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Research Note

Genetically Engineered Crops' Authorizations in the US and the EU: a Struggle Against the Clock

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Abstract

The regulation of genetically engineered crops is important for society: ensuring their safety for humans and the environment. Their authorization starts with a scientific step and ends with a political step. Trends in the time taken for their authorization in the European Union are that they are decreasing, but in the United States there is a break in the overall trend: initially it decreased until 1998 after which it increased.

Keywords: regulation, agriculture, agricultural economics, innovations, GMO, biotechnology

JEL codes: Q16, Q18, N22, N24, N42, N44

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Introduction

Regulations ("governmental oversight") are used for ensuring the safety of new products of biotechnology, such as genetically engineered (GE) crops, for humans and the environment[1]. Adhering to these regulations involves the consumption of resources, including time, by the regulators and developers of novel plants. Developers of new GE crops incur substantial compliance costs imposed by their regulation thereby acting as a potential barrier to all but the largest private organizations from investing in research and development in this field[2,3]. Delays in commercialization cause economic losses in foregone profits, which are further exaggerated by asynchronous approval processes also causing, inter alia, market disruptions, and strained trading relations[4]. The period for applications successfully moving through the regulatory pipeline, unforeseen regulatory delays, and the asynchrony in GE crop approval between trading partners, are of economic importance for all participants in a new GE crop's value chain[5,6]. Also delayed are potential environmental and human health benefits arising from reduced pesticide use; reduced pressure on natural habitats from agricultural land use; lowered greenhouse gas emissions from agricultural activities[7]; and health and associated economic benefits for humans from micronutrient enriched food crops like beta-carotene-containing rice[8]. Additionally, these temporal aspects have wide-ranging socio-political implications for their regulators and policy evolution due to opposing pressures exerted on this 'ecosystem' by the antagonists and protagonists of green biotechnology, a recent example of which was the change to the GE food labelling legislation decided upon at the ballot box in the state of Washington in the US[9].

We investigated the time taken for GE crops passing through the regulatory pipeline of the United States (US) and the European Union (EU) - important trading partners involving GE crops – to highlight the trends that have developed since the first GE crop was approved in the US and also worldwide.

Regulatory Processes in US and Europe

The regulatory process for authorizing a new GE crop in the US and the EU commences with a scientific step involving a rigorous set of scientific investigations for evaluating its overall safety, culminating in a political step assessing these findings for granting approval[10]. In the US, the US Department of Agriculture (USDA) takes the lead role for approving GE crops and is appropriately supported by the Environmental Protection Agency and the Food and Drug Administration[11]. From a temporal perspective, we consider that the regulatory process begins when permission is first sought at the USDA's Animal and Plant Health Inspection Service (APHIS) by a developer for conducting field trials on a new GE crop: called a regulated article, and ends when the developer submits its petition dossier to the APHIS petitioning for non-regulated status – this marking the beginning of the political process, ending (for successful petitions) when the regulated article is deregulated and given non-regulated status. Similarly, the EU's approval process commences (scientific step) when a developer applies to its Member State (MS) for authorizing a new GE crop (always for a specific use, e.g. cultivation, and or use as food and or feed, and or import and processing, or any combination of these), ending when the European Food Safety Authority (EFSA) issues a favorable opinion, this also flagging the political step's beginning as this opinion is then assessed by the European Commission. The political step, and therefore the whole approval process, stops when the Commission reaches its decision. The combined duration of the scientific and political steps gives the total duration of the approval process as we have analyzed it (see supplementary materials for a detailed description of the analysis and corresponding results).

A trend of shorter approval times developing in a given regulatory system[12] is expected as experience with the different steps in the approval process, in scientific research, and the commercialization of GE crops is gained with time so allowing efficiencies to develop[2,3].

The US

Our analysis of all the authorized GE crops in the US save one (we excluded a GE flax plant whose field trials were done in Canada, because no dates are published for its scientific step) thus far (March 18, 2014) show this trend was followed during the period 1988-1997, decreasing by an average of 114 days annually. Surprisingly, from 1998 onwards, the overall trend reversed with approval periods getting longer by an average of 33 days annually (it took ca. five years for this trend to reach its peak during 2001, after which a gradual correction appears to have taken place) (**Fig. 1** and **Supplementary Table 1**). This break in the trend coincides with a number of disruptive events in the biotechnology arena. Examples from the US include the Prodigene[13] and StarLink[14] incidents, and the monarch butterfly controversy; and from the EU: 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)[15]; "debates over Dolly the sheep and GM crops and food"[16], and the occurrence of bovine spongiform encephalopathy[17]. 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 this trend suddenly and conjecturally levelled off[18].

THE EU

For the EU, the overall trend is for approval times getting shorter (**Fig. 1**). It is surprising that over time, the EU's authorization process has sped up, as there is considerable consumer and political resistance for adopting green biotechnology in parts of this heterogeneous (in terms of attitudes towards GE crops) region[15]. In the EU, it is permissible for developers to reference data or “notifications previously submitted by other notifiers”[19] when conducting their scientific investigations - an information spill-over effect possibly contributing to the average duration of the EU’s scientific step being shorter than that of the US (an average of 73 days for those GE crops first authorized in the US and subsequently in the EU (**Supplementary Table 1**)).

Regulatory Efficiency

We found one regulatory change in the US aimed at shortening the authorization time of GE crops. An internal inquiry by the APHIS showed “competing priorities for … staff” as a probable cause for the petition process getting longer[20], which subsequently lead it to introduce procedural changes to the US’s petition process in 2012. It will be insightful to see if these alterations will reach the USDA’s goal of improving customer service[21], and by implication, regulatory efficiency - one measure of which we consider being the speeding up of the approval process, notably the political step. However, repeated calls have been made for the regulatory trigger to be product- rather than process based[2], i.e. regulate the transgenic event and not the plant being altered. This change to the scientific step, if made, has the potential for speeding up the approval of GE plants as it would eliminate duplicating costly and lengthy scientific inquiries, and conjointly shrinking the asynchronous approval of GE crops, so contributing to improving the international trade environment, especially as most GE crops are first developed in the US[4]. Also, political decision makers should consider implementing policies making the regulatory process more affordable (e.g. review all scientific inquiries that are currently prescribed for possible redundancy) thereby stimulating and encouraging investment in agricultural innovation by smaller investors and in a broader spectrum of products[2]. The US is the locus for most of these innovations[18] and from which they diffuse globally. The US's rate of commercialization of new GE crops depends not only upon her regulatory system, but also the compliance requirements of other countries being concurrently addressed by US developers.

Concluding Remarks

In a new regulatory environment, initially the time taken for approving novel crops should decrease due to the learning effect[12,22]. For countries new to this arena of biosafety regulation, valuable lessons can be learnt from the experiences of functioning, yet contrasting regulatory systems like those in the US and EU, particularly in the technical arena (e.g., risk assessment). However, the political side of the regulatory coin poses potentially greater challenges for optimizing approval times. Based on history, it is inevitable that inflated, negative claims of the impacts of GE crops on human health and or the environment will be made in future. It is desirable that mechanisms be in place for minimizing the negative impact of such claims, and also of those ensuing from undesirable and unrelated events causing negative spillover sentiments (as in the case of mad cow disease) into green biotechnology. Including deadlines for the different steps within approval processes can reduce costly delays.

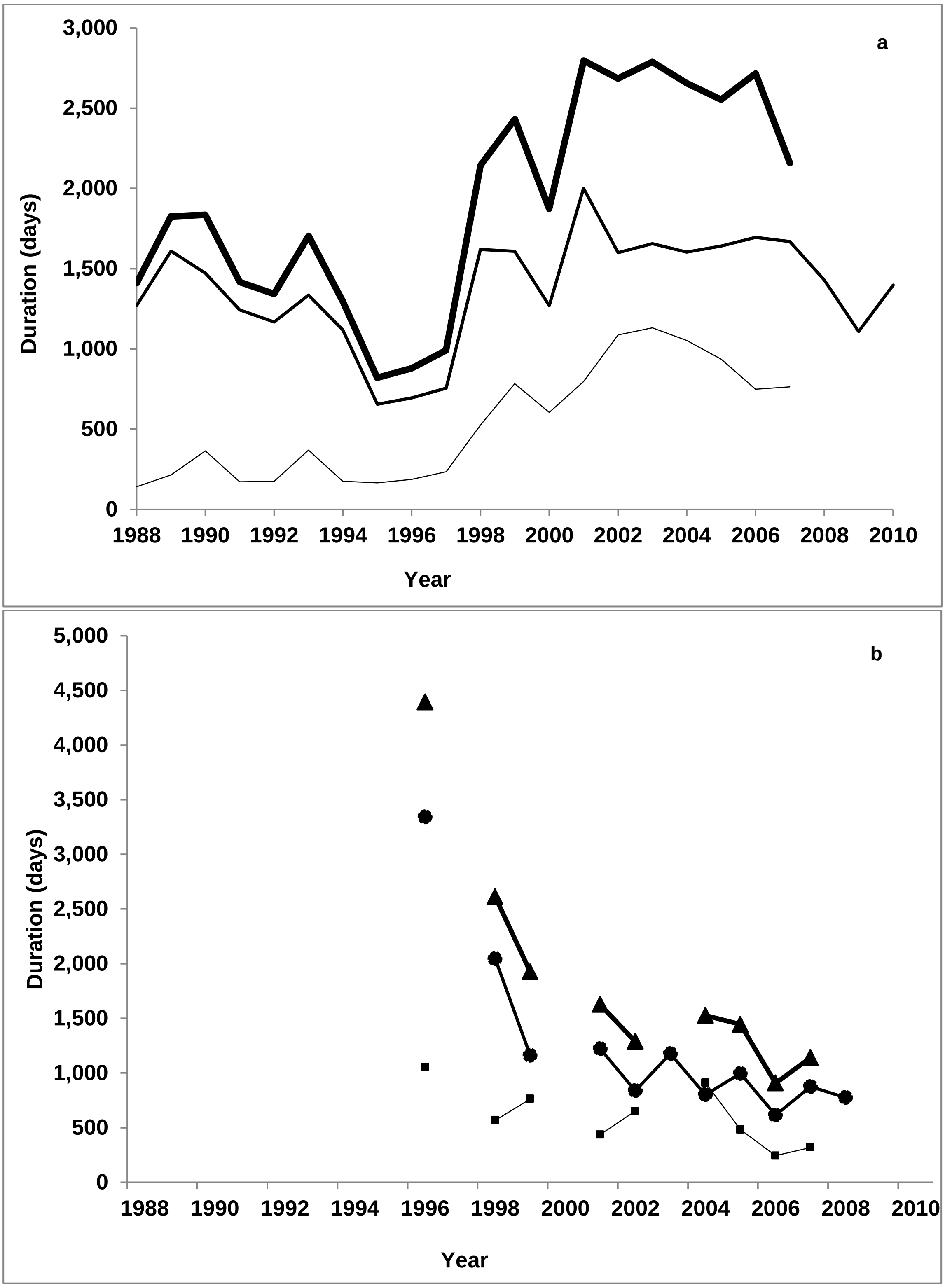

Fig. 1. Trends in time (days) taken for the authorization, split into the scientific (—▪) and political (━●) steps, and overall time (▬▲) taken, for all GE crops authorized as well as those awaiting the completion of the political process, in the US (a GE flax was excluded due to incomplete data) **(a)**, and the EU **(b),** thus far (March 18, 2014).

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The data reported in this paper are tabulated in the Online Supplementary Materials, and are archived at the following database < http://edepot.wur.nl/306240 >

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Supplementary Materials for:

Genetically Engineered Crops' Authorizations in the US and the EU: a Struggle Against the Clock

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Methods

Introduction

The approval processes for new GE crops in the US and the EU are similar in that they comprise two steps, starting with a science-based assessment of its safety for humans and the environment, and concluding with a political decision-making process. We investigated the completion-time for the aforementioned steps, and assumed that their arithmetic sum is the total duration of the authorization process. We sourced our data for all GE crops that have been approved so far (March 18, 2014) from internet-based databases, searching for dates indicating the start and end of each step.

Descriptive Statistics: US and EU

The regulatory history in the US started on December 12, 1988 (application date for permission for the first field trial for the GE tomato: Flavr Savr) and, although ongoing, for this study it ended on December 18, 2010 (submission date to the APHIS of the petition document for the GE maize event MON-87411-9); 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 July 28, 2010 (when the Commission made its decision for the GE maize event Bt11xGA21), respectively.

For the US, we investigated all GE crops listed (together with their petition numbers) by the APHIS's Biotechnology Regulatory Services (BRS) that have already been granted non-regulated status (i.e. passed through the regulatory pipeline and have been authorized), and those that have had their petition documents submitted to the APHIS but have not yet been deregulated (see < http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml >). We assumed that the scientific process for a given GE crop starts when its developer applied to the APHIS for the first time for permission (notification or permit process: see < http://www.aphis.usda.gov/biotechnology/submissions.shtml >) for conducting field trials on it. We found this date by cross-referencing the permit number of the earliest field trial for a given GE crop (published in its petition dossier) with the BRS's online permit information database (see < http://www.aphis.usda.gov/biotechnology/status.shtml >), which also contains the other dates we used. We used 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 political step – and when non-regulated status was awarded: this signaling the conclusion of the political decision-making step as well as the entire regulatory process. The non-regulated status for two glyphosate-tolerant GE crops (alfalfa (lines designated as 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 study as they occurred ex post the awarding of non-regulated status[1,2] and were therefore excluded from our analyses.

For the EU, we investigated all GE crops listed on the GMO Compass website's database < http://www.gmo-compass.org/eng/gmo/db/ > classified as having a risk assessment report (i.e. the scientific- but not the political step is complete), and a valid authorization (approved). This database has links to the EFSA's scientific opinion/s and the Commission's decision for each GE crop. Here we found the following dates for each application: submission for authorization to the EU MS (start of the scientific step); the

EFSA's date of adopting the application (end of the scientific step, start of political step); and the date when the Commission reached its decision for authorizing the GE crop (end of political step and therefore the entire application process). Where the complete date (day, month, year) for the start of the scientific step was not published, we either assumed the date to be the fifteenth day of the month during which its application was submitted to the relevant MS, or we calculated a proxy value (the date of submission to EFSA minus the time for all applications with complete data of the mean time difference between submitting to the EU MS and to the EFSA). **Supplementary Table 1** shows a general trend of the regulatory process getting longer and shorter in the US and EU, respectively.

Supplementary Table 1. Mean time (*days*) taken (and their mean annual changes indicated in parentheses) for completing the scientific and political steps, and the overall regulatory process for GE crops authorised in the US* and EU† from 1988 to 2013, and the information spill-over effect for GE crops first authorised in the US.

Location	Scientific Phase (days)	Political Phase (days)	Entire Regulatory Process (days)
US: early period (1988-1997)	1,090 (-108,0) (n=41)	211 (-6,2) (n=41)	1,301 (-114,2) (n=41)
US: late period (1998-2013)	1,645 (-13,1) (n=52)	842 (+33,3) (n=39)	2,504 (+33,0) (n=39)
EU: 1996-1999	2,472 (n=4)	859 (n=4)	3,330 (n=4)
EU: 2000-2010	924 (n=41)	586 (n=26)	1,412 (n=26)
Information spill-over effect for GE crops (n=15) first authorised in the US and subsequently in the EU			
US	1,242	n/a	n/a
EU	1,169	n/a	n/a
Time difference	73	n/a	n/a

* Data source:< http://www.aphis.usda.gov/biotechnology/status.shtml >

† Data source: < http://www.gmo-compass.org/eng/gmo/db/ >

Empirical Analysis

US

For the US, we collected data for 93 observations (applications): 80 passed through the entire regulatory process; and 13 completed the scientific step and are awaiting the APHIS's decision for deregulation: the outcome of the political step. **Supplementary Table 2** presents an econometric summary of this dataset's composition. We used the start date for each application (see preceding section) for identifying two groups of applications: (1) 'early' (up to and including 1997), and (2) 'late' (1998 onwards), representing 44 and 56 per cent of observations, respectively. US-based and foreign developers submitted 75 and 25 per cent of the applications, respectively, whereas 83 and 17 per cent of the applications were for single- and multiple trait events, respectively. Forty-five per cent of the genetic modifications were for herbicide tolerance; 34 per cent for improving insect resistance; and the remaining 32 per cent for other GE modifications like viral resistance, freeze-tolerance, and quality improvement traits (e.g. reduced browning of apples, and reduced lignin content of alfalfa). The majority of GE organisms were developed for food production; only 23 per cent were developed for non-food purposes. Modified variants of GE maize were the most frequent (31 per cent); followed by soy bean (18 per cent); cotton (16 per cent); tomato, and oilseed rape (6 per cent each); and potato (5 per cent); the remaining 18 per cent were for: alfalfa, sugar beet, chicory, creeping bentgrass, eucalyptus, papaya, rice, rose, squash, and tobacco. We identified the political regime (or 'climate') for each application by including dummies for Republican and Democratic presidencies (corresponding to each regulated article's application start date). More applications were submitted during a Republican (62 per cent) than a Democratic (38 per cent) presidency.

Supplementary Table 2. 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 political step, from 1988 to 2013.

Category	Parameter	Mean	SD	Min	Max
Regulatory step's duration	Scientific step (ln)	7.16	0.43	5.58	8.06
	Political step (ln)	5.93	0.82	4.67	7.58
	Overall process (ln)	7.44	0.47	6.1	8.42
Period	Early	0.44	0.5	0	1
	Late	0.56	0.5	0	1
Date	Year	1998.56	5.92	1988	2010
Developer's domicile	Domestic	0.75	0.43	0	1
	Foreign	0.25	0.43	0	1
Trait multiple	Single	0.83	0.38	0	1
	Multiple	0.17	0.38	0	1
Trait type	Herbicide tolerant	0.45*	0.5	0	1
	Insect resistant	0.34*	0.48	0	1
	Other trait	0.32*	0.47	0	1
Crop's use	Food	0.77	0.42	0	1
	Non-food	0.23	0.42	0	1
Crop	Cotton	0.16	0.37	0	1
	Maize	0.31	0.47	0	1
	Soy	0.18	0.39	0	1
	Tomato	0.06	0.25	0	1
	Potato	0.05	0.23	0	1
	Canola	0.06	0.25	0	1
	Other	0.16	0.37	0	1
Political 'climate'	Republican	0.62	0.49	0	1
	Democratic	0.38	0.49	0	1

* 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).

Empirically, we investigated if the structural break in the trend for the time taken to authorize GE crops (**Fig. 1a** and **Supplementary Table 1**) also holds in a multivariate regression framework. Theoretically, what appears to be a structural break may in fact be a sudden shift in the type of application with respect to a GE organism's characteristic. For example, if during the 'early' and 'late' period the applications were predominantly for annual and perennial crops, respectively, then what appears to have been a structural break was in reality caused by a change in the plants' characteristic (annual vs. perennial). Similarly, theoretically a coinciding change in any other plant characteristic, or the political ‘climatic’, may have caused a shift thereby erroneously indicating a structural break, which was actually the result of unobserved factors. We used a set of ordinary least squares regression models for testing if differences in the regulatory process’ time-line could be explained by plant characteristics or an external, independent factor/s.

For the US, we identified two periods separated in 1998 by a structural break, and captured differences in the time taken for applications completing the scientific step, political step, and the overall authorization 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: domestic or foreign developer; Republican or Democratic presidency at the time of initial submission; food or non-food plants; as well as the number of GE traits involved (single or multiple). If the variable identifying ‘early’ and ‘late’ applications reflected a substantial and statistically significant difference after adding controls, the interpretation is that evidence for a structural break exists.

Supplementary Table 3 presents results for a set of regression models, which were designed for netting out effects unrelated to the structural break. Model 1 (baseline model) suggests that submissions made pre the structural break took ca. 42 per cent less time (ca. 535 days)[1]. This estimate is robust as it remained almost unaffected by the additional explanatory variables. In model 6, the minimal estimate, ‘early’ applications took 39 per cent less time (ca. 488 days) than applications submitted during the ‘late’ period. For the scientific step, neither a developer’s domicile nor the trait multiple played a meaningful role in explaining possible differences in time spent in the regulatory process. Model 5 indicates that potatoes, tomatoes, soy beans, and maize plants spend more time in this step - a finding that may be due to the omission of the political variable. In model 6, we addressed model 5’s potential

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

deficiency by including a dummy variable capturing the political ‘climate’ at the time of a GE crop’s initial submission; the result suggests that applications took ca. 244 days longer when submitted during a Republican than a Democratic presidency.

We performed a similar set of analyses for the time taken for a petition passing through the political step in the US (**Supplementary Table 4**). Petitions from ‘early’ applications had a substantial time advantage according to model 1: our baseline model. Differences between the two periods correspond to ca. 632 days (140 per cent) longer for ‘late’ applications’ petitions: a statistically robust result for all the models. The political step reveals that the process-time for foreign-based developers’ petitions was at least 21 per cent longer (ca. 196 days) than those for local developers (model 3). Moreover, we found that the process-time for single-trait applications was ca. 20 to 35 per cent (78 to 147 days) shorter than that for multiple-trait crops. Similarly, petitions for herbicide tolerance crops seem to have had a time advantage of at least 26 per cent (ca. 145 days). For the political ‘climate’, we found further evidence that applications submitted when a Republican was president took 22 per cent (ca. 171 days) longer than those for a Democrat president.

We performed the same set of tests on the overall time taken (scientific and political steps combined) for approval to provide an overview of the total time taken for a new GE crop to pass through the regulatory pipeline as we have described it. The most striking discovery is that one or more events or factors around 1998 triggered a delay in this process of ca. 1,200 days (64 to 66 per cent) 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 ca. 1,200 days longer in the regulatory pipeline than had their crop’s field trials started in 1997 or earlier. Furthermore, our analyses suggest a 25 per cent delay (ca. 379 days) in overall regulatory time associated with events which were granted permission for their first field trials during a Republican presidency.

Supplementary Table 3. Correlates of time taken to for completing the scientific step of the GE crop authorization process in the US from 1998 to 2013.

Variable	Model					
	1	2	3	4	5	6
	Dependent variable: time taken (in days; ln)					
Early	-0.42***	-0.43***	-0.41***	-0.42***	-0.42***	-0.39***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Domestic		-0.00	0.01	0.00	-0.04	-0.06
		(0.975)	(0.926)	(0.974)	(0.658)	(0.528)
Single trait		-0.04	-0.07	-0.06	0.06	0.02
		(0.713)	(0.514)	(0.567)	(0.518)	(0.873)
Cotton					0.18	0.10
					(0.301)	(0.510)
Maize					0.30*	0.21
					(0.066)	(0.180)
Soy bean					0.30*	0.15
					(0.088)	(0.359)
Tomato					0.31*	0.17
					(0.099)	(0.316)
Potato					0.50***	0.40**
					(0.007)	(0.038)
Oilseed rape					0.05	-0.02
					(0.818)	(0.935)
Herbicide tolerance			-0.06	-0.06		
			(0.476)	(0.481)		
Other traits			-0.15	-0.15		
			(0.137)	(0.129)		
Food				0.08		
				(0.423)		
Republican						0.23***
						(0.003)
Constant	7.34***	7.37***	7.46***	7.40***	7.10***	7.08***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	93	93	93	93	93	93
R-squared	0.25	0.25	0.27	0.27	0.34	0.39

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at the 1, 5, and 10 per cent 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 to 2010 (model 4).

Supplementary Table 4. Correlates of time taken for completing the political step of the GE crop authorization process in the US from 1998 to 2013.

Variable	Model					
	1	2	3	4	5	6
	Dependent variable: time taken (in days; ln)					
Early	-1.40***	-1.39***	-1.37***	-1.38***	-1.43***	-1.41***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Late	reference	reference	reference	reference	reference	Reference
Domestic		-0.11	-0.21**	-0.22**	-0.14	-0.15
		(0.247)	(0.020)	(0.016)	(0.187)	(0.139)
Foreign		reference	reference	reference	reference	Reference
Single trait		-0.24*	-0.35***	-0.35***	-0.20*	-0.24**
		(0.060)	(0.006)	(0.007)	(0.071)	(0.034)
Multiple trait		reference	reference	reference	reference	reference
Cotton					-0.23	-0.32
					(0.296)	(0.148)
Maize					-0.04	-0.15
					(0.845)	(0.490)
Soy bean					-0.02	-0.18
					(0.932)	(0.465)
Tomato					-0.09	-0.24
					(0.681)	(0.343)
Potato					0.30	0.20
					(0.361)	(0.580)
Oilseed rape					-0.13	-0.21
					(0.529)	(0.324)
Herbicide tolerance			-0.27**	-0.26**		
			(0.010)	(0.011)		
Other traits			0.13	0.12		
			(0.232)	(0.267)		
Food/feed				0.07		
				(0.497)		
Republican						0.22*
						(0.062)
Democratic						reference
Constant	6.65***	6.92***	7.15***	7.10***	6.99***	6.98***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	80	80	80	80	80	80
R-squared	0.74	0.76	0.80	0.80	0.78	0.79

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10 per cent levels, respectively. Dependent variable is time taken in days (natural log) for completing the political step. Note: the number of observations dropped to 80 as 18 applications included in Supplementary Table 3 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 to 2010 (model 4).

Supplementary Table 5. Correlates of time taken for completing the overall authorization process of GE crops in the US from 1998 to 2013.

Variable	Model					
	1	2	3	4	5	6
	Overall time taken (days, ln)					
Early	-0.66***	-0.66***	-0.64***	-0.66***	-0.66***	-0.64***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Domestic		-0.03	-0.04	-0.05	-0.08	-0.09
		(0.776)	(0.680)	(0.604)	(0.361)	(0.268)
Single trait		-0.08	-0.13	-0.12	0.01	-0.03
		(0.371)	(0.195)	(0.217)	(0.917)	(0.684)
Cotton					0.15	0.04
					(0.409)	(0.780)
Maize					0.28*	0.16
					(0.076)	(0.301)
Soy bean					0.37**	0.18
					(0.047)	(0.302)
Tomato					0.28	0.10
					(0.115)	(0.513)
Potato					0.56***	0.45**
					(0.002)	(0.019)
Oilseed rape					0.05	-0.04
					(0.813)	(0.808)
Herbicide tolerance			-0.11	-0.10		
			(0.246)	(0.247)		
Other traits			-0.11	-0.12		
			(0.268)	(0.224)		
Food/feed				0.11		
				(0.310)		
Republican						0.25***
						(0.001)
Constant	7.78***	7.87***	7.98***	7.91***	7.60***	7.60***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	80	80	80	80	80	80
R-squared	0.49	0.50	0.51	0.52	0.58	0.64

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10 per cent levels. Dependent variable is time taken in days (log) to overcome the overall process. Please note that the number of observations dropped to 80 here since 18 applications included in Supplementary Table 3 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 to 2010 (model 4).

EU

For the EU, we collected data for 41 observations (applications): 30 were authorized (i.e. passed through the entire regulatory process); and 11 completed the scientific step, and like in the US, are awaiting the outcome of the political step. **Supplementary Table 6** presents an econometric summary of this dataset's composition. The first and most recent applications for commencing the scientific step were submitted in 1996 and 2008, respectively; 39 and 61 per cent of the applications were by developers domiciled locally and abroad (mostly the US), respectively. Forty-nine and 51 per cent of the applications are for single and multiple-trait GE crops, respectively. In 68 and 61per cent of the cases, GE modifications were for improving herbicide tolerance and insect resistance, respectively, while the remaining 12 per cent was for other traits. Most of the applications were for GE crops used for food and feed production (83 per cent); while 17 per cent were for serving industrial and other purposes. Modified variants of GE maize were the most frequent (68 per cent); followed by oilseed rape (7 per cent); with flowers (carnations), soy beans, cotton, and potato contributing 5 per cent each; with the remaining 5 per cent for sugar beet and rice.

We followed a similar strategy for testing the robustness of the trend observed in **Fig. 1b**: a convex development for the scientific step, with long durations for submission during 1996 and 1998, and the absence of a clear trend for the remaining period. We modelled this relationship in our baseline model 1with two metric variables: year and the square of the year. We expected the variables 'year' and 'year (squared)' to have negative and positive signs, respectively, indicating the aforementioned convex-shaped relationship. Signs and magnitudes of the variables: 'year' and 'year (squared)' confirm the development of a convex shape (**Supplementary Table 7**). We subsequently added additional variables for controlling for other potential effects related to the developer's domicile; the crop's GE trait; and the crop's intended use (food and feed vs. non-food/feed). We found no statistically significant influences other than the aforementioned non-linear trend. Given the low number of observations, we focused on economic- rather than statistical significance since standard errors tend to be disproportionately large for small samples, leading to statistically insignificant coefficients and an erroneous acceptance of the null hypothesis that a correlation is absent[3]. The magnitude of these coefficients reveals that applications for cotton took approximately 50 per cent longer (ca. 586 days), while those for potatoes completed the scientific step 66 per cent quicker (ca. 129 days).

Supplementary Table 6. 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, from 1988 to 2013.

Category	Parameter	Mean	SD	Min	Max
Regulatory step's duration	Scientific step (ln)	6.8	0.6	5.51	8.13
	Political step (ln)	6.18	0.7	5.02	7.45
	Overall process (ln)	7.33	0.41	6.64	8.51
Period	Year	2003.76	2.75	1996	2008
Developer's domicile	Domestic	0.39	0.49	0	1
	Foreign	0.61	0.49	0	1
Trait multiple	Single	0.49	0.5	0	1
	Multiple	0.51	0.5	0	1
Crop trait	Herbicide tolerant	0.68*	0.46	0	1
	Insect resistant	0.61*	0.49	0	1
	Other trait	0.12*	0.32	0	1
Crop's use	Food	0.83	0.37	0	1
	Non-food	0.17	0.37	0	1
Crop	Cotton	0.05	0.25	0	1
	Maize	0.68	0.47	0	1
	Soy	0.05	0.21	0	1
	Potato	0.05	0.21	0	1
	Canola	0.07	0.25	0	1
	Other	0.10	0.29	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).

There is a slightly negatively-sloping linear relationship for the political process: a trend that we captured with a metric variable measuring the change in approval time by year, the results of which confirm our observation showing that with every additional year the approval time decreases by seven to ten per cent (ca. 32 to 50 days): a robust finding throughout our regression models. Only two coefficients, cotton and potato (model 5), are statistically significant, meaning that completing the political step took substantially longer. Conversely, applications for single traits and herbicide tolerance took less time (**Supplementary Table 8**).

When analyzing the overall time taken for authorizing a new GM crop, we expected the regression results to conform to those of the scientific step's analysis since overall time is largely driven by duration of the scientific step. Surprisingly, this expectation was weakly met. Regression models 1 to 4 confirm a negative and convex (or negative followed by a convex) development of overall time taken; coefficients in our baseline model have the expected signs and are statistically significant at the 10 per cent level. However, once control variables were included, the magnitude and level of statistical significance changed for the worse. In model 5, estimated coefficients suggest a negative and concave relationship. Moreover, single trait applications required 28 to 36 per cent less time (ca. 368 to 515 days), confirming earlier findings (**Supplementary Table 8**); applications for potatoes took about 73 per cent more time (approximately 1,280 days).

Supplementary Table 7. Correlates of time taken for completing the scientific step of the GE crop authorization process in the EU.

Variable	Model				
	1	2	3	4	5
	Dependent variable: time taken (days, ln)				
Year	-74.42***	-72.17**	-100.20***	-76.12***	-99.07***
	(0.000)	(0.011)	(0.003)	(0.006)	(0.005)
Year (squared)	0.02***	0.02**	0.02***	0.02***	0.02***
	(0.000)	(0.011)	(0.003)	(0.006)	(0.005)
Domestic		0.01	-0.03	-0.02	0.02
		(0.928)	(0.843)	(0.900)	(0.910)
Single trait		-0.04	0.06	-0.00	0.06
		(0.803)	(0.744)	(0.996)	(0.776)
Cotton					0.50
					(0.411)
Maize					0.04
					(0.885)
Soy bean					-0.15
					(0.552)
Potato					-0.66
					(0.115)
Oilseed rape					-0.09
					(0.755)
Herbicide tolerance			0.05		
			(0.839)		
Other trait			-0.48*		
			(0.054)		
Food/feed				0.14	
				(0.345)	
Constant	74,609.11***	72,356.47**	100,439.44***	76,319.30***	99,305.83***
	(0.000)	(0.011)	(0.003)	(0.006)	(0.005)
Observations	41	41	41	41	41
R-squared	0.34	0.34	0.40	0.35	0.42

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10 per cent 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).

Supplementary Table 8. Correlates of time taken for completing the political step of the GE crop authorization process in the EU.

Variable	Model				
	1	2	3	4	5
	Dependent variable: time taken (days, ln)				
Year	-0.09***	-0.10**	-0.07*	-0.09**	-0.08**
	(0.007)	(0.021)	(0.074)	(0.036)	(0.043)
Domestic		0.03	0.04	0.06	-0.22
		(0.902)	(0.887)	(0.827)	(0.317)
Single trait		-0.25	-0.45	-0.28	-0.32
		(0.318)	(0.109)	(0.273)	(0.188)
Cotton					0.88***
					(0.000)
Maize					0.01
					(0.963)
Soy bean					-0.17
					(0.730)
Potato					1.34***
					(0.001)
Oilseed rape					-0.03
					(0.929)
Herbicide tolerance			-0.49		
			(0.204)		
Other trait			0.19		
			(0.710)		
Food/feed				-0.13	
				(0.639)	
Constant	183.12***	197.81**	156.83*	184.46**	159.83**
	(0.005)	(0.018)	(0.063)	(0.031)	(0.036)
Observations	30	30	30	30	30
R-squared	0.13	0.16	0.26	0.16	0.39

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at 1, 5, and 10 per cent levels, respectively. Dependent variable is time taken in days (natural log) for passing through the scientific process. Note: the number of observations dropped to 30 here since 11 applications included in Supplementary Table 7 have not completed the political step at the time that this study was done. Reference category refers to a non-EU (foreign) based company, submitting a multiple trait and insect resistant GE plant (model 3).

Supplementary Table 9. Correlates of time taken for completing the overall authorization process for GE crops in the EU.

Variable	Model				
	1	2	3	4	5
	Dependent variable: time taken (days, ln)				
Year	-32.07*	-17.62	-16.57	-9.95	1.79
	(0.096)	(0.433)	(0.459)	(0.655)	(0.922)
Year (squared)	0.01*	0.00	0.00	0.00	-0.00
	(0.097)	(0.435)	(0.462)	(0.658)	(0.918)
Domestic		0.11	0.12	0.16	0.05
		(0.297)	(0.279)	(0.188)	(0.634)
Single trait		-0.28***	-0.36***	-0.33***	-0.29***
		(0.010)	(0.002)	(0.006)	(0.008)
Cotton					0.33***
					(0.000)
Maize					0.18*
					(0.059)
Soy bean					0.06
					(0.657)
Potato					0.73***
					(0.000)
Oilseed rape					0.30***
					(0.001)
Herbicide tolerance			-0.19*		
			(0.066)		
Other trait			0.03		
			(0.877)		
Food				-0.17	
				(0.437)	
Constant	32,209.69*	17,756.53	16,695.31	10,069.11	-1,685.38
	(0.095)	(0.429)	(0.456)	(0.651)	(0.926)
Observations	30	30	30	30	30
R-squared	0.61	0.70	0.74	0.71	0.80

Note: Robust p-values in parentheses. ***, **, * indicate statistical significance at the 1, 5, and 10 per cent levels, respectively. Dependent variable is time taken in days (natural log) for passing through the scientific process. Note: the number of observations dropped to 30 here since 11 applications included in Supplementary Table 7 have not completed the political step at the time that this study was done. Reference category refers to a non-EU (foreign) based company, submitting a multiple trait and insect resistant GE plant (model 3).

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