



Indian Legislative Experience with Socio-Economic Provisions with GM Crops

RIS



Indian Regulatory Framework

- Simple, Straight and Safety Oriented
- India's biosafety system provides for evaluation of the economic benefits of LMOs through systematic evaluation of agronomic performance.
- Environment Protection Act, 1986
- India has its Biosafety Guidelines concerning: Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989.



Indian Regulatory Framework

- The Act aims to:
 - 'ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking into account the risks to human health, and specifically focusing on transboundary movements'



Indian Regulatory Framework with regards to Socio-Economic Consideration for LMOs

- Under the Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998, it has been specified that:
 - The field trials for GMOs should be approved by the RCGM (Review Committee on Genetic Manipulation) with specific concern for animal and human health.
 - It also requires that, Data should be generated on economic advantage of the transgenic over the existing varieties.

Socio-Economic Impact of Bt Cotton in India

- Empirical studies suggest that
 - Bt technology is a major factor in boosting cotton productivity
 - with additional positive effect on human health and environment due to reduced use of pesticide and increased farmers' net return

- Within a span of eight years the adoption rate of Bt cotton has increased 168 fold from 50,000 hectares in 2002, when Bt cotton was first commercialized) to 8.4 million hectares in 2009.

Elements of Socio-Economic Considerations Covered in the Studies on Bt Cotton Experience in India

Study	Location	Sample/Data	Methodology	Criteria/Focus
Subrahmanian and Qaim (2009)	Maharashtra Andhra Pradesh Karnataka Tamil Nadu	Survey of 341 farmers including Bt and non Bt farmers in 2002-03	Micro-social accounting matrix	Revenue Production costs for crops and livestock activities Off-farm activities Labour market participation Household transactions in consumer and producer durables, financial assets, borrowing, lending, and consumption expenditure of food and non-food.
Herring (2008)	Andhra Pradesh	One village, 2006	Interviews with NGOs, Seed Companies, Farmers and Officials from Dept. Agriculture.	Crop failure/success Adoption of the technology Yield Incidence of pest infestation Net Returns
Rao, Rao, Naraiah, Malathi, and Reddy (2007)	Andhra Pradesh, Guntur	180 Farmers surveyed practicing IPM with and without Bt and non-IPM, 2004-05	Linier Regression	Farm and household characteristics Crop protection practices Crop production practices Use of inputs Price obtained for the produce

Elements of Socio-Economic Considerations Covered in the Studies on Bt Cotton Experience in India

Study	Location	Sample/Data	Methodology	Criteria/Focus
Morse, Bennett, and Ismael (2005)	Gujarat	Survey of 450 covering both Bt cotton and non Bt cotton farmers.	Farm survey analysis, Regression and Gini Coefficient.	Inputs (seed, insecticide, fertilizer, labour) Output (yield, revenue)
Kambhampati, Morse, Bennett, and Ismael (2005)	Gujarat	Interview: 22 Up-stream and down-stream companies: Sabarkantha, Ahmedabad, Gandhinagar, Mahesana, 2004	Survey data analysis	Yield Quality Expenditure on pesticide Labour cost Price obtained for the produce Economic returns
Bennett, Ismael, Kambhampati, and Morse (2004)	Maharashtra	Two random samples of Bt cotton farmers in two seasons 2002 and 2003. Sample size in (2002) - 2709 farmers and in (2003)-787 farmers. Personal interviews undertaken.	Farm survey analysis	Seed quantity/cost Number and cost of sprays Yields Price of output

Elements of Socio-Economic Considerations Covered in the Studies on Bt Cotton Experience in India

Study	Location	Sample/Data	Methodology	Criteria/Focus
Narayanamooorthy A. and S. S. Kalamkar (2006)	Maharashtra	Field Survey based in 2 districts of Maharashtra. Sample Size: 150 100 adopters and 50 non- adopters. Sample included marginal (<1ha) small (1-2ha) medium (4-10ha) and large (>10ha) Balance for rain-fed and irrigated -Balance for soil quality	Linear Regression.	Input use patterns -Cost of cultivation -Productivity -Inter-farm productivity variation. -Relative Profit Comparisons. -Extension support from seed companies.
Naik Gopal (2001)		Gains assumed with standard 60 per cent reduction in pesticide consumption Global cotton price data.	Domestic Resource Cost Coefficient.	Returns to farmers -Competitiveness
Qaim Matin (2003)	Maharashtra, Madhya Pradesh and Tamil Nadu	Field survey in 3 states of Maharashtra, MP and TN Sample Size: 157 (all adopters of Bt)	Cobb- Douglas Production Function	Pesticide use and yields Welfare and distributive effects

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Study	Location	Sample/Data	Methodology	Criteria/Focus
Dev Mahendra S. and N.Chandrashekar Rao (2006)	Andhra Pradesh	Field Survey in 4 districts of AP in 4 agro-climatic zones. Sample Size: 623 (Adopters 437 and non adopters 186) Sample included small (less than 4.99 acres) medium (5-9.99acres) and large (>10acres) Balance for gender/religion and social categories. Type of land and size. Nature of employment.	Multi-stage stratified random sampling.	Cost of Production across social categories. -Impact on employment across social categories
Gandhi P. Vasantha and N V Nambodari (2006)	Maharashtra Andhra Pradesh Tamil Nadu Gujrat	Field Survey in 4 states of Maharashtra, AP, TN and Gujarat. Sample Size: 694 (355 adopters and 339 non adopters) Average farm size 3.73 ha for Bt cotton and 3.02 for non Bt growers.	Regression analysis	Yield and pesticide use. Costs and returns. Cotton quality.

Issues Emerging from Socio-Economic Studies

- Bt cotton has been a success story as it has spread rapidly in ten years with increase in yields
- Farmers have switched over to Bt cotton at rate faster than what was anticipated
- BUT there are some issues that need attention and have to be addressed




Issues Emerging from Socio-Economic Studies

- High price of seeds and availability of hybrids only with no OPVs
- Private sector dominance, public sector's share limited
- Need for varieties with traits more relevant for small/marginal farmers not met
- Lack of awareness on setting aside land as refugia




Issues Emerging from Socio-Economic Studies

- How best to take this forward and what steps needed to delay development of insect resistant
- Stacking of genes and development of varieties with multiple traits
- Linking this with issues in ag-biotech for pro-poor and inclusive and sustainable development in agriculture



Regulation & Technology

- Three criteria relevant for regulators
 - Safety, Efficacy, Effectiveness
- Safety->Environmental & Health
- Assessed by globally accepted methodologies, protocols, and standards in testing and data analysis
- Safety assessment needs science based risk assessment
- Quantifiable, verifiable and experimental evidence is at the core of testing safety



Regulation & Technology-2

- Effectiveness – how it works in real life in different contexts & conditions
 - Many factors influence the outcome
 - Technology independent factors play an important role in it
 - Handling of technology, use of inputs, climatic conditions, soil condition etc can impact the performance of a LMO used in agriculture
- Effectiveness thus will vary and it is directly relevant for Socio-Economic Impacts



Regulation & Technology-3

- For regulators and decision makers understanding the role of non-technological factors and their impact on the effectiveness is important.
- This can result in better evaluation of SE aspects of LMOs
- Regulatory regime should take into account all the three and segregate them among agencies so that their roles are demarcated
- Evaluation after commercialization should be done but with an understanding of different factors that affect the outcomes



New Biotech Regulation in India

- BRAI bill in draft form
- Envisages setting up different bodies for regulation
- Inter-Departmental governance
- Separation of promotion of innovation and regulatory functions
- Involvement of more than one regulatory agencies
- Different structures to represent stakeholder interests and through consultative processes



BRAI Structure -1

Units at BRAI

- **Risk Assessment Unit**
- **Inter-ministerial Governing Board and Biotechnology advisory Board** (promote inter-ministerial cooperation)
- **Biotechnology Advisory Council** (Advise the authority on matters related to developments in modern biotechnology and their applications in India)
- **Environmental Appraisal Panel** (Recommend on environmental safety of organism and products in such matters required under the Environment (Protection) Act 1986).
- **Product Ruling Committee** Recommend to BRAI for use or manufacture of organisms and products
- **Economic Analysis Unit:** Ex ante analysis; Post approval impact analysis



BRAI STRUCTURE 2

- **Regulatory Divisions (3)**
 1. Division dealing with agriculture, forestry and fisheries
 2. Division dealing with human and animal health
 3. Division dealing with industrial and environmental applications
- **Biotechnology Regulatory Appellate Tribunal**
- Any person aggrieved by the decision of NBA can appeal to BRAT within 30 days from the date of the decision



Remaining Issues

- The proposed BRAI structure is a very holistic one but the challenges are
 - capacity building for putting it on the ground
 - political will to execute
 - different levels and mind set and political set ups of state governments in india
 - awareness and education in policy makers and farmers alike
 - developing an indigenous simplistic mechanism/ legal provisions for approvals ... not confusing with regulations and research done elsewhere



Thanks
