

Richard D. Smart¹

Technische Universität München

Germany

Prof. Dr. Justus Wesseler²

Wageningen University

The Netherlands

Dr. Matthias Blum³

Queens University Belfast

United Kingdom

Genetically Engineered Crops' Approval Times in the EU & US

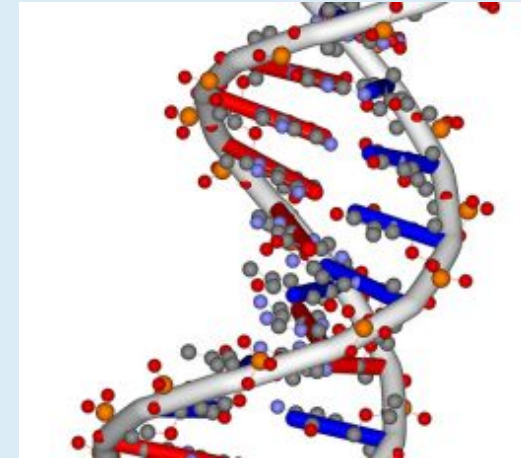
¹ richard.smart@tum.de; ² justus.wesseler@wur.nl; ³ matthias.blum@qub.ac.uk

Outline

- Background: regulatory oversight in US & EU
- Research question
- Methodology
- Results
- Discussion
- Conclusion

Regulatory trigger

- recombinant DNA process
- not the product itself
- crops developed by any other means: not regulated



Source: <http://www.hghexclusive.com/wp-content/uploads/2014/05/DNA.jpg>

Developers of GE crops

overcome regulatory hurdles

for commercialization



Source: <https://boluwatifiedavid.files.wordpress.com/2013/11/pole-vaulting.jpg>



Regulatory processes

Start: scientific investigations for evaluating a new crop's safety

End: US: 'bureaucratic' step, developer petitions

EU: political step



Source: <http://mogadishufox.com/wp-content/uploads/2015/10/EU..jpg>



Source: <https://twitter.com/usda>

EU

Approval process: legally guided by precautionary principle

Authorization for a specific use:



cultivation



food &/ feed



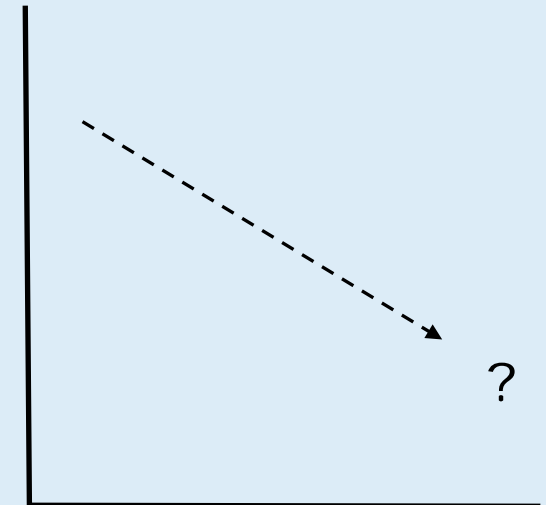
import & processing

or any combinations

Source: iStock

Research question

Does approval-time decrease with time?



Methodology



Source: iStock

US

Regulatory pipeline: 2-step process



US

Step 1: Scientific step (field trial)



Source: <http://www.theguardian.com/environment/2012/may/21/farmer-charged-damage-gm-crop>

Start: developer 1st seeks permission for field trials

Ends: developer petitions USDA for non-regulated status ...

Step 2: 'Bureaucratic' step

USDA's Animal & Plant Health Inspection Service: assessment of developer's petition



US

Total time taken = scientific step + 'bureaucratic' step

↑
new

EU

Step 1: Member State (MS) application

Step 2: Risk assessment



(similar to US's 'bureaucratic' step)

Step 3: Political decision-making



(risk management)

EU

Total time taken =

- + MS application step
- + risk assessment step
- + political decision-making step

Table 1. Study period

Country	Start	End
US	12 Dec 1988	20 Jan 2015
Crop	Tomato: FlavrSavr	Soy MON87708 Cotton MON877013
EU	05 Aug 1996	21 May 2014
Crop	Potato EH92-527-1 (Sweden)	Oilseed rape MON83302

Results



Source: <http://davidsoergel.com/>

Table 2. US avg time to complete steps for GE crop approvals

Period	Step	Scientific (days)	Bureaucratic (days)	Entire Process (days)
Early: 1988-1997		1,090 (n=40)	211 (n=42)	1,301 (n=40)
Late: 1998-2015		1,610 (n=52)	929 (n=51)	2,498 (n=47)

GE Crops' Approval Times in the EU & US

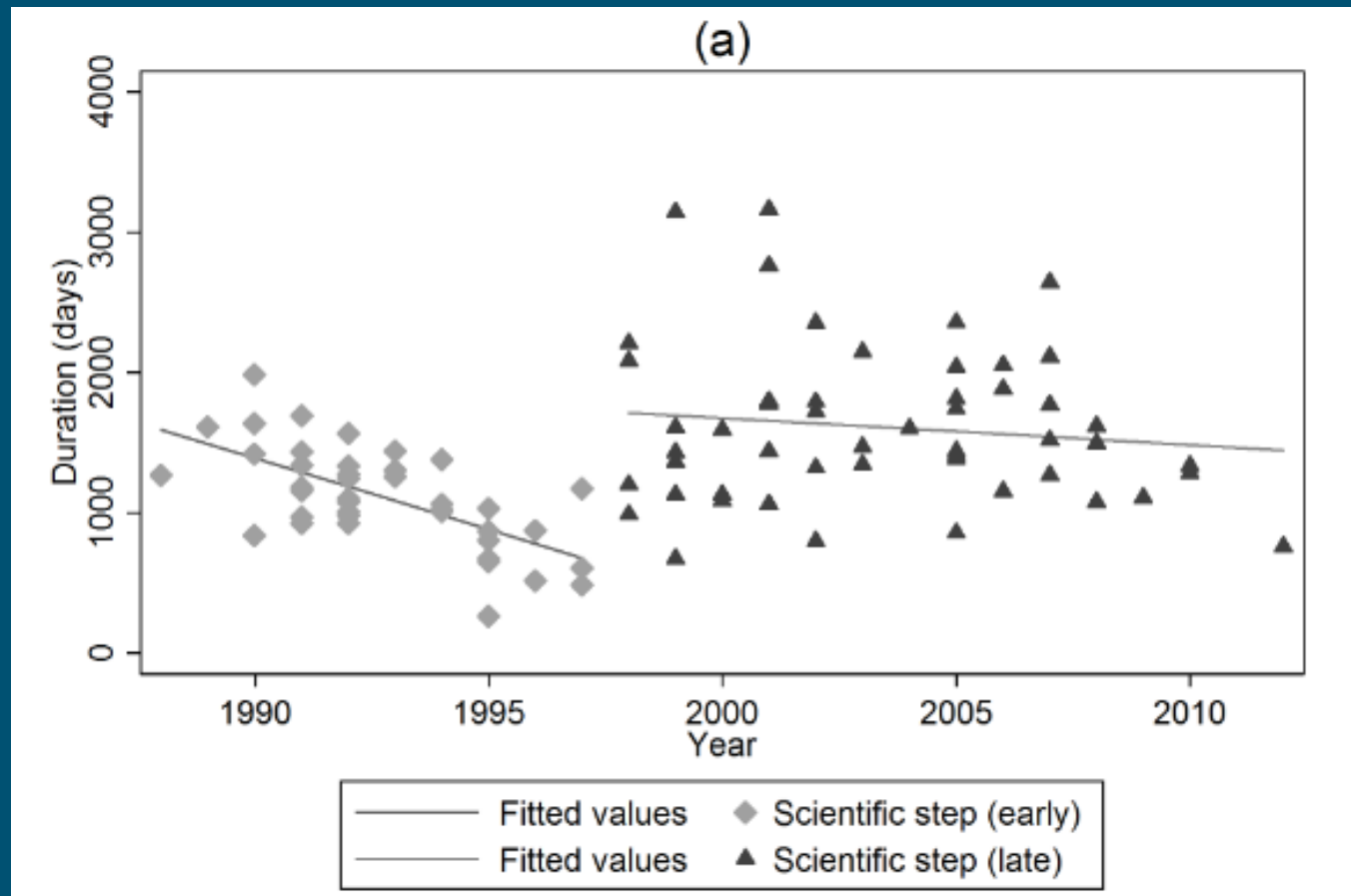


Fig.1. US scientific step

GE Crops' Approval Times in the EU & US

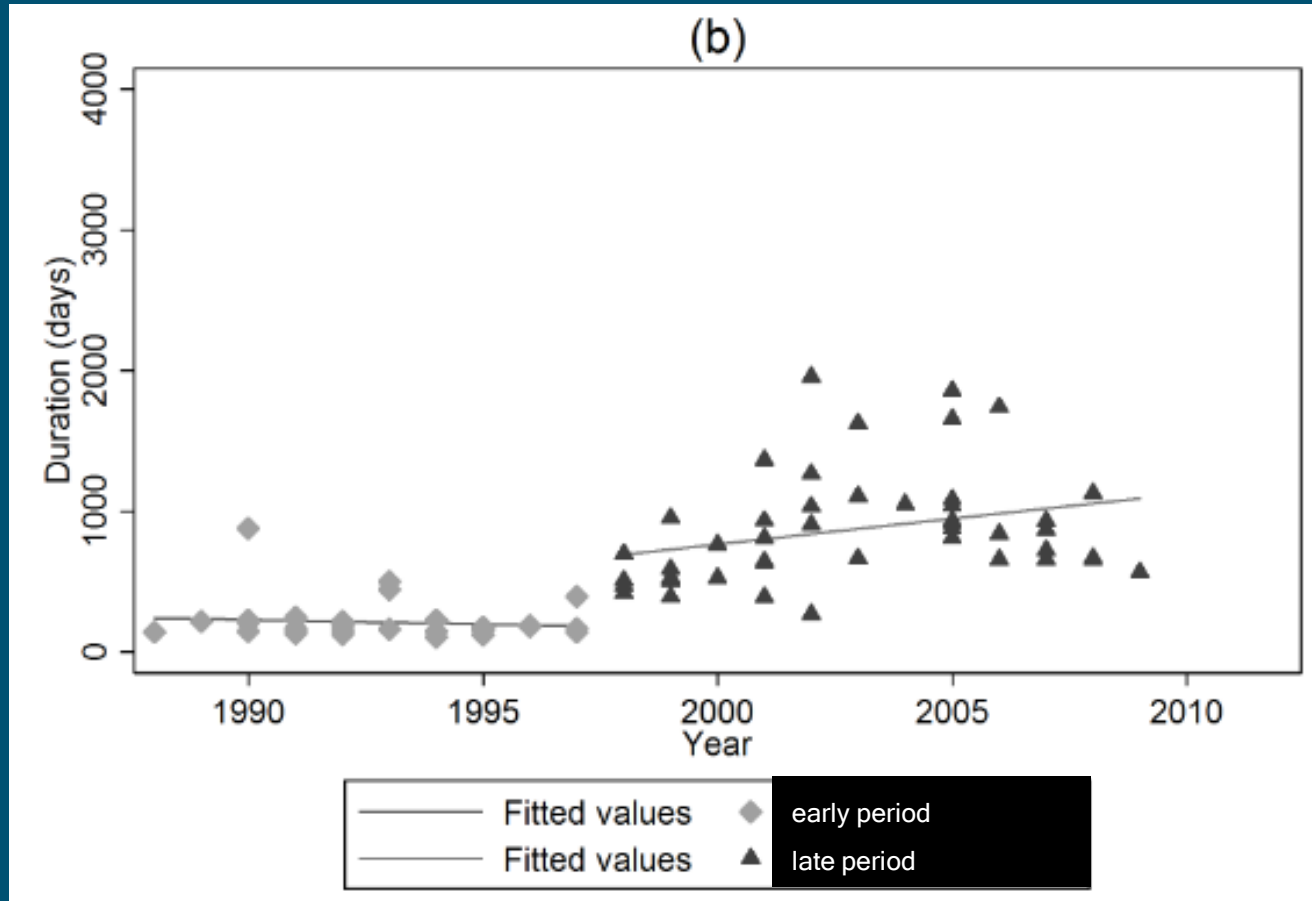


Fig. 2. US 'bureaucratic' step (petition)

GE Crops' Approval Times in the EU & US

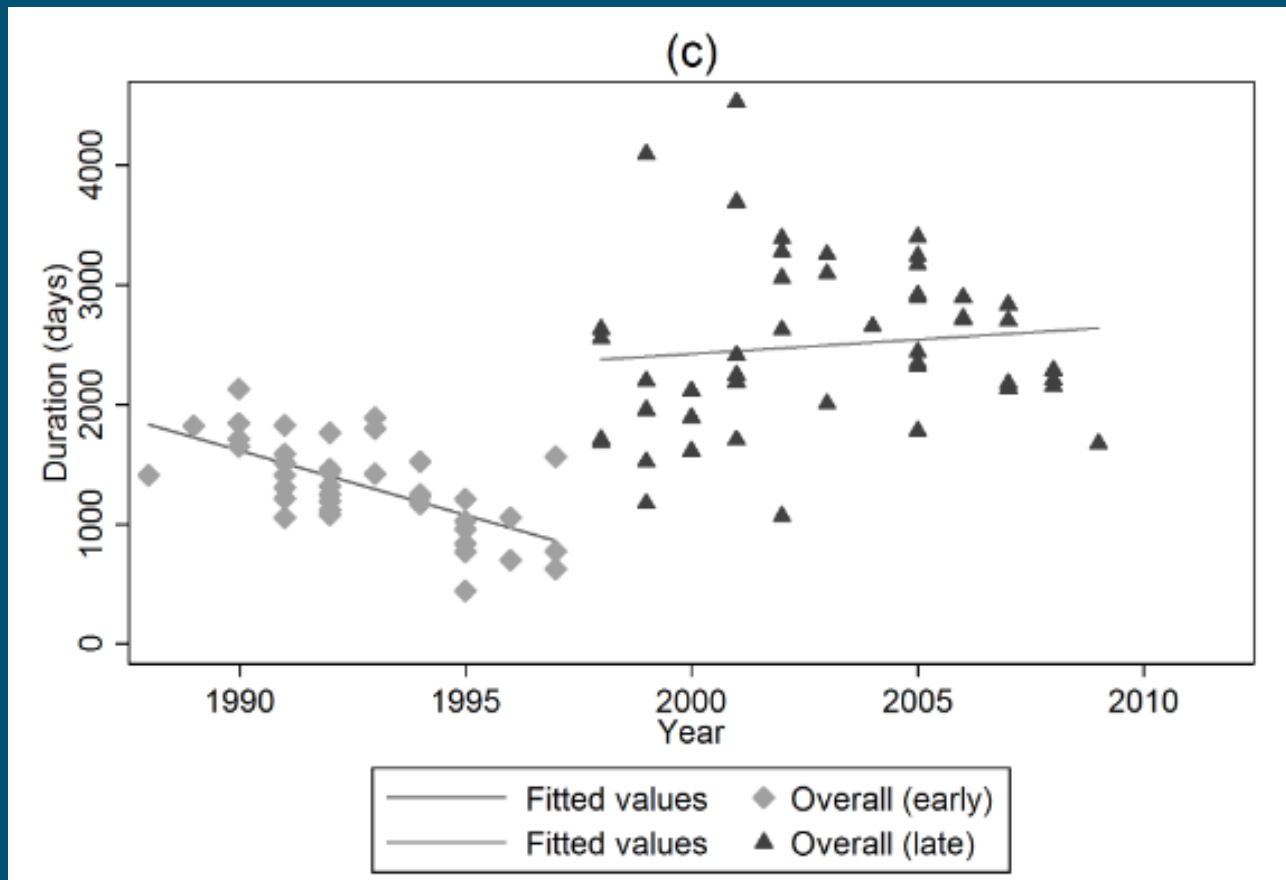


Fig. 3. US overall time taken

Trends for overall time taken US

1988 - 1997: ↓ avg 114 days / yr

1998 - 2015: ↑ avg 33 days / yr

Table 3. EU avg time to complete steps for GE crop approvals

Step Period	MS Application (days)	Risk Assessment (at EFSA from 2002) (days)	Risk Management (EU Commission) (days)	Entire Process (days)
Early: 1988-1997	2,745 (n=2)	596 (n=2)	1,052 (n=2)	4,393 (n=2)
Late: 1998-2015	170 (n=56)	857 (n=56)	616 (n=42)	1,524 (n=42)

GE Crops' Approval Times in the EU & US

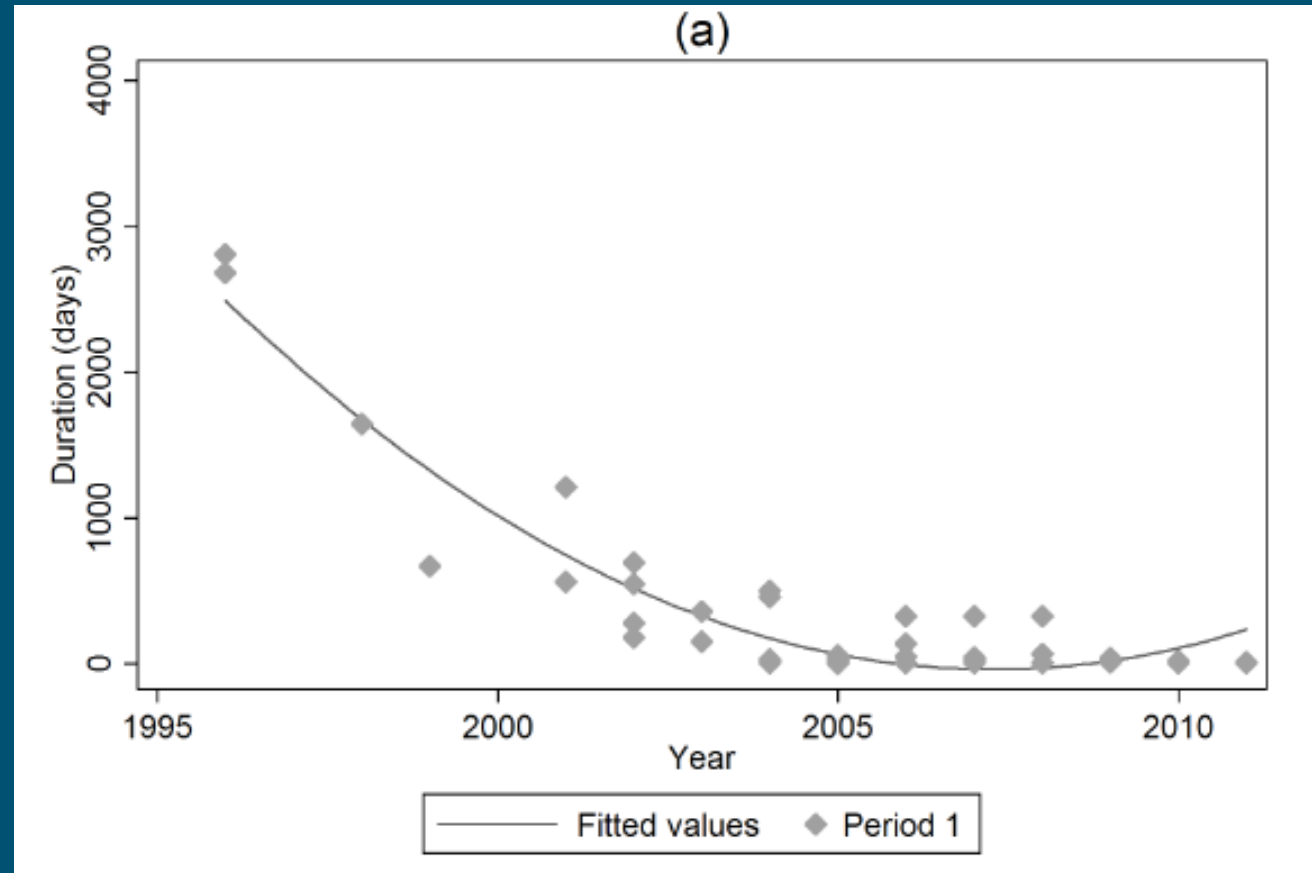


Fig. 4. EU MS application step

GE Crops' Approval Times in the EU & US

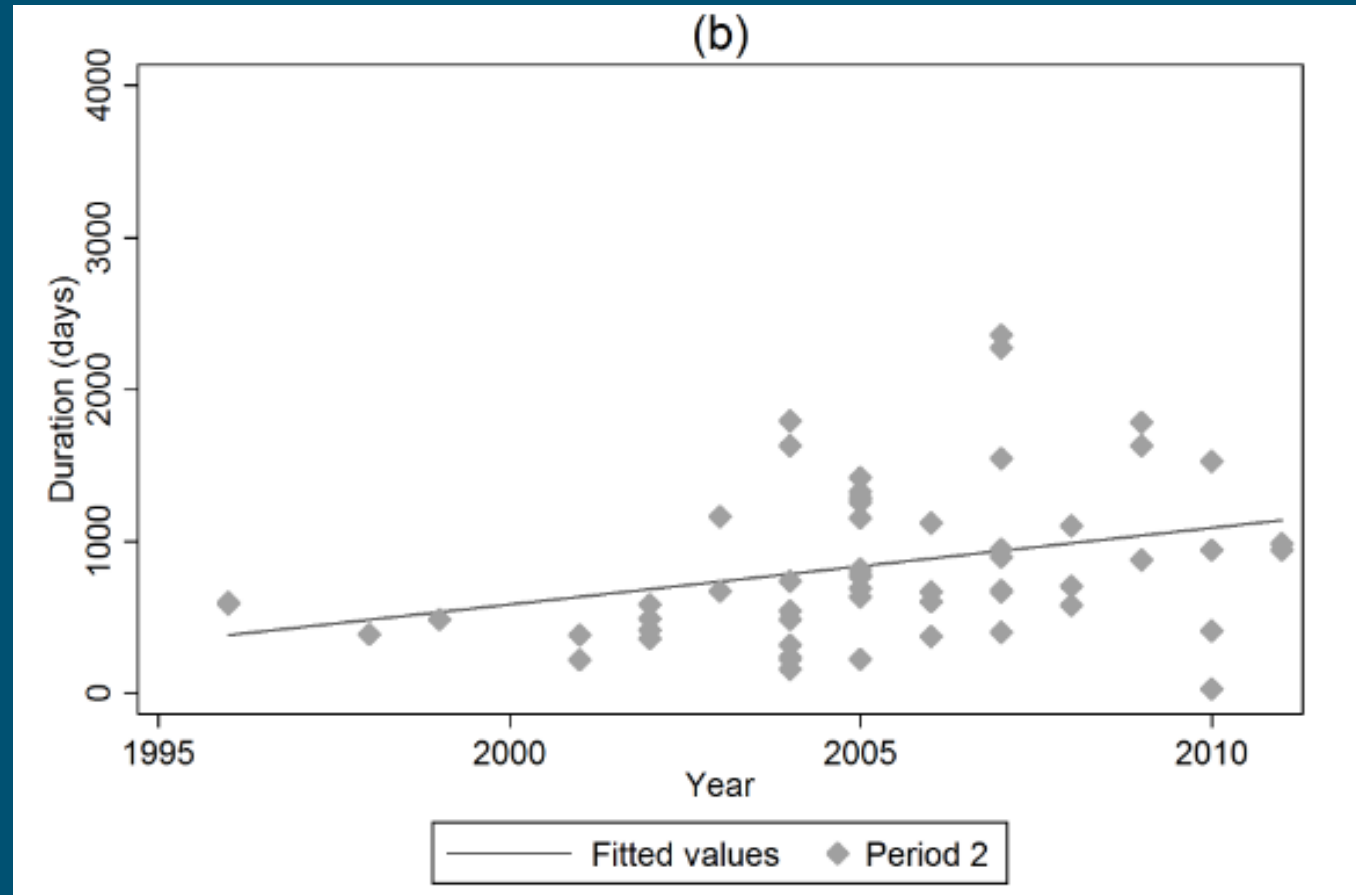


Fig. 5. EU risk assessment step (EFSA)

GE Crops' Approval Times in the EU & US

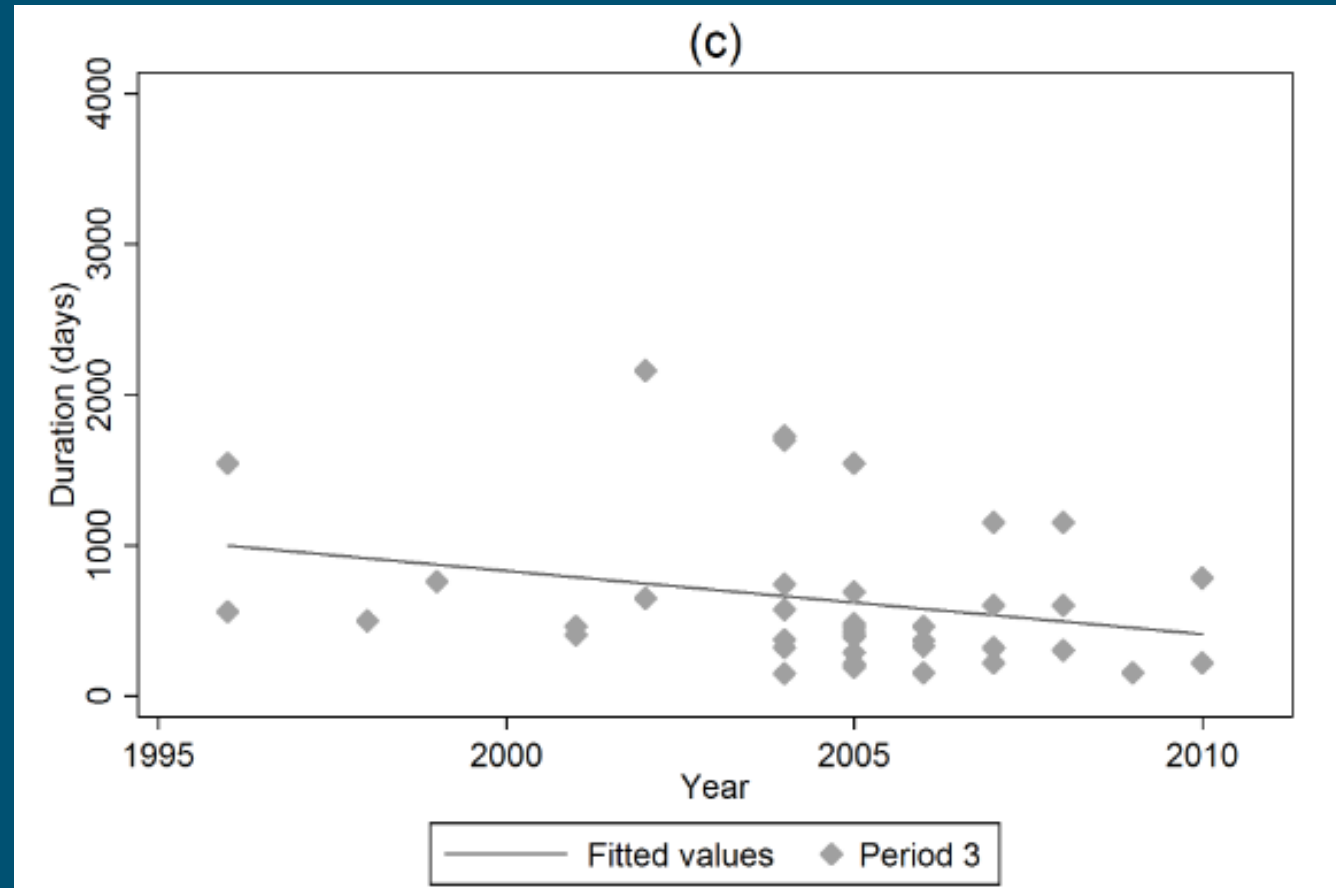


Fig. 6. EU political step (risk management)

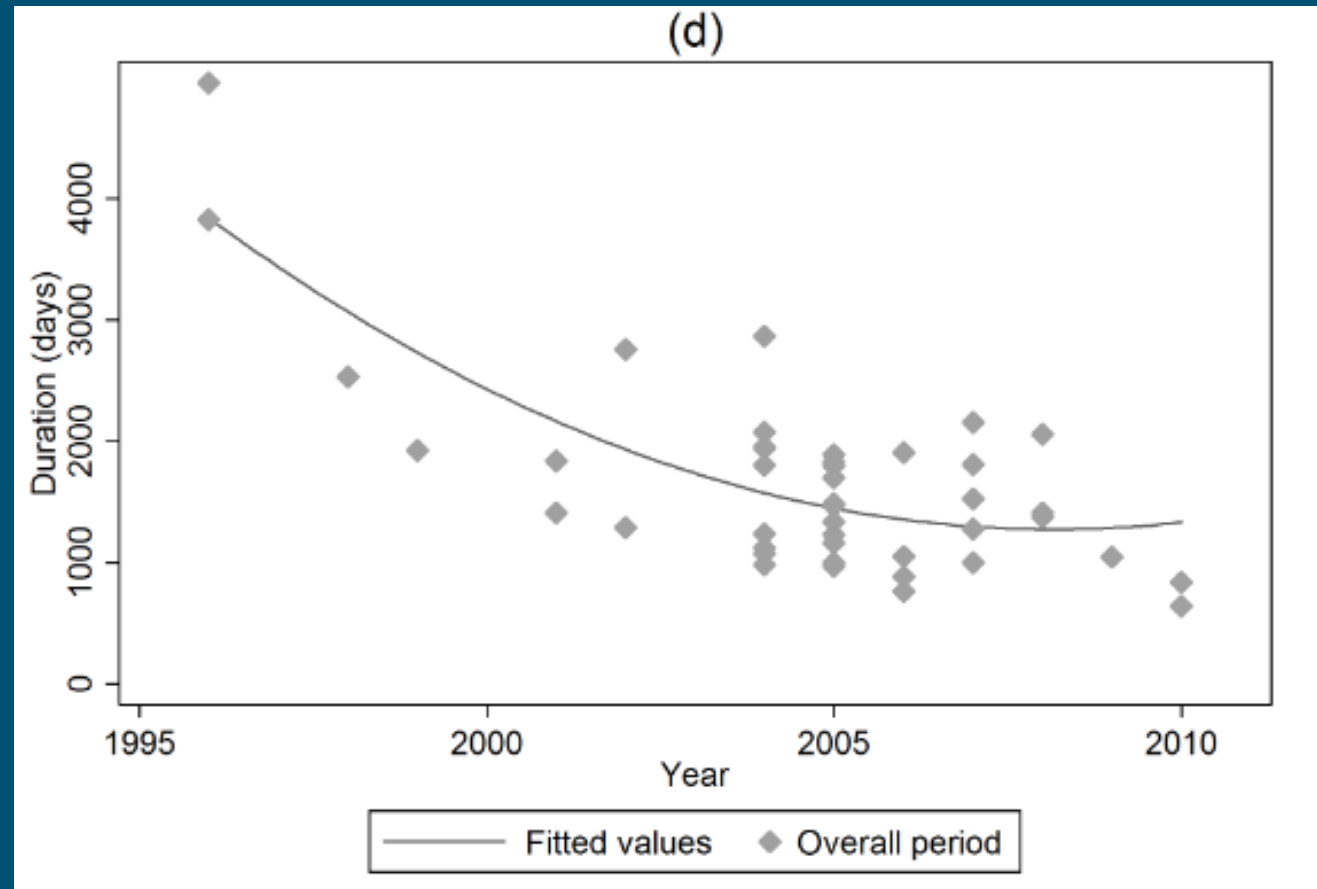
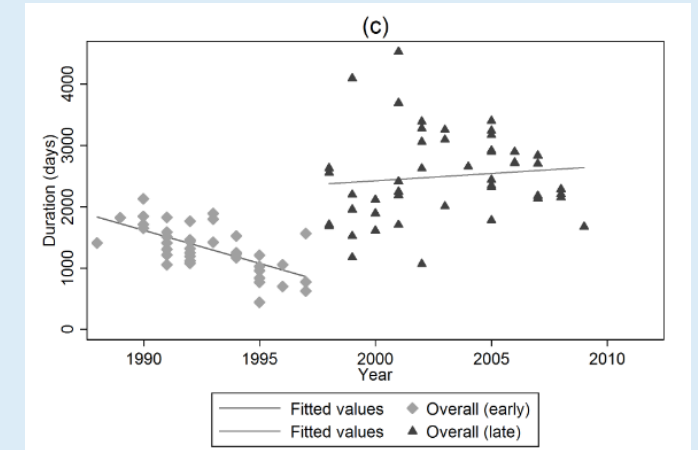


Fig. 7. EU overall time taken

Question

Is there stat. evidence for US's structural break?



Tested if differences in time-line explained by

- plant characteristics, or
- external factors

Control variables

- developer's domicile *foreign / domestic*
- crop's use *food / non-food*
- No. GE traits / crop *single / multiple*
- trait type *h'cide tolerant / insect resistant / other*
- plant species *maize, cotton, soy, oilseed rape, etc.*

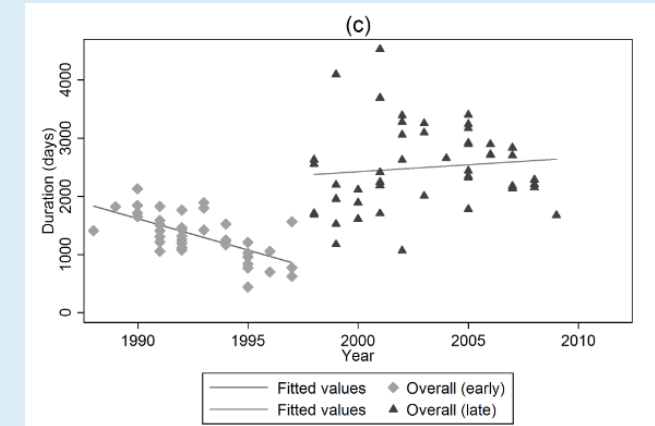
Result

No stat. significant factor/s contributing to structural break

Discussion

“Structural break“ in the US

➤ coincided with ‘disruptive‘ events in the biotech sector

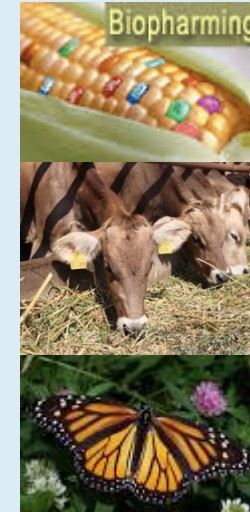


US

Prodigene

StarLink

Monarch butterfly



Court cases: herbicide resistant alfalfa & sugar beet

➤ developers ordered to submit environmental impact statements

Sources: <http://nwrage.org/category/topics/biopharming?page=12>; iStock; https://en.wikipedia.org/wiki/Monarch_butterfly

EU

Dr. Pusztai's work on GE potatoes

de facto moratorium

debates about cloning (Dolly the sheep)

earlier outbreak of BSE (mad cow disease)



=> ***General mistrust by the public in regulations ???***

US

March 2012

1 regulatory change in US to speed up the petition step:
public granted a 2nd opportunity to comment on the petition



US

July 2015

US Govt. memo to FDA, EPA & USDA

need to modernize regulatory system for biotech

Aim: reduce regulatory burdens for small- & mid-sized firms



EU

April 2015

'opt-out' regulation for cultivation

? impact, if any



Conclusion

Repeat the research question

Does approval-time in the EU & US decrease with time?

Conclusion

Answer

EU: yes

US: yes for period 1988-97
no for period 1998-today



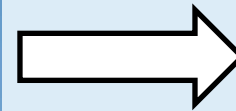
Time = mon€y

Long approval times are costly (foregone benefits)

Only affordable by large firms

Need: regulations to shorten approval time\$

GE Crops' Approval Times in the EU & US



Sources : <https://boluwatifiedavid.files.wordpress.com/2013/11/pole-vaulting.jpg>; http://i.dailymail.co.uk/i/pix/2012/08/08/article-2185470-146EAC6100005DC-561_634x418.jpg