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An Overview of Regulation, Perceptions and Priorities for GM Crops in Asian Countries

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Abstract: Resolving hunger and poverty requires many diverse interventions. In certain cases, use of genetically modified (GM) crops can play a role. Rapid adoption of GM crops has occurred for those incorporating traits most relevant for industrial or market oriented farming. Some private sector GM crops are also found in specific regions of Asian countries, like insect resistant cotton and maize in the Philippines. Approvals to use food and feed crops from public sector research lag behind those of the private sector, as only China has released products from its own public research.

What will be the future for acceptance, regulatory approval, and use of publicly developed GM crops in developing countries? To address this question, we identified and examined public research pipelines for GM crops in Malaysia, Pakistan, Philippines, Thailand, Indonesia, China and India, with records updated through 2003. In addition, special studies were made in India on farmer acceptance, opinion, and on farmer's understanding of GM crops and biotechnology. Genetic transformation events are reported for 30 crops and for the Indian analysis of perceptions. Findings are presented for events nearing final stages of development, analysis of the crops, traits and genes involved, and details regarding biosafety. The paper concludes with a summary offering various policy, institutional, perceptual, and regulatory suggestions.

Keywords: Asia, biosafety; biotechnology; genetic modification, public research

Introduction

Over the past 10 to 15 years, scientists have applied new genetic technologies to a diverse range of crops. Many of these technologies hold promise for addressing productivity constraints faced by farmers in Asian countries.[1] This is accomplished by transforming local or foreign (imported) plant varieties to provide new opportunities for

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socioeconomically diverse farming systems. In many developing countries, public research institutes are actively involved and lead this research, while working with national, international and private partners.

This study focuses on GM crop pipelines from public research in 7 Asian countries: China, Indonesia, India, the Philippines, Thailand, Pakistan, and Malaysia. It provides essential information regarding GM crops under development, status of biosafety approvals, implications of genes to be deployed, distribution of seed or improved planting material, and the range of partnerships available.

Much has been accomplished with the investments in public agricultural biotechnology research. A study was implemented to assess the state of publicly developed GM crops[2] in 16 developing countries.[3] This research shows that for Asian countries, 40 public institutions have stably transformed 30 crops, incorporating a wide range of genes for insect, fungal, viral, and bacterial resistance; protein and quality improvements; herbicide tolerance, and salt and drought stress.

However, the primary source of GM crops continues to be the private sector. Multinational companies lead in the development of GM technologies and given the technology's market potential, have invested significant resources in facilitating technologies through regulatory processes. With the exception of GM cotton in China, and more recently rice in field tests,[4] public research products lag behind.

This study reviews public research pipelines for GM crop research, acceptance or perception studies, and updated information from a few key Asian countries. Cotton is also included since it is a valuable cash crop for some small-scale, resource-poor farmers, emerging from public research pipelines in Asia.

Methodology

This study highlights expectations and limitations on public GM crops and traits in China, Indonesia, India, the Philippines, Thailand, Pakistan, and Malaysia, using crop research data through 2003. An expert survey approach was used, and given the fact that the development of biotechnology products is knowledge and resource-intensive, the survey was directed to pre-selected experts. The study team analyzed the information and consulted further with scientific and research leaders in their respective countries. Collection of information

Table 1: Number of transformation events by country.

Continent	Country	Number of Events
Asia	China	30
	Indonesia	24
	India	21
	Philippines	17
	Thailand	7
	Pakistan	5
	Malaysia	5
	Total	109

Source: Atanassov *et al.* 2004; Cohen 2005.

was coordinated with key national research organizations. Continent, country and lead institute provided details on GM crop development. Table 1 shows the total number of events[5] included in the final assessment for each country.

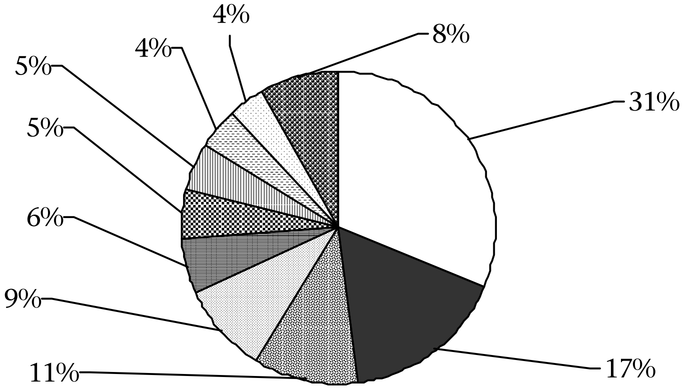
All crops were categorized and sorted following the FAOSTAT crop classification.[6] Transgene data were gathered as specifically as possible for each gene, but in a few cases such detail was either not clear or listed as “confidential”. Information was also collected for phenotypic trait expression.[7] Detailed information at the gene level was obtained wherever possible.

As for the relation between regulatory processes and GM research, data were collected by regulatory stage, emphasizing the most advanced events possible. Four stages were used: experimental, confined field trial, scale-up, and commercial release. For experimental stage entries, experts were asked to identify only highly developed biotechnologies coming from laboratory, greenhouse, or glasshouse. A very high standard for the laboratory/greenhouse stages was set, as we cannot account for all the technologies in the research pipeline, particularly before proof of concept has been presented. As such, the survey cannot measure the flow of technologies from one stage to the next, nor can it tell whether technologies are getting stuck in a particular stage.[8]

Pipelines for GM Crops and Transgenes Employed

To date, our research includes 109 transformation events from 40 scientific institutes in 7 Asian countries (Table 1). These countries maintain an ongoing commitment to biotechnology research, supported by universities and agricultural research institutes with good laboratory and agronomic capacity.

Figure 1: Transformation events distribution by crop groups



Transformation events organized by crop groups are shown in Figure 1. While transformation of rice predominates, there are significant numbers of transformation events for vegetables and fruits, potatoes, and cotton with each group representing a fairly diverse set of crop species. The greatest numbers of transformation events are for: rice (31 per cent), vegetables (17 per cent), papayas (11 per cent), and potatoes (9 per cent).

The percentage distribution of events by phenotypic groups is presented in Figure 2. Virus and insect resistance cover almost 60 per cent of the 109 events surveyed, and interestingly for Asia nine per cent of all transformation events are under product quality.

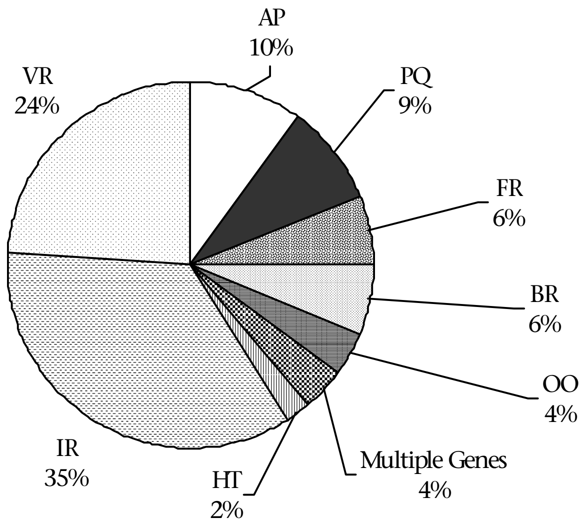
Ensuring Safety in the Field

To examine the relationship between the transgenic events reported above and biosafety regulations for GM crops, the survey proposed a well-defined set of regulatory stages to classify each product, especially regarding field-testing and advancement. Respondents were asked to indicate in what stage of regulation their respective events were most accurately placed.

Events in the *experimental stage* contain research products that are presently being subjected to laboratory confirmatory tests with respect to stability of gene integration and expression or undergoing extensive greenhouse/glasshouse test or evaluations.

For *confined field trials*, expression of traits remains stable in small-scale, single or multi-location confined trials. These trials are designed

Figure 2: Transformation events distributed by phenotypic groups



AP- Agronomic Properties; **BR**- Bacterial Resistance; **FR**- Fungal Resistance; **HT**-Herbicide Tolerance; **IR**- Insect Resistance; **OO**– Other; **PQ**- Product Quality; **VR**- Virus Resistance.

to mitigate any environmental damage by their containment, thus their regulatory standards are different from those established for subsequent stages. Confined field trials are a special focus of this work, as it is for the global study.[9] This level of research trials is crucial for bringing experiments to conclusions, and knowing what, if anything, to advance for wider trials. Without this information, public research comes to a stop.

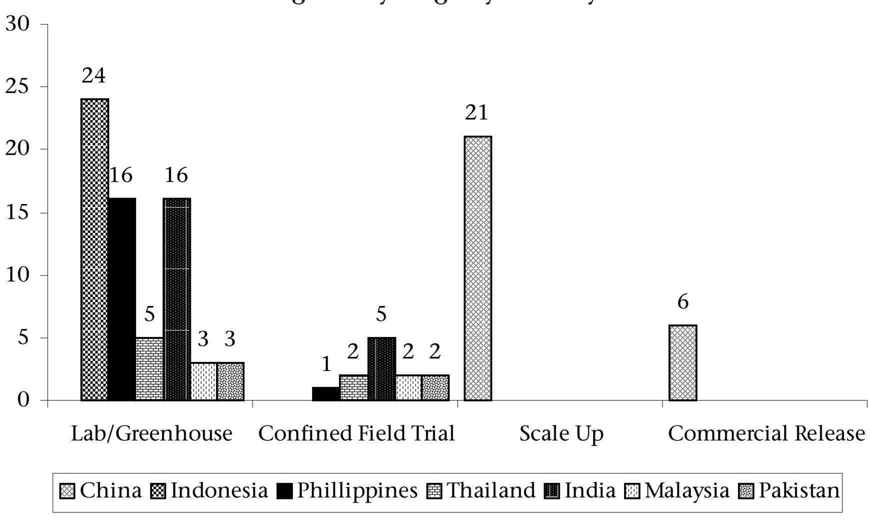
The *scale-up* stage occurs when products advance from confined trials to pre-commercial trials, requiring the ability to increase seed amounts, and larger areas for testing purposes. These tests may be conducted for environmental safety purposes, efficacy trials, or both. Finally, products are made available to farmers only after *commercial release*, through privately- or publicly-owned seed companies or other institutional mechanisms.

The survey data show that a total of 67 events are at the experimental stage, while 15 are in confined trials, and 21 have reached the scale up stage and 6 have completed the regulatory face (Figure 3). China's public sector is a clear leader not only in the region but worldwide in getting events into farmers' fields. All 27 transformation events in Asia that have reached the scale-up and commercialization phases come from this country. China has successfully released for commercialization two insect resistant cotton varieties, virus resistant varieties of tomato, chili, and sweet pepper, and one tomato developed for product quality.

Those events in the confined testing represent the most promising public research for GM crops (Figure 3). It is expected that these 15 events will decline in number during rigorous evaluation. The public sector cannot just monitor confined trials for safety and efficacy, but it must also guarantee seed supplies to evaluate product performance on a large scale, and include experiments designed specifically for safety evaluation.

We do not know the number of initial transformation events required to reach the event records in Figure 3. Are the 15 events in confined testing (spread over several crops, traits and countries) sufficient to select superior GM material, increase seed, perform biosafety trials, and finally, advance to commercial use? Implications of these numbers require analysis among participating countries and institutes. This would allow institutes to better assess their role from a product perspective and not for research alone.

Figure 3: Number of public events classified by regulatory stage by country



Safety, Regulation, and Required Assessments

The most important benefit of biosafety regulation is ensuring that biotechnologies deployed in a country are safe, effective and can be implemented by the farmers.[10] Making rules and regulations is one aspect of regulation, but, if required, implementation of these rules by farmers is another aspect to be considered. For example, in India, it is observed that the majority of cotton farmers have not planted refugia lines (non B*t* varieties) as required by the national biosafety laws.[11] Implementing such laws require great awareness at the grass roots level, a strong extension network which can carry forward the message, and special attention for monitoring implementation.[12] This requires infrastructure and capacity at state and village level.[13]

As all participating public institutes place safety paramount, they wish to understand regulatory costs that may come to the GM crop applicant, as well as to society. These may occur from opportunities lost if biotechnologies having a potentially high social value are not approved, and hence not able to provide its net benefits to society. In many countries, such as India, delay in releasing varieties are also one of the major causes for illegal trade, where some transgenic cotton varieties were reported to be planted illegally before the official release of GM cotton. This type of illegal trade causes serious regulatory, policy, and trade implications.[14]

As knowledge, experiences, and exchange of information continue to grow, increased familiarity with GM technologies will enable regulatory agencies to have confidence to reduce requirements, thereby decreasing the approval costs per event. The significant increase in the rate of adaptation of the technology by farmers, endorsing farmer's acceptance of the technology will also play a very important role in facilitating regulatory and political will for future crops.

Phenotypes and Transgenes

Specific transgenes or gene groups were identified and classified according to the phenotype expressed. This allows comparisons of regulatory information available and expected for genes in wide use, or those that are more unique. The entire set of 109 events is grouped under 7 phenotypic groups (Table 2). Here, insect resistance has the highest number of entries with 39, followed by 27 for virus resistance, 11 for agronomic properties and 10 for product quality.

Table 2: Classification by gene group.

Gene group (as best could be described)		Transformation events No.	Subtotal
Agronomic Properties (AP)			**11**
	Ethylene regulation	3	
	Salt Tolerance	2	
	Antisense	1	
	Arabidopsis annexin gene	1	
	BADH	1	
	Drought tolerance	1	
	Stress tolerance	1	
	Rol. C Dwarf ness	1	
Bacterial resistance (BR)			**6**
	Xa21	5	
	Antibacterial	1	
Fungal resistance (FR)			**6**
	Glucanase, Chitinase	3	
	Blast resistance	2	
	Chitinase	1	
Herbicide tolerant (HT)			**2**
	PsbA,atrazin	1	
	BAR	1	
Insect resistant (IR)			**39**
	Bt	24	
	GNA (Snowdrop lectin)	5	
	Pin	4	
	Bt and Trypsin inhibitor	2	
	Trypsin inhibitor	2	
	Gall midge(Gm2)	1	
	Alpha amylase inhibitor	1	
Product quality (PQ)			**10**
	Nutritional	3	
	ACC oxidase	2	
	Ethylene regulation	2	
	Ipt/z11	1	
	Not provided	1	
	EFE	1	
Virus resistance (VR)			**27**
	Coat protein	24	
	Coat protein and Reporter genes	1	
	Coat protein and replicase	1	
	Replicase	1	
Stacked genes			**4**
IR/BR	Pin and Xa21	1	
IR/BR	Bt and XA2	1	
HT/AP	Bar, Barnase, Barstar	1	
HT/AP	Bar, Barstar	1	
Other			**4**
	Vaccines	4	
Total		109	**109**

Source: Atanassov *et al.* 2004; Cohen 2005.

Worldwide there are primarily three gene groups with sufficiently robust utility and suitability for wide use, and those are *Cry* genes from *Bacillus thuringiensis* (*Bt* genes) that provide insect resistance, coat protein genes for virus resistance and thirdly those genes conferring herbicide tolerance. Interestingly for Asia one of the first gene groups consists of coat proteins of plant viruses used for virus resistance. The same number of events is seen for *Bt* genes for insect resistance, while the third group consists of genes conferring agronomic performance. Most other gene groups and their associated phenotypic traits have not yet demonstrated robust applicability in the field. For example, no gene group has yet to confer-effective fungal resistance, although much experimental activity has been spent on investigating the glucanases and chitinases. For Asia this group represented six entries alone.

Updates and New Findings

As shown in Table 3 below, Indonesia conducts research on the largest variety of crops, followed closely by India and China. A separate list of crops under GM development has been compiled.[15] However, most of these examples are in containment, and add updated information at that level for crops and institutes.

Virtually, all Asian countries are undertaking research in GM rice. For Asia, this means working on the essential food security crop of the region, in areas of genetic and biological diversity, and a crop on which millions of people depend. As it has not been approved for open release anywhere else in the world, GM rice is being reviewed and considered in a cautious manner by regulators because of unique environmental implications. To consider these implications, OECD has published a consensus document on rice and other reports and studies have been published regarding biosafety and potential risks of GM rice.[16] Recent news from China[17] indicates tentative performance and acceptance of GM rice in field trials is positive. Expanded examples of public research on GM rice in India are listed in the table, "The ongoing main research work",[18] as one example as well as data on rice in the study reported here.

GM research in rice is also significant for nutritional enhancement. As various lines of beta carotene enriched rice become available for testing, Asia has a new opportunity to fight Vitamin A deficiency. Research is now leading to stable, transgenic lines of importance, with new genes used to increase yet again the percentage of available beta carotene.[19] At the same time, rice lines are being developed to ease

Table 3: Distribution of phenotypic traits by country

	Crops under research	Insect resistant (IR)	Virus resistance (VR)	Agronomic Properties (AP)	Product quality (PQ)	Fungal resistance (FR)	Bacterial resistance (BR)	Other	Multiple genes	Herbicide tolerant (HT)	All
	No.	*Number of transformation events*									
China	11	10	9	1	3	1	4		1	1	30
India	11	9	2	4	1	1		2	2		21
Indonesia	14	13	5	2	1	3					24
Malaysia	5	1	2		1					1	5
Pakistan	5	2	1	1			1				5
Philippines	6	3	4	1	4	1	1	2	1		17
Thailand	4	1	4	2							7
		39	27	11	10	6	6	4	4	2	109

Source: Atanassov *et al.* 2004; Cohen 2005.

regulatory concerns by putting biosafety first in the construction of the inserted genetic information.[20]

China, however, has the largest variety of events under research and development. Herbicide resistance is the most limited; while the most important group across all countries is the expression of insect resistance and virus resistance. As will be discussed later, such commonalities could lead to new forms of collaboration among neighboring countries, including new opportunities for exchanging transgenes and germplasm.

Other changes are underway, as will be reflected in future *Next Harvest* studies. As an example, in 2002, when the information for Next Harvest was first collected, Indonesia reported 24 transformation events. Today, three years later, 11 or almost half of these events have been suspended, and three new have been added (Table 4). The reasons cited for this decline include lack of funds to pursue R&D and regulation, lack of sufficient progress, and technical and logistical problems. The crop portfolio has decline at the same time, with eleven crops today compared to 14 in 2002. Of the 14 crops under development in 2002, only 8 have survived. Currently there are 11 crops as three additional crops have been added.

The three new crops are citrus, cabbage, and oil palm. Citrus is under development by Airlangga University (UNAIR) and is targeting disease resistance. The University of Udayana (UNUD) is working on cabbage developing resistance to CPVD. Lastly, the Agency for Assessment and Application of Technology (BPPT) is currently developing an oil palm event working with genes that enable low saturated fatty acids.

In the Philippines, further public research has not yet been examined beyond that contained in the current analysis. However, in regards to regulation, the Philippines has just approved for commercial use and planting a second GM insect resistant yellow maize.[21] This is the Bt-11 corn from Syngenta. The Philippines continues to be the only Asian country to approve GM maize production for use as food and feed. For more comprehensive updates on biotechnology research among Asian countries, consult Chaturvedi and Rao (2004).

Pilot study on farmer's perception to biotechnology in India

Direction of research, commercialization and regulatory strategies should consider the end user, in this case the farmer's, perception to

Table 4: Indonesia: Transformation Events in 2002 and 2004

Food Crop	2002	2005
Cabbage	-	1
Cacao	1	1
Cassava	1	1
Chili pepper	1	1
Citrus	-	1
Coffee	1	1
Groundnuts	1	-
Maize	2	-
Mung Beans	1	-
Oil Palm	-	1
Papayas	2	1
Potatoes	2	2
Rice	6	5
Shallot	1	-
Soybeans	2	-
Sugar cane	1	1
Sweet Potatoes	2	-
Number of. events	24	14
Number of crops	14	11

Source: Patricia Zambrano.

the technology. A pilot study in the state of Gujarat (western India) involving 1000 farmers. The study covered a cross section of farmers across the state representing different economic, educational and agro climatic backgrounds, gender, age etc. The study focused on understanding their level of understanding of biotechnology, the most preferred extension method for farmers and key factors affecting their decision of adoption of new technology like the GM technology.

Following general observations were made from the study:

1. Most respondents (97.2 per cent), regardless of their economic and educational backgrounds were interested in knowing about biotechnology but were cautious and needed to be personally convinced that the use of the technology will be economically beneficial to them.
2. Economic benefits from the new technology was the most important factor influencing farmer's decision of adoption of the technology. Higher seed cost of GM technology (especially comparing with BT cotton where the GM seeds cost is about 4-5 times higher then most non GM hybrid seeds available in market) is not a prime concern for the farmer who is willing to invest more in the seeds provided he is convinced about the 'end of the day' economic benefit of the technology.

3. 83.6 per cent farmers in the study did not find the present extension system adequate and capable of 'handling' new technologies. A need to strengthen extension machineries at the grass root level was exhibited.
4. The study revealed that farmers were interested in demonstration of the technology on their own village/area, this was put forward as the most effective way of extension and the most important factor influencing their decision regarding the use of the technology.

GM technology is a new concept for farmers in most developing countries. Adopting a new concept shall mean modifying their current farming practice. This will require full confidence and convincing of the farmers and preparing the system so that they are able to take informed decision on using or not using the technology.

Summary and Discussion

Will policies and research in the developing world stimulate the safe use of publicly developed GM food crops? We addressed this question with an analysis that takes readers from North to South on the Asian continent, and from genes and crops used for transformation. To do so, the paper summarized information for GM crop research conducted by public research institutes in seven Asian countries.

Research institutes covered in this study demonstrate capabilities across 30 plants, several different phenotypes, and the ability to use transgenes together with available genetic resources. In so doing, scientists have harnessed an assortment of genes in pursuit of traits relevant to farmers. Some have also gained familiarity with regulatory dossiers as needed for biosafety determinations. The range and diversity of these crops is wide, exceeding that carried out through international programs. However, desired phenotypes are few when compared to traits being developed by multinational firms or advanced research institutes in industrialized countries.[22]

The public sector is a viable, but largely unproven, player in the bioengineering of local crops. While on the policy front, regulatory systems and policies have been under development for over 10 years in Asia. Some of these systems have already conducted biosafety assessments, and have determined which crops are acceptable for trials and use. The fact that there are approximately 14 per cent of the 109 events in various phases of confined testing indicates opportunities for advancement of public sector research products. However, the longer the waiting period, the more likely the trait and or germplasm becomes ineffective as disease pressures change and more productive varieties are released.

A combined policy/institutional issue also arise for public GM crops because so many institutes work alone, without research or development partners. Of the 109 transformation events identified in this study, only 35 per cent are being developed under some type of collaboration, meaning that public institutes are working mainly in isolation. The data and analysis presented here can reduce such isolation by finding commonalities among crops, genes, regulatory stages, and collaboration. With this information, private firms and public research institutes can pursue greater collaboration based on these commonalities and complementarities.

Apart from development of GM products, there are greater opportunities for cross sector collaborations for capacity at the grass roots level. In most Asian counties, where 60-70 per cent of the total population is farmers, they simultaneously are also the major consumers or end users. A major thrust is needed to build awareness among farmers of this new technology, its safety precautions, and such consequences to build an informed society and to help growers to take informed decisions on GM crops and biotechnology. In largely populated countries, capacity building at the grass roots level is an important, yet challenging task and shall need partnership efforts from public, private, and international stakeholders.

Moreover, information and data of the type reported here can be used to build greater South-to-South collaboration, a mode of partnership that does not presently exist in any appreciable quantity. Greater South-South collaboration will provide one more way to strengthen inter-institutional research and experiences. This can occur by building on common approaches, genes, and stage of regulatory trials and required safety information. This would be especially valuable for Asia since most countries share similar crop and traits of priority, such as yield, disease/insect resistance, and nutrition enhancement in rice and wheat, for example.

Building on these new opportunities to strengthen public GM crop research and exchange experiences, does not mean that all decisions are in the researcher's hands alone. Rather, it is a process involving several policy dimensions concerning the regulatory system, the political and trade environment, the management of development opportunities and partnerships, and keeping in constant dialogue with farmers-end users to address their needs and the needs of specific communities.

There is a need for multi partner collaboration in taking the technology forward as a 'relay race' where development of technology, taking it through the regulatory process, preparing the system, including farmers, for it's safe and suitable use and market access should be taken with equal importance. While investments in research is very important, equal amount of attention needs to be given to education and capacity building efforts so that the products of research reaches its ultimate goal – successful adaptation of the research product by farmers.

However, all of these events and policies can also be used against the very technologies they are there to evaluate and to advance once proven. Delays can mean rising costs, lack of impact at the rural level, regulatory requirements in need of clarification, loss of confidence among the stakeholders, particularly farmers and consumers, and more direct accountability. Such concerns are emerging issues in developing countries. The combined effect is delayed impact and uncertainty of the technologies, used by biotechnology's detractors nationally and internationally.

Endnotes

1 See for example, TERI 2001; Chaturvedi and Rao 2004

2 In this context, publicly developed GM crops are those developed by public or national institutes, including universities, agricultural research organizations, or biotechnology institutes

3 Atanassov *et al.*, 2004; Cohen, 2005

4 Huang *et al.*, 2005

5 For this study, a single, unique transformation event represents a combination of crop, transgene, lead research institute, and the specific country of origin, thus recognizing both the transformation event and its institutional context. [6]http://apps.fao.org/faostat/form?version=ext&collection=Production.Crops.Primary&Domain=Production&language=EN&servlet=1&axis=item&xsl=areareflist

7 Phenotypic traits were categorized as per USDA APHIS classification. "Phenotype/Phenotype Category - the nature of the introduced trait. Each is assigned a two-letter code which describes the category into which the trait falls, as determined by the Animal and Plant Health Inspection Service (APHIS)" See http://www.nbiap.vt.edu/biomon/datacat.cfm

8 For further information on methodology, consult Cohen (2005).

9 Cohen 2005

10 Mehta-Bhatt 2000

11 Mehta-Bhatt 2005; Tabashnik 2005

12 FAO 2005

13 Mehta-Bhatt 2000

14 Mehta-Bhatt 2005; Jayaraman 2005

15 Indira *et al.* 2005

16 Chopra *et al.* 2005

[17] Huang *et al.* 2005
[18] Indira *et al.* 2005
[19] Grusak 2005
[20] Hoa *et al.* 2003
[21] Aglay 2005
[22] Nuffield Council on Bioethics 2004

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