

Biosafety Regulation: Costs & Enforcement Issues

Bharat Ramaswami
Indian Statistical Institute
Delhi

- Two pieces of ongoing research
- Carl Pray and Prajakta Bengali (Rutgers U)
- N. Lalitha (GIDR) & Carl Pray (Rutgers U)

Why do we study regulatory costs?

- Debate on the design and implementation of biosafety regulation.
- However, regulation is not costless.
- Analysis of regulatory costs is a missing element in debate.
- Knowledge about costs can help in improving efficiency of regulation.
- International comparisons

Costs of Regulation

- Direct costs: Compliance costs + Administrative costs
- Indirect Costs: Benefits foregone if regulation prevents or delays useful products.
- Indirect Costs: Impacts on market structure – biosafety approval is akin to IPRs.

Compliance Costs

- Bt Cotton (Monsanto/MAHYCO)
- Hybrid Mustard (Bayer)
- Bt Eggplant (National Research Centre for Biotechnology)
- High protein potato (Centre for Plant Genomics Research)

Bt Cotton

Goat Feeding study – 90 day	1	55,000	55,000	No
Cow feeding study	1	10,000	10,000	No
Water buffalo feeding study	1	10,000	10,000	No
Pollen flow	1	40,000	40,000	yes
Soil microflora	1	Small		yes
Absence of terminator	1	Small		No
Poultry feeding studies	1	5,000	5,000	No
Fish feeding studies	1	5,000	5,000	No
Brown Norway rat allergenicity	1	150,000	150,000	No
Gene stability	1	Small		
Expression in oil and lint	1	Small		
Socio-economic study	1	15,000	15,000	No
Baseline resistance study	1	20,000	20,000	NA
Greenhouse trials 1996		Small		
Limited field trials 96, 97-98	6	5,000	30,000	yes
Multi location field trials 98/99	41	5,000	205,000	yes
Multi location field trials 99/00	10	5,000	50,000	yes
Large scale trials 2000/1	40	2,500	100,000	
Large scale farm trials 2001/2	400	0	0	yes
Preapproval Sub-Total			695,000	
Salaries & office expenses				
Years 1996 – 2001	6 years	50,000/year	900,000	
Total Pre Approval			1,595,000	

Hybrid Mustard

	Studies	Costs (US \$ Million)
Product characterization*	Unique identifier, reference material, validations, etc.	2
Environmental safety studies**	Gene flow, impact on key species of insects, etc.	0.5 -1
Food safety studies*	Allergenicity, toxicology	1.5
Nutritional assessment**		0.5
Total		4 – 5
*Primarily conducted in U.S. or Europe.		
** Primarily conducted in India		

Bt Eggplant (Public Sector)

Allergenicity/toxicity	U.S.\$s
Estimated	33,333
Agronomic trials completed	
Contained trial 1998/9	2,222
Contained 1999/2000	2,222
Contained 2000/1	2,222
Multilocation (5) in 2003	2,778
Agronomic trials needed	
Multilocation (10) in 2004	5,556
Multilocation (10) in 2005	5,556
Total	53,889

Regulatory costs for public sector

- Costs have been negligible for high protein Potato – contained trials and allergenicity/toxicity tests.
- The trials and tests done by other public sector organizations which absorbed the costs.

Future Costs

Type of Crop (example)	Event approved in U.S., Europe, Canada, Australia, or Japan	Event approved in India	Estimated Costs of Meeting Regulations
Non-food crop (MMB cotton)	Yes	Yes	\$100,000
Non-Food Crop (cotton)	Yes	No	\$500,000 - 1,000,000
Food Crop (maize)	Yes	No	\$500,000 - 1,500,000
Non-Food Crop (jute ??)	No	No	\$1,000,000 - 1,500,000
Food Crop (rice)	No	No	\$1,500,000-2,000,000
Food crop – possible exports (vegetable)	No & have to seek approval in export markets	No	\$4,000,000

Why is cost lower for public sector?

- Public sector underestimates compliance costs – compliance is not separately budgeted, salary costs of scientists not included etc
- Govt. labs charge the private sector more than they charge the government
- Private sector exaggerates costs
- The private sector products are the early ones in the system

Indirect Costs

- The Bt cotton approval was delayed by one year because of additional field trials.
- In the case of Bt cotton, how much would have farmers gained if the product had been released a year earlier?
- Rough estimates indicate that additional gains would have been of the order of \$50 million.

Some consequences

- Given regulatory costs, private sector will be most interested in hybrids with large markets.
- Entry will be limited to the large firms – small firms can at best hope to license biotech products from large firms.
- Cannot have regulation and competitive markets at the same time.

Some consequences II

- High rewards to the first entrant because of barriers to entry.
- Assuming regulatory costs were the principal costs to Monsanto-Mahyco, the rate of return on their investment is 38%.
- Would have been more but for illegal Bt.
- Cotton biotech research on the rise
- Private sector research on food crops (rice)/vegetables on hold or declining.

Enforcement Issues

- How can biosafety regulation be enforced?
- In 2003/04, legal Bt is estimated to have accounted for 25% of all Bt.
- This is not expected to change substantially in 2004/05.
- Should this be a concern of biosafety regulators?

Gujarat Survey: 2004

- Randomly picked sample of 160 cotton growers in Rajkot, Bhavnagar, Bharuch, Vadodara.
- Spread of Bt: 62% of cotton growers
- Lots of first time users.
- Only use MM (legal) seeds: 13%
- Only use NB (illegal) seeds: 71%
- Both: 16%

Information Environment

- Awareness of Bt cotton is high
- Neighbours, friends and farmers are important sources of information.
- Newspapers, company publicity are less important.
- Contact with government officials is unimportant.

Information	Legal	Illegal
Refuge requirement	83%	26%
No pesticide on refuge	9%	0%
Timing of use of pesticide	60%	44%
Quantity of pesticide	46%	36%

Refuge compliance

Legal	Illegal
55%	5%

Regulatory Policy

- Our survey evidence suggests that in the Bt cotton case, noncompliance was driven by both performance and price of the legal seed.
- Pressure on regulators – to increase the availability of legal alternatives – competitive markets.

Regulatory Policy II

- Farmers are willing to pay a premium for govt. approval.
- How can it be made larger?
- Guarantee of quality and extension services from the government/seed firm – insurance services
- Collapse of extension system – minimal contact with formal systems.
- These wider issues impact on the success of regulation.

Parameters for Regulation

- Environmental impacts
- Food safety
- Agronomic performance
- Economic viability

Economic Rationale

- Economic rationale for monitoring environmental and food safety impacts stems from the “externality” argument.
- These are externalities because even if firms were legally liable, their liability would be limited in the face of possibly huge claims. Hence firms cannot fully internalise the costs of their actions.

Agronomic and Economic Evaluation

- Why do we need this?
- Products that are not useful will not be adopted – surely farmers are better placed to decide on value of seed than a committee of experts?
- Opposing argument: protect farmers against poor products
- Standard setting works when consumers cannot evaluate products.

Future Costs

- Obtained estimates from Monsanto, MAHYCO, Avesthagen, Meta-Helix and Nunhems (Bayer).
- Estimates vary depending on type of crop: food Vs nonfood, whether gene has been already approved in India, whether approved elsewhere and whether tests can be done in India.

What drives noncompliance?

- Price of legal Vs illegal alternative
- Performance of legal Vs illegal alternative
- Penalty on offenders
- Information