"Economic Impact of Regulations"

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Content and Rationale

- Discuss issues related to the biosafety system process that are important to assessing the impact of regulations
- Important impacts
  - Cost of compliance with biosafety regulations important as a barrier to entry
  - Time delays due to unnecessary requirements have a negative effect on stream of benefits
  - Regulatory uncertainty and investments
- Suggestions for supporting public sector

Why regulate Genetically Modified (GM) technologies?

- Three distinct issues
  - Safety: Prevent the introduction of potentially harmful technologies to the environment and public health.
  - Efficacy: Prevent the introduction of unimportant or inefficacious technologies
  - Public confidence: On both safety and efficacy of approved technologies and the regulatory process
- Addressing the call from a group of stakeholders for 100% safe technologies

•Prudent to judge technologies based on their individual merits as
•GM biotechnologies have own costs, benefits and risks; which may vary across technologies, individuals, households, regions, and countries

What is a functional and protective biosafety system?

- Characteristics of a functional and protective biosafety system
  - Adequate legal authority
  - Comprehensive
  - Clear safety standard
  - Proportionate risk-based reviews
  - Transparent and understandable
  - Participatory
  - Post approval oversight
  - Flexible and adaptable
  - Efficient, workable, and fair

Source: Jaffe, 2006

Are harmful/ineffective technologies the only ones excluded by regulations?

- Answer is usually… no!
  - Safe and effective technologies may not have been approved by existing regulations
- Why?
  - Societies establish a process that includes a "safety" standard and a set of decision making rules
  - No process is perfect as regulatory mistakes happen
  - Although the safety record of GM technologies is quite remarkable
- Need clear bounds, decision making rules, time limitations

Address stopping problem => "When (and if) to take costly regulatory actions that are also costly to reverse"

Who and what will affect and be affected by regulations?

- Actors
  - Producers
  - Rural and urban consumers
  - Policy makers
  - Decision makers
  - Public and private sector developers
  - Multi-national corporations
- Levels
  - National
  - Regional
  - International
- Instruments
  - International agreements
  - Laws
  - Regulations
  - Policies
  - Standard operating procedures
  - Guidelines
  - National capacities

What are the competing issues and trade-offs important to measure impact?

- Tension between quantity of information required and innovation/technology
  - Innovation as a pathway to address poverty and promote sustainable growth
  - Inverse relation between the information required 'above and beyond' what is sufficient/necessary to demonstrate safety and the number of innovations
- Consider potential trade-offs:
  - Right vs. wrong regulatory decisions
  - Risk-Risk exchanges
    - Potential risk of a biotechnology and the risk of 'doing nothing' (Nuffield Council on Bioethics)

Technology innovation/deployment inversely related to excessively precautionary approaches

Biosafety as a sequential process...

Increase in Knowledge

Blue Sky research through Proof of Concept

Biosafety application

- Laboratory / Greenhouse (Containment)
  - Reduce environmental rate of exposure to zero

Biosafety application

- Confined field trial
  - Reduce environmental rate of exposure to zero

Biosafety application

- Multi-location trials
  - Reduce environmental rate of exposure to a low level

Biosafety application

- Commercialization
  - Exposure determined to be safe
  - Food safety evaluations

Is this process: Flexible? A model?

Photo credits Falck Zepeda 2007, Linacre 2006, Danforth Center,2006; Herman, 2006; Yorobe Jr. and Bercilla,2006

The cost of compliance with biosafety regulations

- Rationale for examining the cost of compliance with biosafety regulations
  - Focus is to explore balance between a **country-defined acceptable level of safety** and the necessary **cost** to achieve it
  - Critical to include all direct and opportunity benefits and costs of **adopting** and **not adopting** biotechnologies and alternatives
  - Identify which areas contribute more overall to safety and net benefits, and those that are not needed to demonstrate safety

> "Avoid investing (good) money in safety issues that are trivial, manageable or irrelevant"

Cost of compliance with Biosafety regulations

Type of Crop (example)	Crop	Country	Event approved in Developed Countries	Estimated Costs of Biosafety Regulations (US$)
Food Crop	Maize	India	Yes	500,000 - 1,500,000
	Maize	Kenya	Yes	980,000
	Rice	India	No	1,500,000- 2,000,000
	Rice	Costa Rica	No	2,800,00
	Beans	Brazil	No	700,000
	Mustard	India	No & have to seek approval in export markets	4,000,000
	Soybeans	Brazil	Yes	4,000,000
	Potatoes	South Africa	Yes	980,000
	Potatoes	Brazil		980,000
	Papaya	Brazil	Yes	
Non-Food Crop	Cotton	India	Yes	500,000 - 1,000,000
	Jute	India	No	1,000,000 - 1,500,000

Note: Compilation presented in Falck Zepeda (2006) based on estimates from Quemada(2004), Odhiambo(2003), Sampaio(2002), Sittenfeld(2002). India data from a study by Pray, Bengali and Ramaswamy (2004).

Cost of compliance with biosafety regulations in Indonesia and the Philippines: A PBS study

Country	Technology	Developer	Actual Costs (US$)
Indonesia	Bt cotton	Monsanto	99,870
	Herbicide resistant cotton	Monsanto	112,480
	Bt rice	RCB-IIS / LIPI	64,730
	Drought tolerant sugarcane	PTPN XI Perseroan Terbatas Perkebunan Negara - Government Enterprise for Estate Crops	98,879
	Transgenic Citrus Resistant to CPVD	Udayana University	Abandoned
	Potato Resistance to Fungi / Nematode	Bogor Agricultural University	Still analyzing regulatory pathway
Philippines	Golden Rice	IRRI	104,698
	Bacterial blight resistant rice (Xa-21)	Phil-Rice	99,213
	Bt maize	Monsanto	1,690,000
	Delayed ripening papaya	IPB-UPLB	Still analyzing regulatory pathway

Cost of regulations can have a negative effect on the development of technologies developed by the public sector

Impacts of biosafety costs on GM technology flows?

- Cannot conclude conclusively that cost of regulations have had a significant effect on the flow of GM technologies in developing countries…yet
- But some effects observed:
  - Technologies have been abandoned, delayed or not approved citing cost of regulation (amongst other things)
  - Migration to non-regulated technologies, which may imply less potential gains to society
  - Need for well defined development and technology transfer plans early on R&D process?

Need to evaluate cost of compliance with biosafety regulations on a regular basis, as what is needed to demonstrate safety can be different than what is required

Cost of compliance with biosafety regulations as an investment on public goods

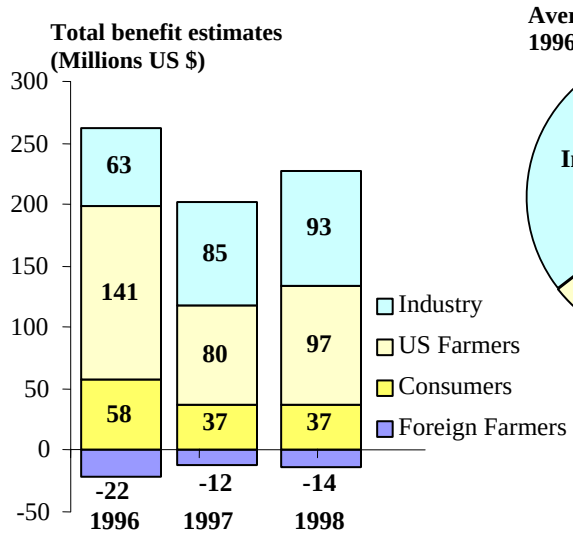
- Costs of biosafety should be viewed as part of an investment framework on public goods
- Contrast with (potential) farmer benefits gained from adoption
  - Who will pay?
  - Public vs. private goods

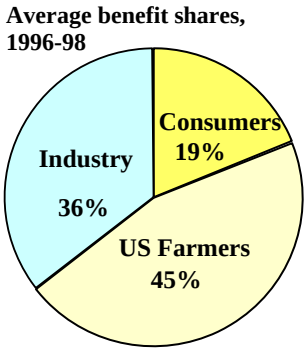
How to facilitate biosafety approval of those safe, appropriate and sustainable technologies of national interest produced by the **public sector** (universities, NAROs..) and the (national) private sector

A practical example with Bt cotton

- A simple experiment to show (gross) effects of time delays and impact of biosafety regulations on the value of money
- In the real world, we need to focus on the additional /unneeded activities required to demonstrate safety and net their effect our calculations

U.S. Distribution of Benefits From Insect Resistant Cotton





Falck-Zepeda, Traxler & Nelson 1999, 2000

The baseline of insect resistant (Bt) cotton in the USA

Benefits from the introduction of Bt cotton in the United States (Million US$)

Year	Producer	Industry	Consumer	Total
1996	141	63	58	262
1997	80	65	37	182
1998	97	93	37	227
Total	318	221	132	671
Present value	291	199	121	611

Source: Falck-Zepeda 1999,2000

Note: Present value estimated using a 5% interest rate

The 1st experiment

Year	Producer	Industry	Consumer	Total
1996	0	0	0	0
1997	0	0	0	0
1998	0	0	0	0
1999	141	63	58	262
2000	80	65	37	182
2001	97	93	37	227
Total	318	221	132	671
Present value	251	172	104	528

Present Value of Total Benefits decreased by 13.6% with respect to baseline

Assumptions
- Interest rate= 5% per year
- Biosafety = 3 additional years to deliver to farmers
- Cost of compliance = 0

The 2nd experiment

Year	Producer	Industry	Consumer	Cost of regulations	Total
1996	0	0	0	-0.57	-0.566
1997	0	0	0	-0.57	-0.566
1998	0	0	0	-0.57	-0.566
1999	141	63	58	0	262
2000	80	65	37	0	182
2001	97	93	37	0	227
Total	318	221	132	-1.698	669
Present value	251	172	104	(2)	526

Present Value of Total Benefits decreased by 13.9% with respect to baseline

Assumptions
- Interest rate= 5% per year
- Biosafety = 3 additional years to deliver to farmers
- Cost of compliance = 1.7 US$ million dollars over the three years

Impact on Developers

- Cost of compliance with biosafety regulations are usually not significant with respect to net present values of investments
- Time delay impacts due to delayed reception of benefits, are important
- Cost of compliance become significant as “barriers to entry”
  - The higher the cost of compliance, the more likely it becomes a barrier to entry, the less likely developers enter the market, and thus less technologies may make it to market
  - Of interest to those developing pro-poor technologies:
    - International agricultural research centers
    - Public and (national) private sectors in developing countries

Impact on Developers (continued)

- More importantly, developers need predictability to focus investments
- To make investments decision Developers consider:
  - The cost taking a product to market
  - Potential benefits
  - The probability of success (amongst other things)
- In the face of uncertainty decision making is much more difficult and may be a disincentive for investments

Impact to producers and consumers

- Price impacts
  - Who pays for biosafety regulations?
    - Developers' and producers' price transmission ability
    - Market structure
  - Producers may face higher prices for technology
    - Especially if developers include the R&D cost of those technologies that did not make it or "failed"
  - Public sector is an entirely different analysis
- Technology supply
  - Shift to non-regulated technologies
    - Bu, there technologies may have lower rates of return to investments
  - Cost / Benefits including opportunity costs and benefits
    - Not approve a good technology => Loss
    - Approve a bad technology => Gain

Global farm income benefits from growing GM crops 1996-2005: million US$

Traits	Increase in farm income in 2005	Increase in farm income in 1996-2005	Farm income benefit in 2005 as % of total value of production of these crops in GM adopting countries	Farm income benefit in 2005 as % of total value of global production of these crops
GM herbicide tolerant soybeans	2,281 (2,842)	11,686 (14,417)	5.72 (7.1)	4.86 (6.05)
GM herbicide tolerant maize	212	795	0.82	0.39
GM herbicide tolerant cotton	166	927	1.16	0.64
GM herbicide tolerant canola	195	893	9.45	1.86
GM insect resistant maize	416	2,367	1.57	0.77
GM insect resistant cotton	1,732	7,510	12.1	6.68
Others	25	66	n/a	n/a
Totals	5,027 (5,588)	24,244 (26,975)	6.0 (6.7)	3.6 (4.0)

Notes: Source is Brookes and Barfoot (2006), Others = Virus resistant papaya and squash, rootworm resistant maize, Bracketed figures include second crop benefits in Argentina; Totals for the value shares exclude 'other crops' (ie, relate to the 4 main crops of soybeans, maize, canola and cotton)

GM crop farm income benefits 2005: developing versus developed countries: million US $

Trait	Developed	Developing	% developed	% developing
GM HT soybeans	1,183	1,658	41.6	58.4
GM IR maize	364	53	86.5	13.5
GM HT maize	212	0.3	99.9	0.1
GM IR cotton	354	1,378	20.4	79.6
GM HT cotton	163	3	98.4	1.6
GM HT canola	195	0	100	0
GM VR papaya and squash	25	0	100	0
Total	2,496	3,092	45	55

Notes: Source is Brookes and Barfoot (2006), Developing countries includes those in South America

How can the support public sector be supported to meet biosafety requirements?

Capacity strengthening efforts directed to scientists, regulators, and implementers and other stakeholders

- Scientific capacity – R&D and evaluation
- Intellectual Property / Public Private Partnerships negotiations
- Ability to submit biosafety dossiers
- Priority setting and technology transfer plans early on
- "Foreign" disciplines such as socio-economics and risk communications

Regulatory Approaches

- Avoid requiring data that is not necessary, irrelevant or unnecessary
- Use of data generated elsewhere (certified labs...)
- Continued efforts to evaluate regulatory processes and systems
- Exploration of alternative/innovative models to assess food/feed and environmental assessments and analysis including flexible regulatory systems
- Regional approaches to assessments and decision making
- Science, science and more science....but with a social touch