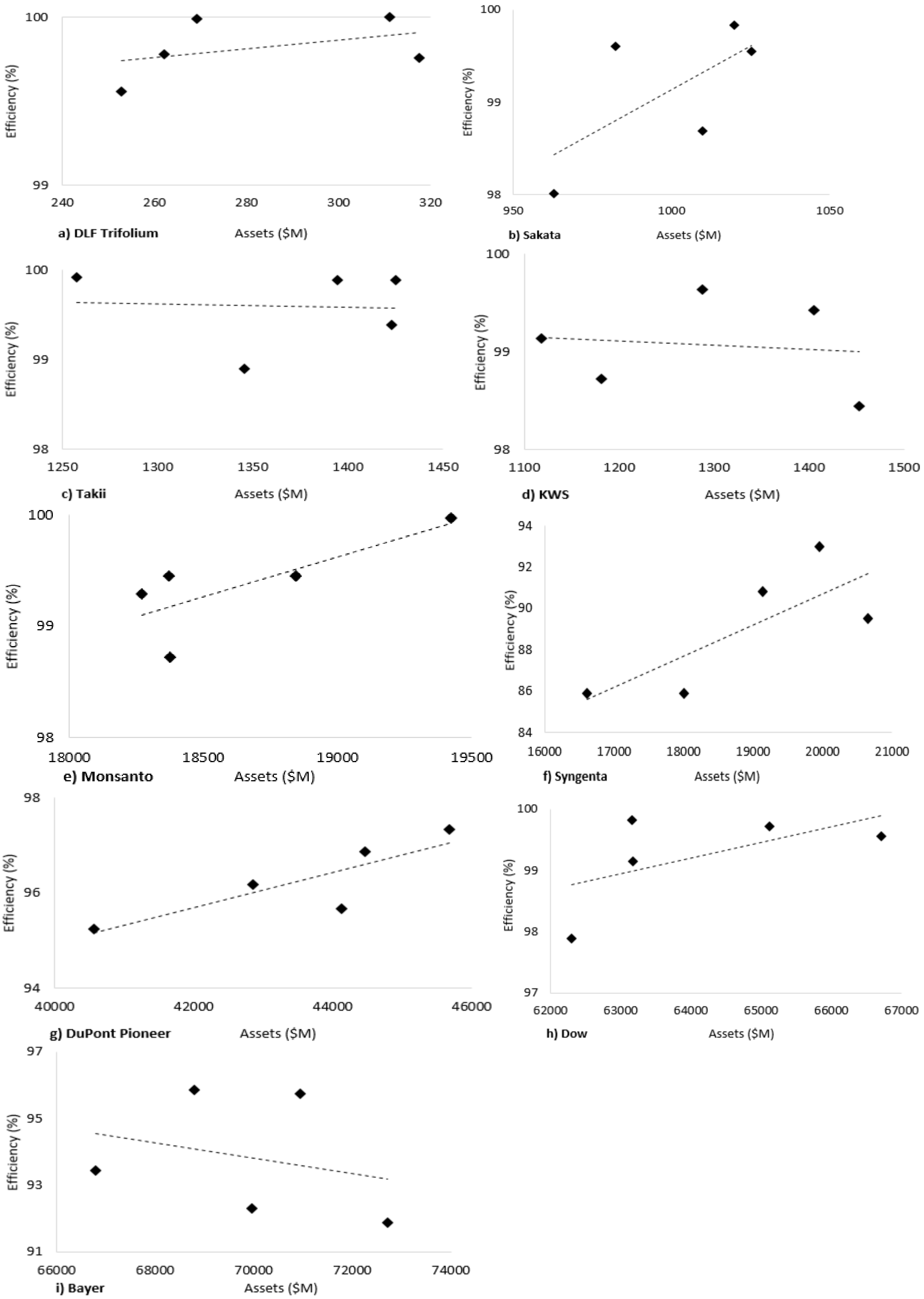

Figure 7-3. PTE versus assets for each firm (rescaled x- and y-axes; linear trend line included).

DuPont Pioneer, Monsanto, and Syngenta show an overall positive relationship between PTE and asset size, with Sakata's relationship weakly positive (Figures 7-3g, 7-3e, 7-3f, 7-3b). Thus, it appears that these firms operated under IRS, and in terms of PTE, their management could have considered expanding operations.

DuPont Pioneer expanded by making acquisitions every year except 2008 and 2014 (Table A7-1). In mid-2008, DuPont Pioneer opened new seed research centers in Hungary and Italy. The following year it invested in information technology firms that develop and market proprietary crop management software, and online marketing and procurement; and it expanded seed production sites and facilities in Asia. In 2012, it opened a soybean seed production facility in Missouri, US. Other noteworthy expansions in production included ones in Austria and the Philippines in 2011, and in Ukraine in 2013. In 2013, it expanded its operations in Africa by acquiring Pannar Seed in South Africa, which operated in eight other African countries. During our study period, it expanded its office space, and seed mixing and packaging facilities in Denmark (Phillips McDougall, 2016).

DLF Trifolium operated at, or close to CRS (Figure 7-3a, Table 7-6). It made two acquisitions, one each in 2012 and 2013—the second least number of acquisitions made by the firms in this study (Tables 7-2, A7-1). The sizes of these acquisitions are unknown, however, it appears that this expansion strategy contributed to achieving its optimal size.

Takii's PTE score of 99.9% corresponds to its lowest asset value and implies CRS. Its next PTE score was marginally lower by about 1%, after which it returned to a level that effectively represents CRS (Figure 7-3c), which might reveal the effect of the merger between Takii Europe and K Sahin Zaden of The Netherlands (Phillips McDougall, 2016).

The relationship between PTE and asset size for Sakata and Bayer has a sawtooth trend. It is important to note that Figure 7-3 does not display a temporal trend. When we inspect the overall temporal trend in PTE (slightly negative) in Table 7-6 for these firms, Sakata's scores from W1-W3 were fairly constant at just below 100% (implying CRS), after which they declined marginally thereby implying DRS. Bayer's PTE scores from W1-W3 were ca. 96% after which they declined to around 92%. Bayer's slightly negative temporal trend in PTE implies that from W4 onwards it operated under DRS.

In terms of PTE, Sakata's divestments in 2009 from Frisa Planter in Denmark and its UK ornamentals subsidiary are questionable at it was operating close to CRS at that time. It made acquisitions in 2008 and 2009, which appear to have had a tiny positive impact on PTE. However, its acquisition in 2013 (Table A7-1), the size of which is unknown, is arguable as it was operating under DRS.

From 2008-2010, Bayer made one acquisition. During the remaining 5-year period it made 12 acquisitions (Table A7-1). The acquisitions might have formed part of a long-term business strategy. For example, each year during this study Bayer expanded its R&D capacities across the globe, which included acquiring firms specializing in R&D (see Phillips McDougall, 2016). The economic impacts of these investments were probably delayed due to lengthy periods for developing and commercializing new seeds, especially GE seeds (Smart et al., 2016). However, from a PTE perspective, these acquisitions—all contributing to firm size—were theoretically unjustified.

Dow's initial sharply positive relationship between PTE and size (IRS) coincided with the period when it made most of its acquisitions (13 of 15 acquisitions from 2008-2012 (Table A7-1)). This trend peaked at an asset level of 63,154 M USD (99.82%) where the firm effectively achieved and maintained CRS as its PTE scores remained above 99.9% (Figure 7-3h).

Monsanto is an interesting case as it had a positive trend in PTE versus assets size, which peaked at 100%, thus indicating that up to this point it theoretically operated under IRS (Figure 7-3e). Monsanto's acquisition strategy (acquisitions were made in all but two years (Table A7-1)) was therefore legitimate from a PTE perspective.

The relationship between PTE and asset size for Syngenta increased to peak at ca. 93% (asset level of 19,947 M USD) after which it declined (Figure 7-3h). The overall trend, however, was positive thus indicating IRS, which supported its expansion strategy (it made 19 acquisitions (Tables 7-2, A7-1)).

The y-axis's exaggerated scale in Figure 7-3d (KWS) reflects the following trend for PTE versus asset size: a slight decrease from a PTE score of over 99%, an increase that peaked at 99.6% in W3 where it remained stable, and a slight decrease to 98.4% (Table 7-5). Therefore, KWS did not reach the efficient frontier. KWS made eight acquisitions, six of which were made during 2011-2012 when its PTE score peaked. This expansion strategy is supported by theory as it is likely that the firm was operating under IRS.

To sum up: we used the BCC model to measure PTE. No clear relationship between PTE and asset size is evident (Figure 7-2). In measuring PTE, the BCC model ignores the impact of scale size by comparing firms of similar scale (Ma et al., 2002). The firms in our sample span a wide range in terms of size, which may be problematic. Nevertheless, the results of this model reflect that the strong corporate activity (i.e., expansion via acquisitions) of most firms, except Bayer, was probably theoretically justified with Dow, DuPont Pioneer, Syngenta, and Monsanto being the best examples (Monsanto ended with a PTE score of 100% in W5 (Figure 7-3e, Table 7-6)). Takii and DLF Trifolium effectively operated under CRS as their PTE scores were consistently above 99%, except in W5 for Takii (98.9%). Next, we complete the decomposition of the OTE scores by analyzing the SE scores.

7.3.4 Scale Efficiency

SE is the ratio of CRS efficiency (OTE) to VRS efficiency (PTE), which cannot exceed unity. SE measures how the scale size affects efficiency (Al-Refaie et al., 2019). A difference between the OTE and PTE scores for a given firm indicates scale inefficiency (Sufian and Majid, 2007). At a ratio of unity, firms theoretically operate at their optimal scale size, which is the level where the CRS and VRS technologies coincide. The larger the SE score, the closer a firm is to operating at optimal scale (Bogetoft and Otto, 2011). The results of the CCR model (with CRS) are lower than those of the BCR model (with VRS): see the columns for OTE and PTE scores for each window in Table 7-6. As noted by Řepková (2014), this outcome is the consequence of the BCC model decomposing the efficiency of firms into PTE and SE.

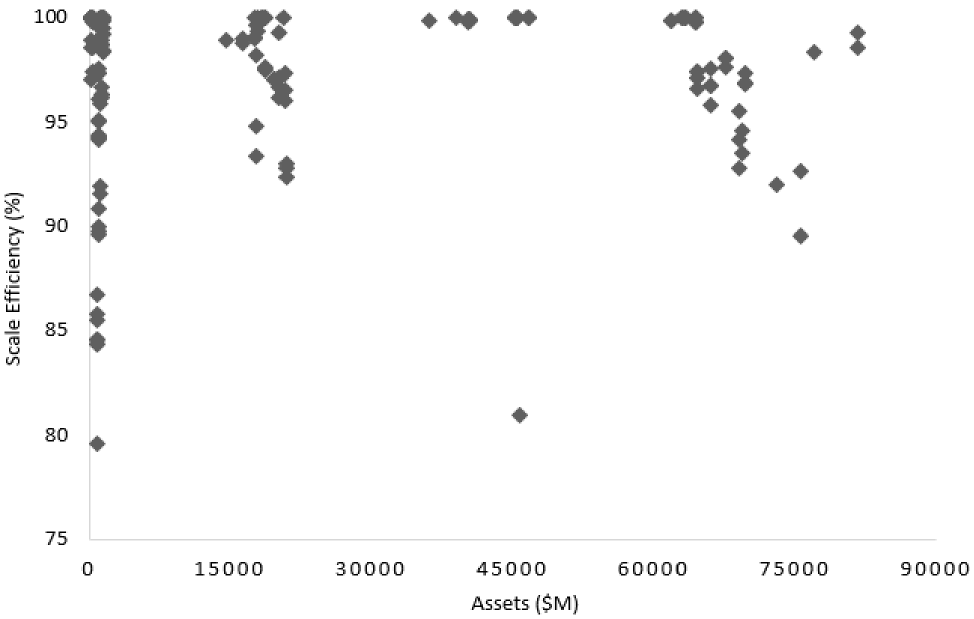

Figure 7-4. Scale efficiency for all firms for all years and all windows.

SE is reported for all asset sizes up to a maximum of ca. 81,700 M USD. If we ignore the reported ‘outlier’ SE score of 80.9% for an asset level of 45,747 M USD (Dow is the firm), the most scale efficient cluster is bound by the asset range of 36,209-46,694 M USD. SE exhibits a downward trend for assets greater than ca. 64,000 M USD—an asset level up to which SE appears to be possible. Aside from this observation, no clear-cut relationship between SE and size is evident (Figure 7-4, note that its y-axis is rescaled to start at an efficiency score of 75%). As with the preceding subsection, we use Figure 7-5 to display each firm’s results individually in panels (the x- and y-axes of each firm’s graph were rescaled to reveal any trends, and a linear trend line is displayed).

DLF Trifolium achieved SE at an asset level of 262 M USD (Figure 7-5a) in W1 (Table 7-6). Scale inefficiency resulted at asset levels on either side of this value. Sakata and Takii show an upward trend in SE (Figures 7-5b, 7-5c), but remained scale inefficient.

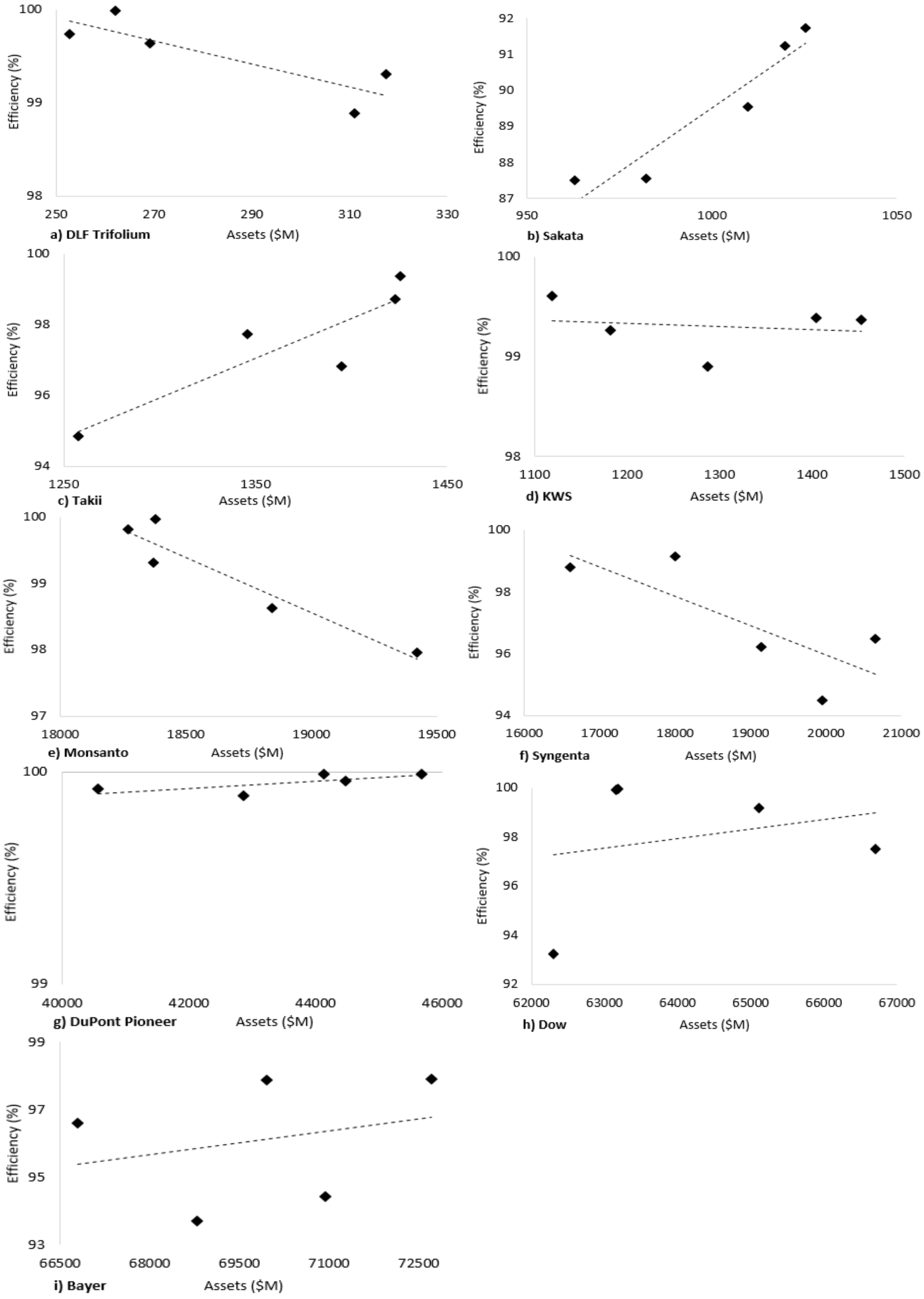

Figure 7-5. SE versus size (assets) for each firm (rescaled x- and y-axes; linear trend line).

KWS's SE scores range between 98.9% and 99.6% (Figure 7-5d, Table 7-6). It, therefore, operated under slight scale inefficiency. Monsanto effectively operated in terms of SE at an asset level of about 18,340 M USD, after which it was scale inefficient (Figure 7-5e).

Syngenta was always scale inefficient (Figure 7-5f). Despite Syngenta nearly reaching SE in W2 (99.1%), a minute difference between its OTE and PTE scores existed then, but both scores were below 86% (Table 7-6). Syngenta's relatively poor OTE and PTE scores are likely to be linked to challenges associated with its high corporate activity, corporate structure, and management ability to efficiently convert inputs to output. Although DuPont Pioneer was effectively scale efficient (Figure 7-5g), there was room for modicum improvement in both its managerial efficiency (OTE) and PTE scores (Table 7-6). Dow reached SE at an asset level of ca. 63,160 M USD. On both sides of this asset level, Dow was scale inefficient (Figure 7-5h). From W2-W5, Dow's PTE scores exceeded 99%. Therefore, managerial ability (OTE) was the main contributing factor to it being scale inefficient. A possible cause for managerial inefficiency could have been troubles associated with integrating the 15 firms it acquired during the study period (Tables 7-3, A7-1). In all windows, Bayer was scale inefficient. Its best SE score of 97.9% corresponds to its highest asset level of ca. 72,700 M USD (Figure 7-5i). Bayer's highest PTE of 95.9% means that it never achieved the efficient frontier (Table 7-6). Thus, Bayer needed to improve both its managerial ability (OTE) and PTE scores in all windows. For it to have achieved SE, these efficiency scores would have had to be equal in the same window.

Table 7-6. Mean OTE, PTE and SE scores for all firms for windows 1-5

Firm	Window 1			Window 2			Window 3			Window 4			Window 5		
	OTE (%)	PTE (%)	SE (%)	OTE (%)	PTE (%)	SE (%)	OTE (%)	PTE (%)	SE (%)	OTE (%)	PTE (%)	SE (%)	OTE (%)	PTE (%)	SE (%)
Bayer	90.0	95.4	94.4	89.8	95.9	93.7	90.2	93.5	96.6	90.3	92.3	97.9	90.0	91.9	97.9
DLF Trifolium	99.8	99.8	100.0	99.3	99.6	99.7	99.6	100.0	99.6	98.9	100.0	98.9	99.1	99.8	99.3
Dow	91.4	97.9	93.2	97.1	99.6	97.5	98.9	99.7	99.2	99.7	99.8	99.9	99.1	99.1	100.0
DuPont Pioneer	95.7	95.8	99.9	96.1	96.2	99.9	96.8	96.9	100.0	97.3	97.3	100.0	95.7	95.7	100.0
KWS	98.7	99.1	99.6	98.0	98.7	99.3	98.5	99.6	98.9	98.8	99.4	99.4	97.8	98.4	99.4
Monsanto	99.1	99.3	99.8	98.7	98.7	100.0	98.8	99.5	99.3	98.1	99.5	98.6	97.9	100.0	98.0
Sakata	87.2	99.6	87.6	91.3	99.6	91.7	91.1	99.8	91.2	88.4	98.7	89.5	85.8	98.0	87.5
Syngenta	84.8	85.9	98.8	85.2	85.9	99.1	87.3	90.8	96.2	87.9	93.0	94.5	86.3	89.5	96.5
Takii	94.8	99.9	94.9	96.7	99.9	96.8	99.3	99.9	99.4	98.1	99.4	98.7	96.7	98.9	97.7

7.4 Conclusion

In this study, we used DEA to analyze the efficiency levels of nine of the largest commercial seed producing firms globally for the period 2008-2015 and assessed if there was a relationship between firm size and efficiency score, specifically PTE and SE. We used the DEA windows analysis method to allow for the assumption of time invariance of the frontier. An input-oriented model (one output, three inputs) is used to represent the technology of a balanced panel dataset. First, we analyzed OTE, which indicates a firm's ability to maximize seed sales from a defined set of inputs under conditions of CRS. Second, we relaxed the CRS assumption by analyzing efficiency under VRS or PTE, which reveals if firms are operating under IRS, CRS, or DRS and whether an expansion or a contraction in operation was justified. Third, we decomposed the OTE scores by analyzing SE, which indicates how scale size affects efficiency. SE is achieved when a firm's OTE and PTE scores converge.

Our results show that: (1) the mean temporal OTE increased by a mere 0.8%—an unremarkable reflection on managerial ability to improve on maximizing seed sales from inputs. The less than 1% overall change in mean OTE, however, reflects stability in managerial ability in this sector. Dow was the exception with an overall increase in OTE of 7.75%, which, for the firms in our dataset, implies that its strategies were the most successful for improving OTE. (2) There is no clear relationship between PTE and asset size. On a firm level, DuPont Pioneer, Syngenta, Monsanto, and Dow operated under IRS with the latter two reaching CRS—the most productive scale size. DLF Trifolium and Takii operated at, or close to CRS. Sakata and Bayer displayed an inconsistent sawtooth-shaped trend in PTE versus size. Thus, they operated under both IRS and DRS. (3) No conspicuous overall relationship between SE and asset size is apparent. DuPont Pioneer was scale efficient in three consecutive windows, while DLF Trifolium, Dow, and Monsanto achieved this outcome in one (but not the same) window. All other firms were consistently scale inefficient with Sakata having the lowest SE scores (87.5-91.7%).

Our OTE results reveal that under conditions of CRS, seed firms consistently operated at a relatively high level of efficiency. Consolidation in this sector continued unabated during our study period, which Bonny (2014), inter alia, view critically. In terms of efficiency, and relevance from a policy perspective, our PTE analysis reveals that the corporate activity (M&As) of most firms was theoretically justified (Dow, DuPont Pioneer, Syngenta, and

Monsanto were the best examples), but that Bayer's was not. However, the impact of market concentration on competition and innovation, for example, lay beyond the scope of our inquiry.

To summarize, we found that managerial ability as measured by OTE was at a consistently high level (> 93.5%) and stable, with Dow the only firm where a meaningful, positive improvement was shown. All firms expanded through acquisitions, and in terms of PTE only, Bayer is the only firm whose expansion strategy we question. SE appears to be difficult to achieve consistently as it depends on OTE and PTE converging. DuPont Pioneer achieved SE in three windows. No obvious relationship between efficiency, specifically PTE and SE, and firm size was evident from our analyses.

Our study could be strengthened in four areas. Firstly, our analysis of OTE scores—a measure of managerial ability, is bound by the assumption of CRS. This assumption is unrealistic as these results are likely to be tainted with scale efficiencies (Sufian and Majid, 2007). All the firms in our study expanded inorganically. In most cases, this growth was via M&As. Information on transaction sizes was unavailable. Therefore, we were unable to quantify the impact of this corporate activity on their growth. Also, growth of this sort does not necessarily translate into a proportional short-term improvement in firm performance (efficiency). Incorporating a new firm into an existing corporate structure and culture can present challenges that hinder a firm's OTE scores from improving (Bogetoft and Wang, 2005). Secondly, in measuring PTE, the BCC model ignores the impact of scale size by comparing firms of similar scale (Ma et al., 2002). The firms included in our sample span a wide range in terms of size (assets), which might be problematic. Thirdly, as Kazley and Ozcan (2009) point out, "since DEA relies on relative measurement, peer groupings are essential for homogenous comparison". In terms of a generic output, all firms produced seed. However, on closer inspection and as remarked by Bonny (2017), this solitary output is heterogeneous: firms neither produced the same kinds of seeds (some firms focus on horticultural crops, others on forage and grain crops, for example), nor competed in the same geographical markets (for example, Japan is the largest market for Sakata and Takii). Another source of heterogeneity is the use of biotechnology; not all firms in our sample produced GE seeds. We argue (also see **Section 7.2.1 Methodology**) that GE seeds could be considered a second category of output. Some seed-producing firms also develop and produce agrochemicals, which are a complimentary output to seeds, and may impact firm efficiency. Fourthly, our empirical analysis is limited by the availability of data, which neither allowed us to investigate the causes underlying the efficiency performance of the largest seed producers globally, nor to include all 11 of these firms (Vilmorin and AgReliant Genetics, the fourth- and eighth largest firm, respectively (Table 7-3), were excluded) in our analysis.

Future studies may aim to understand: (1) the causes underlying the efficiency performance of the world's largest seed producers, which can be done by using bootstrapping techniques such as those proposed by Simar and Wilson (2007), and (2) the impact of market concentration on competition and innovation. We emphasize that the evidence reported in this study concerns only the firms' technical performance within the limits of our dataset, and does not account for other aspects of firm performance. In particular, current changes in the business model have involved a fundamental shift in the measurement of firm performance that has moved beyond technical indicators to adopt environmental- and social indicators. Hence, a future avenue for research is to study the corporate social responsibility performance of the global seed industry along the lines of Chambers and Serra (2018) or Puggioni and Stefanou (2019).

7.5 Appendix

Table A7-1. Number of acquisitions made by seed firms, 2008-2015 [a]

Firm	Year								Total
	2008	2009	2010	2011	2012	2013	2014	2015	
Bayer		1		4	2	3	1	2	13
DLF Trifolium					1	1			2
Dow	5	2	1	3	2		2		15
DuPont Pioneer		2	4	2	1	1		1	11
KWS		1		3	3			1	8
Monsanto	3	2		2	1	5			13
Sakata	2	1				1			4
Syngenta	4	3	2		3	4	3		19
Takii	1								1
Total	15	12	7	14	13	15	6	4	86

[a] Data source: Phillips McDougall (2016a)

Table A7-2. Number of acquisitions for each firm and window

Firm	Window				
	W1	W2	W3	W4	W5
Bayer	5	7	9	10	8
DLF Trifolium	0	1	2	2	2
Dow	11	8	6	7	4
DuPont Pioneer	8	9	8	4	3
KWS	4	7	6	6	4
Monsanto	7	5	8	8	6
Sakata	3	1	1	1	1
Syngenta	9	8	9	10	10
Takii	1	0	0	0	0

Table A7-3. Number of GE events (crops) approved [a] for firms in the US, 2008-2015 [b]

Firm	Year								Total
	2008	2009	2010	2011	2012	2013	2014	2015	
Bayer		1		1	1	1			4
Dow							4	1	5
DuPont Pioneer	1	2	1	1		2			7
KWS						1			1
Monsanto	1			3	1	3	2	4	14
Syngenta			1	2		1	1	1	6
Total	2	3	2	7	2	8	7	6	37

[a] Includes extensions of existing approved crops

[b] Data source: USDA Animal and Plant Health Inspection Service website (2020)

Chapter 8

8 General Discussion, Conclusion and Policy Implications

This chapter synthesizes the results and conclusions of the studies documented in **Chapters 3-7**, and points to further research that could expand on the findings of this thesis. Additionally, possible implications for policy makers are discussed.

Chapter 3 is a qualitative investigation into the social and economic challenges for the bioeconomies of Europe and Africa, specifically SSA. The public acceptance of green biotechnology in particular, and the relatively stringent regulatory requirements for authorizing its innovations, such as GE crops, in Europe and multiple African states hinder their bioeconomies' competitiveness. The question addressed in **Chapter 3** is: what pathways are there for unlocking the potential of the bioeconomies of Europe and Africa?

A SWOT analysis showed that Europe's strengths include high levels of expertise (skilled labor), a well-established logistics and communication infrastructure; few, stable currencies; a reliable judicial system; and strong institutions (banks, input suppliers, knowledge transfer). Europe's weaknesses are, inter alia, an aging population that is exacerbated by low birth rates (Eurostat, 2014); stifling regulatory policies and divergent views on green biotechnology. Africa's strengths include its "enormous transformative potential" (Chambers et al., 2014); abilities to cope with, and to adapt to, crises (Hall and Clark, 2010); and the availability of land and labor for developing value-adding activities. Africa's weaknesses include low levels of formal education (Obonyo et al., 2011); inadequate infrastructure; a poorly functioning judiciary; food insecurity; pockets of political instability; asymmetrical and obstructing regulations (Paarlberg, 2008); costly supply chains (Chambers et al., 2014); low investments in bioscience R&D; many currencies with volatile exchange rates (Kirchner, 2014); and poor information networks (World Bank, 2006). Opportunities exist for bilateral cooperation between Europe and Africa, especially for developing the latter's bioeconomy by adapting existing technologies. Threats to Europe's bioeconomy stem from regulations (Wesseler and Kalaitzandonakes, 2011) and a loss of expertise and investments to more accommodating and developed bioeconomies (Dunwell, 2014; Malyska and Twardowski, 2014). Africa is vulnerable due to its weak position in the global economy, inaction by its political leaders, and weak governance.

A blanket approach for innovation success in the biosciences does not exist. However, each region should tailor pathways unique to its circumstances for sustainably developing its bioeconomy. Socioeconomic and technical challenges and opportunities of bioeconomies must be addressed simultaneously (Fok et al., 2007). Pathways to success require a conflict-free and stable political environment.

At a policy level, Europe and Africa should formulate and implement bioeconomy plans that coordinate their internal approaches and actions with clear visions, aims, schedules and systems for measuring and monitoring their progress to implement corrective action when needed. They should have policies targeted at supporting sustainable bioeconomic development. Influential leaders in government, education, and business should address the bioeconomy challenges together proactively (as was done in Berlin in 2015 (Global Bioeconomy Summit 2015, 2015)) to avoid their global competitiveness from being compromised and welfare lost to competitors.

Governments should stimulate their bioeconomies through policies such as preferential procurement programs and providing financial incentives for initiatives that will be of long-term benefit to society, for example: climate-smart farming and the generation of ‘green’ electricity. Public and private sector R&D investments and capacities (infrastructure and expertise) should be increased to accelerate innovation development in the bioeconomy. In Africa, investments in communication and transport infrastructure should be increased for coordinating and transporting produce in rural areas to markets and value-adding facilities.

In Africa, secure land tenure systems should be implemented to avoid controversies about land use (for example: ‘land grabbing’). Fair and equitable employment conditions need to be upheld to prevent the exploitation of workers. Support for women farmers should be enhanced to improve gender inequality by including them in economic and education activities, amongst others. Value-added activities should be established in rural areas to keep the bioeconomy decentralized and sustainable (World Bank, 2012; Pfau et al., 2014; Wiggins et al., 2015), and to reduce pressure on urbanization.

Europe and many African countries need to lighten their regulatory ‘millstones’ (Spielman and Zambrano, 2013; Chambers et al., 2014) for authorizing innovations, especially GE crops. The Economist (2019) comments that poor crop yields in Africa are partly due to a lack of good quality seed and “that government policies prevent farmers from getting” them. “The bravest governments could also relax the bans that almost all have imposed on [GMOs]”. Another application of biotechnology would be “producing seeds that will flourish in a changing climate.”

To overcome its capacity, expertise and funding limitations, Africa should centralize risk assessment (Adenle et al., 2013), harmonize regulations and facilitate cooperation through regional economic communities (Chambers et al., 2014). Africa should implement practical and implementable biosafety regulations so that it can adopt existing innovations approved elsewhere. This strategy would avoid lengthy and costly regulatory delays, and could generate substantial immediate economic benefits (e.g., Kikulwe et al. (2011)).

Areas for further research include finding answers to the following questions:

- What specific support do women farmers need to increase their participation in the bioeconomies of Africa and Europe?
- Which value chains in Africa, excluding coffee and cotton, have the potential for being substantially improved and how?
- What is the socioeconomic cost to Europe from losing expertise and investments to more accommodating (from a regulatory perspective) bioeconomies, and how can these losses be mitigated?

Since this chapter was first published, one notable and positive policy change took place in Africa, namely, the African Comprehensive Free Trade Agreement. This agreement “promises free movement of people, goods and services” (POLITICO website, 2021), and has the potential for stimulating its bioeconomy.

Chapter 4 researches the trends in approval time of new GE crops in the US and the EU. The approval time for these innovations is of significant economic interest to stakeholders in their value chains (Stein and Rodríguez-Cerezo, 2009; Nowicki et al., 2010). A trend of shorter approval times in a given regulatory system is expected (Pray et al., 2005a). The hypothesis tested is that approval times of GE crops in the US and EU are shortening. This chapter investigates the time taken for GE crops to be approved by analyzing: (1) each step in the regulatory ‘path’ for its contribution to the overall regulatory process, and (2) the impact of crop characteristics on regulatory time.

The results for the US show that initially, from 1988 until 1997, the trend decreased with a mean approval time of 1,321 days. From 1998-2015, the trend almost stagnated with a mean approval time of 2,467 days. In 1998, there was a break in the trend of the overall approval time. In the EU, from 1996-2015, the overall temporal trend for approval decreased and then flattened off, with an overall mean completion-time of 1,763 days. However, the duration of the 'risk assessment' step tended to increase (Figure 4-5 (b)).

One or more events, or factors around 1998 triggered a delay in the US's approval process, i.e., developers who applied to the APHIS from 1998 onwards for permission to conduct field trials for the first time on a new GE crop, spent 1,146 days longer (63%) in the regulatory pipeline than had permission for their crops' field trials been applied for in 1997 or earlier (model 1 in Table 4-6). This break in the trend coincided with a number of disruptive events in the biotechnology arena. Examples include: the Prodigene (Federation of American Scientists, 2011) and StarLink (Carter and Smith, 2007) incidents, and the monarch butterfly controversy (Shelton and Sears, 2001) in the US; and from the EU, Pusztai's research on the health effect of GM potatoes on rats (Loder, 1999), the de facto moratorium on new GE crop authorizations (Devos et al., 2006), "debates over Dolly the [cloned] sheep and GM crops and food" (Bauer, 2002), and the occurrence of bovine spongiform encephalopathy (The Economist, 2000), commonly known as mad cow disease.

In the US, no statistically significant correlations between crop characteristics and regulatory time were found.

In the EU, some crop features were correlated with the time taken to complete the MS-application step: applications for maize took 82% (15 days) longer than those for soy beans, while applications with the insect resistance trait, took 150% (88 days) longer than those for herbicide tolerance. Similarly, applications for non-food/feed took 208% (559 days) longer than those for 'food and feed' purposes (Table 4-8). Results presented in Table 4-10 indicate a negatively-sloping linear relationship for the 'political' step. The results confirmed the observation by my colleagues and me that with every additional year, the approval time decreased by 7-8% (35-48 days): a robust finding for all five models. This model has evidence that applications for multiple traits took somewhat longer compared with the single trait category. Coefficients for cotton and potato (model 5) are statistically significantly different to maize, meaning that completing this step took approximately 49% (163 days) and

118% (977 days) longer for these applications, respectively, compared with maize. For the overall time, there was no robust evidence for statistically significant differences between domestic and foreign developers, herbicide tolerant and insecticide resistant crops, or ‘food and feed’ and non-food/feed crops.

In March 2012, a regulatory change was introduced in the US to facilitate earlier public involvement and the way in which public comments are solicited and used in the approval process (see Figure 4-2) (USDA APHIS, 2012). Further research could investigate the impact of this policy-induced change on regulatory time.

There are two areas for further research in the EU. Firstly, EFSA’s ‘risk assessment’ step could be analyzed to investigate if (and therefore, how) its completion-time can be shortened. Secondly, the ‘opt-out’ legislation introduced in 2015 in the EU allows MSs to restrict or prohibit the cultivation of EU-approved GE crops on their territories (Directive (EU) 215/412). This policy change could accelerate the ‘political’ step as MSs could approve applications for cultivation at their first voting opportunity at the SCFCAH. This hypothesis could be tested by empirical research into the impact of this regulatory change on approval times.

Policy implications are that the long approval times remain a significant cost for developers of GE crops. These high costs continue to hamper innovation by discouraging, or even preventing, smaller seed firms from developing GE crops. The longer it takes for a new crop to be authorized, the longer the delay in the potential benefits to society. Should policy makers in the US and the EU wish to foster innovation without compromising the safety of humans and the environment, they should investigate ways of shortening the approval times of GE crops.

Chapter 5 analyzes the voting behavior of EU MSs for voting results on applications of GE crops from 2003-2015. In the EU, politics plays a decisive role in the authorization process of GE plants. GE crops are approved for one or more uses, namely, (1) food and or feed, (2) industrial use (import and processing), and (3) cultivation, or any combination of these uses. Most applications end in a political gridlock. The following research questions were addressed: (1) are individual MS characteristics more relevant for explaining their voting behavior than other factors such as the crop type? And, (2) which MSs' voting behavior must change to avert a gridlock for approval?

A QM has been achieved on one occasion at SCFCAH, but never at Council. At the Council/AC level, Austria and Croatia have consistently voted against an approval, whereas The Netherlands has always supported approvals. All other MSs showed inconsistencies at least once in their voting decisions at SCFCAH and Council/AC level.

Empirical results revealed that MS fixed effects was the major factor explaining the voting results supporting the gridlock hypothesis. Crop characteristics and crop use played no apparent role in MSs' voting behavior. Despite the voting gridlock, the EU's current voting mechanism allows for the importation of certain GE crops as food and or feed. The slowness of its authorization process contributes to approval asynchrony with the US. Applications by developers to cultivate GE crops in the EU are generally avoided. Unity is lacking amongst EU MSs concerning the approval of GE crops for their various uses.

Three of the four 'heavy-weight' MSs in France, Germany, and Italy (UK is the fourth) featured prominently in preventing a QM. Poland, which joined the EU in 2004, has become an important and consistent opponent (contributor to the 'against' vote) due to its sizable vote weight, while Spain (Poland's equal in vote weight) switched to being a consistent supporter from 2007 onwards. Although the number of ballots with the double majority voting rule is low, early evidence revealed that the influence of Germany, France, and Italy—in this order—on achieving a QM has strengthened due to their new, larger vote weights. Thus, the voting behavior of these three MSs, c.p., must change to a 'for' vote for a gridlock to be averted.

Further research is required to understand the MS endogenous factors driving voting behavior, such as: (1) the core reasons for each MS's stance on GE plants, (2) the factors driving politicians' voting behavior, and (3) at MS-level, the link between the public's stance on genetic engineering and the voting behavior of its representatives at the Union. Another avenue for research is to test the hypothesis that in the EU, the political-economic benefit-cost ratio is too low for politicians to vote in favor of approving GE crops. Finally, the UK, a former 'heavy-weight' MS in favor of GE crops, left the Union in January 2020. The implications on the voting gridlock of this change in the EU's membership could also be investigated.

Policy implications of this study are twofold. Firstly, GE crops do not appear to be beneficial enough to the heavy weight MSs for them to change their voting patterns. Secondly, the two-tier voting system (first at SCFCAH, followed by Council/AC) appears to be unnecessary as it could theoretically end at SCFCAH with the risk assessment. Abolishing the political step could represent an important saving in resources.

Chapter 6 researches the foregone benefits of delaying the approval of varieties of the following staple food crops developed using genetic engineering to be resistant to their crop-specific pests in their respective countries in SSA:

- cooking banana in Uganda that is susceptible to a fungus causing black sigatoka (leaf spot) disease (Ploetz, 2001),
- cowpea in Benin, Niger, and Nigeria, that is susceptible to a pod boring insect, and
- corn in Kenya that is susceptible to insects. The corn variety was also developed to withstand droughts. Dry spells frequently compromise crop yields in Kenya.

When this research was done, these crops were unavailable to the public as their applications were still awaiting approval. The following theoretical research question was asked: what are the foregone benefits of delaying the approval of these crops in their respective African states?

Amongst other African countries, Kenya and Uganda had the chance to follow South Africa’s example of adopting GE crops. If Kenya had adopted GE corn in 2006, between 440 and 4,000 lives could theoretically have been saved. Similarly, Uganda had the possibility in 2007 to introduce the black sigatoka resistant banana, thereby potentially saving between 500 and 5,500 lives over the next decade. The introduction of insect resistant cowpea in Benin, Niger, and Nigeria was expected to have been in 2017. The foregone benefits in terms of consumer and producer surplus of a 1-year delay in the approval of the GE cowpea in Benin, Niger, and Nigeria is estimated to be 2-2.4 M USD, 14.9 M USD, and 33.1-46.6 M USD, and in terms of lives lost for a 40% adoption ceiling reached after 10 years: 10, 4, and 401 lives, respectively. The foregone consumer- and producer surplus benefits of a 1-year delay in the approval of GE corn in Kenya and GE cooking banana in Uganda is 21.9-49.8 M USD and 56.9-97.3 M USD, and in terms of lives lost for a 40% adoption ceiling reached after 10 years: 572 and 862 lives, respectively.

The cost of delay, especially in evaluating the benefit of adopting insect resistant cowpea, might have been underestimated because only the energy content of this leguminous crop was considered—its relatively high protein content was ignored. The results highlight that delaying the approval of GE crops not only theoretically reduces consumer and producer surplus of households (mainly in rural areas), but it also costs human lives! Reducing the approval time of GE crops can generate economic gains, potentially contributing to reducing malnutrition and saving lives. Moreover, it can be an inexpensive strategy for reaching the Sustainable Development Goal of eradicating malnutrition by 2030.

Further research is needed to investigate: (1) the cost of delay in adopting insect resistant cowpea in Benin, Niger, and Niger by accounting for this crop's relatively high protein content; and (2) for all crops in this study: the environmental and health benefits from reduced pesticide use.

Policy implications for the countries that have not yet approved the GE crops developed for their regions are that lives continue to be lost that otherwise could potentially be saved. Also, the socioeconomic benefits of a healthier, better nourished population are forgone and the socioeconomic hardships faced by these populations are prolonged and possibly even exacerbated.

Finally, **Chapter 7** analyzes the efficiency levels of nine of the largest commercial seed producing firms globally for the period 2008-2015 and assess if there is a relationship between firm size and efficiency. Firms criticized for contributing to the concentration of the global seed market are included in the dataset; these firms are also producers of GE crops.

The results showed that the mean temporal OTE increased by a mere 0.8%, which reflects stability in managerial ability for these firms. Dow was the exception by having an overall increase in OTE of 7.75%. Furthermore, there was no clear relationship between PTE and asset size. On a firm level, DuPont Pioneer, Syngenta, Monsanto, and Dow operated under IRS with the latter two reaching CRS—the most productive scale size. DLF Trifolium and Takii operated at, or close to CRS. Sakata and Bayer displayed an inconsistent sawtooth-shaped trend in PTE versus size (Figure 7-3b and Figure 7-3i, respectively). Thus, they operated under both IRS and DRS. No obvious overall relationship between SE and asset size was apparent. DuPont Pioneer was scale efficient in three consecutive windows, while DLF

Trifolium, Dow, and Monsanto achieved this outcome in one (but not the same) window. All other firms were consistently scale inefficient with Sakata having the lowest SE scores (87.5-91.7%).

In terms of efficiency, the PTE analysis revealed that the corporate activity (M&As) of most firms was theoretically justified (Bayer was the exception). However, the impact of market concentration on competition and innovation, for example, lay beyond the scope of this study, and could be the focus of future research.

The causes underlying the efficiency performance of the world's largest seed producers could be the subject of future studies. Bootstrapping techniques such as those proposed by Simar and Wilson (2007) could be employed in these investigations.

This study concentrated on firms' technical performance. However, firm performance measured by environmental- and social indicators is an opportunity for the corporate social responsibility performance of the global seed industry along the lines of Chambers and Serra (2018) or Puggioni and Stefanou (2019) to be researched.

A policy implication flowing from this study is that in terms of efficiency, the market concentration of firms (mainly via M&As) in the global seed industry has not compromised efficiency. However, efficiency is not the only parameter that policy makers can focus on when regulating corporate activity. Three other important areas are: (1) the impact of market concentration on competition, (2) levels of innovation, and (3) geopolitical stability.

A final synopsis of my research questions and their main findings is given in Table 8-1.

Table 8-1. A summary of the main research findings of each chapter

Chapter and Topic	**Research Question / Hypothesis**	**Main Research Findings**
Chapter 3: The social and economic challenges for a bioeconomy.	What pathways are there for unlocking the potential of the bioeconomies of Europe and SSA?	SSA should harmonize regulations for GE crops; implement biosafety regulations allowing for the adoption of innovations approved elsewhere; implement secure land tenure systems.

		Europe should lighten the regulatory burdens imposed on biotech innovations; promote climate-smart farming; invest more in bioeconomy centric R&D. Both regions should improve existing bilateral cooperation to grow their bioeconomies.
Chapter 4: Trends in GE crops' approval times in the US and the EU.	Approval times of GE crops in the US and EU shorten with the progression of time.	In the US: for the periods 1988-1997 and 1998-2015, the trend in approval times decreased and almost stagnated, respectively. In 1998, there was a break in the trend of the overall approval time. In the EU, from 1996-2015, the overall temporal trend for approval decreased and then flattened off. The duration of the 'risk assessment' step tended to increase.
Chapter 5: EU MSs' voting for authorizing GE crops: A regulatory gridlock.	Are individual MS characteristics more relevant for explaining their voting behavior than other factors such as the crop type? Which MSs' voting behavior should change to avert a gridlock for approval?	MS fixed effects are the major factors explaining the voting results. Crop characteristics and crop use played no apparent role in MSs' voting behavior. Germany's, France's, and Italy's voting behavior should change to a 'for' vote to avert a gridlock.
Chapter 6: Foregone benefits of important food crop improvements in SSA.	What are the theoretical costs for delaying the approval of three GE food crops in five SSA states? (Fungus resistant cooking banana in Uganda; insect resistant cowpea in Benin, Niger, and Nigeria; drought tolerant and insect resistant maize in Kenya.)	The estimated foregone benefits (consumer and producer surplus) of a 1-year delay in the approval of the GE cowpea in Benin, Niger, and Nigeria are 2-2.4 M USD, 14.9 M USD, and 33.1-46.6 M USD, and in terms of lives lost for a 40% adoption ceiling after 10 years: 10, 4, and 401 lives, respectively; for GE maize in Kenya and GE cooking banana in Uganda it is 21.9-49.8 M USD and 56.9-97.3 M USD, and in terms of lives lost: 572 and 862 lives, respectively.
Chapter 7: Decomposition of efficiency in the global geed industry: a nonparametric approach.	What are the efficiency levels of nine of the largest commercial seed producing firms globally for the period 2008-2015, and is there a relationship between firm size and efficiency?	Mean aggregate OTE was 93.5% and 94.3% in W1 and W5, respectively. There is no clear relationship between either PTE or SE, and asset (firm) size.

The common thread of this dissertation is the socioeconomic impact of regulations on the adoption of GE crops. In the late 1990s, vitamin A enriched 'golden' rice was developed using genetic engineering to alleviate vitamin A deficient diets in the impoverished rice-eating regions of the world. Delays in authorizing the cultivation of this GE rice variety are potentially costly. From empirical modelling, "the economic power of the opposition towards Golden Rice [has resulted] in about 1.4 million life years lost over the past decade in India." (Wesseler and Zilberman, 2014). In 2018, the US Food and Drug Administration declared golden rice to be safe for human consumption (Owens, 2018), and in 2021, the Philippines was the first country to approve it for commercial cultivation (International Service for the Acquisition of Agri-biotech Applications (ISAAA) website, 2021a). This example illustrates how difficult and potentially costly it is to implement a relatively easy and low-cost solution for a known dire socioeconomic problem. With respect to the GE crops covered in **Chapter 6**, as of August 2021, Nigeria authorized GE cowpea in 2019. None of the other countries had authorized the GE crops investigated (ISAAA website, 2021b).

Green biotechnology is a field that can continue making meaningful contributions to solving mankind's challenge of feeding its growing population, which is predicted to peak at ca. 9.73 billion in 2064 (Vollset et al., 2020), and mitigating some of the impacts of climate change. According to Oritz-Bobea et al. (2021), since 1961, anthropogenic climate change has caused a reduction in global agricultural total factor productivity by about 21%. They comment that global agriculture has grown more vulnerable to ongoing climate change. King et al. (2018) calculated that by 2099, about 76% of the boreal region might be climatically suitable for farming certain crops, compared to the current 32%. This forecast represents a large northward spread in the area potentially suitable for growing crops, resulting from climate change. These empirical predictions show that it is highly likely that humankind will face new challenges, such as developing crops to withstand warmer temperatures and severe weather conditions. Solutions to these challenges will need to be found to keep the world's human population fed. Employing genetic engineering to fast-track the development of crops with desirable genetic traits is one tool in humankind's current toolkit that can be used to mitigate some of these challenges.

No matter how suitable new GE crops may be, it is likely that there will continue to be proponents and opponents to the adoption of this green biotechnology, just as there are pros and cons. Regulations are in place to protect humans and the environment from the potential negative effects of adopting these technologies. Scientists use, amongst others, benefit-cost models to demonstrate the impacts of delaying the adoption of these innovations. It is, and will be, up to the politicians mandated by their constituencies to take responsible decisions about authorizing the use of GE crops by carefully weighing up the advantages of adoption against the disadvantages. Equally important is that proponents and opponents of the technology understand the implications of their stances. This dissertation is a contribution to this ongoing debate.

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- Justus Wesseler provided the concept for the chapter, and contributed in a minor way to the text, and did the final proofreading.
- Richard Smart did the literature research and the bulk of the writing.

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- Justus Wesseler provided the concept, guided the theoretical approach, and provided oversight.
- Richard Smart gathered the data, prepared them for empirical analysis, conducted the literature review, and wrote the bulk of the text.
- Matthias Blum performed the econometric analysis and provided its interpretation.

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- Matthias Blum performed the econometric analysis and provided its interpretation.

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- Richard Smart contributed the following: Data curation, investigation, writing the original draft, and reviewing and editing the final draft.
- Jennifer Thomson contributed to the concept, data curation, investigation, validation, and reviewing and editing the manuscript.
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A quote from page 96 of the 2018 published edition of Abdulrazak Gurnah's 2021 Nobel prize winning novel: **Gravel Heart**, Bloomsbury Publishing Plc, London, UK:

" *... concentrate on your studies. There is nothing more important than learning.*"