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EPTD Discussion Paper No. 116

TO REACH THE POOR – RESULTS FROM THE ISNAR-IFPRI *NEXT HARVEST* STUDY ON GENETICALLY MODIFIED CROPS, PUBLIC RESEARCH, AND POLICY IMPLICATIONS

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ABSTRACT

Local farming communities throughout the world face productivity constraints, environmental concerns, and diverse nutritional needs. Developing countries address these challenges in a number of ways. One way is public research that produces genetically modified (GM) crops and recognize biotechnology as a part of the solution. To reach these communities, GM crops, after receiving biosafety agreement, must be approved for evaluation under local conditions.

However, gaps between approvals in the developed and developing world grow larger, as the process of advancing GM crops in developing countries becomes increasingly difficult. In several countries, only insect resistant cotton has successfully moved from small, confined experimental trials to larger, open trials and to farms. By far, most GM crop approvals have been for commercial products that perform well under tropical conditions.

However, complete information on public GM crop research in developing countries has not been assessed. "Will policies and research institutions in the developing world stimulate the safe use of publicly funded GM food crops?" The relatively few GM crops approved from public research, coupled with growing regulatory, biosafety capacity, trade, and political concerns, argue to the contrary.

To tackle this issue, we identified and analyzed public research pipelines for GM crops among 16 developing countries and transition economies. Respondents reported 209 genetic transformation events[1] for 46 different crops at the time when the survey was conducted. The pipelines demonstrate scientific progress among publicly funded crop research institutes in participating countries. Information and findings are presented for GM crops nearing final stages of selection. Additional details are provided for the types of genes and traits used, the breadth of genetic resources documented, implications for regulation, and the type of research partnerships employed.

Regulations, GM crop approvals, choice of transgene, and policy implications are discussed as they affect this research. Based on these findings, recommendations are presented that would help sustain and increase efficiency of publicly supported research while meeting biosafety requirements. To do so, the study examines results concerning investments and choices made in research, capacity, and policy development for biotechnology. These indicate the risk and potential for GM technologies in developing countries. Policy makers, those funding biotechnology, and other stakeholders can use this information to prioritize investments, consider product advancement, and assess relative magnitude of potential risks, and benefits.

Keywords: biosafety; regulation; biotechnology; genetic modification; public research

[1] The definition of an *event,* as used in this study, means the stable transformation (incorporation of foreign DNA into a living plant cell) undertaken by a single institute among the participating countries, thereby providing a unique crop and trait combination.

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1. INTRODUCTION

Working with limited human resources and financial restrictions (Falck-Zepeda et al. 2002), scientists across the developing world are making important gains in biotechnology research. Over the past 10 to 15 years, scientists in developing countries have been applying new genetic technologies to a diverse range of crops and traits. Many of these new technologies hold promise for addressing productivity constraints faced by smallholder, resource-poor farmers. This is accomplished by transforming local or foreign (imported) plant varieties to provide new opportunities for socioeconomically diverse farming systems. Publicly funded institutes in developing countries, that rely to various degrees on national, international and private partners, lead this research.

Most studies regarding the impact of genetically modified (GM) crops[3] have focused on commercial biotechnology or seed company products used primarily in four industrialized nations ((Falck-Zepeda et al. 1999; 2000). This study focuses on GM crop pipelines derived from publicly funded research in developing countries. 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.

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[3] Genetic modification allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. The technology can be used to promote a desirable crop character or to suppress and undesirable trait. (Nuffield Council on Bioethics, 2003).

However, detailed information on the institutes developing these GM crops is lacking, making technology assessments and progress difficult to assess.

Currently, the number of GM crops that have been approved and are cultivated in the developing world is largely limited to insect-protected cotton in Argentina, China, India, Mexico, and South Africa. Virtually all of this improved seed is available from commercial providers, with the exception of China, where publicly developed seed is available as well (Huang et al. 2002). Growers in these countries include poor, smallholder farmers (Thirtle et al. 2003). One reason why the approval and use of insect-protected cotton is widespread is that cotton is not a food crop, but rather used for fiber, oil and livestock meal. Consequently, most regulatory authorities in developing countries have found it easier to approve this crop because they are not required to assess food safety—an area in which few developing country regulatory authorities feel competent. The exceptions to this are South Africa and the Philippines where assessments have been conducted.

Approvals of transgenic crops for use as food or feed, lag behind those for non-food crops. Among developing countries and transition economies, only three have approved a single transgenic event (soybean in Brazil, Czech Republic and Uruguay; maize in the Philippines), while two have approved two events (soybean and tomato in Mexico; soybean and maize in South Africa) and one, Korea, has approved three events (one in soybean and two in maize). Pre-commercial cultivation of GM soybeans in Romania and GM maize in Bulgaria and Honduras also took place last year. Argentina, the world's second largest producer of transgenic crops by acreage, stands alone amongst the developing countries in having approved planting for seven transgenic events: one in soybeans, two in cotton, and four in maize (AgBios 2003). Eighteen

different transgenic events have received approvals for planting in developing economies (Annex 1), compared with 79 events in 14 different food/feed crops in developed countries (Annex 2).

Yet, much has been accomplished over the past decades of investment in agricultural biotechnology research. In order to assess this status of publicly-developed GM crops[4] in developing countries, the International Service for National Agricultural Research (ISNAR) initiated a study entitled *Next Harvest*. This research shows that 76 public institutions in 16 participating countries have stably transformed 46 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. Despite progress, 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 China, public research products lag behind, causing concern when private investments are not finding their way to countries, crops, traits and technologies that are most relevant to small-scale, resource-poor farmers.

Unless products developed by public research in developing countries gain similar approval as those developed by the private sector, many GM crops will not reach farmers and the impact of public sector biotechnology research in developing countries will remain negligible. This could mean that transgenic research would remain absent among alternative technologies foreseen to meet the growing agricultural demands, as in the case of China (Tso 2004), and that all potential benefits from this research could bypass the poor.

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

The *Next Harvest* study addresses these points by examining in detail GM crops emerging from public research pipelines in 16 countries with developing or transitional economies. The focus of this study is placed on food crops, with the inclusion of cotton, since it is a valuable cash crop for some small-scale, resource-poor farmers in certain developing countries.

Specific crops and traits are described, grouped by continent, phenotypic category, and in relation to crops researched by centers of the Consultative Group for International Agricultural Research (CGIAR). The type of genetic resources used for transformation is documented. Events are also grouped by their location in the stages of regulatory processes with those in confined field-testing are examined in more detail.

2. METHODOLOGY

Biotechnology can be defined quite broadly[5] allowing room for future technologies that may prove at least as useful as genetic modification of crops. In the future, as useful genes within the same or similar genomes become available, safety requirements for crops engineered with these genes may also change. Such crops would pose less public concern, since the genes used for transformation would be plant genes from known food crops and therefore have a history of safe use.

However, due to regulatory, safety, access, dissemination, and funding considerations, it is critical to understand the status of GM crops being developed for use by and for developing countries. *Next Harvest* was initiated in the beginning of 2002 to determine expectations and

[5] For example, Biotech Life Science Dictionary of the University of Texas Institute for Cellular and Molecular Biology, defines biotechnology as : "The industrial use of living organisms or biological techniques developed through basic research. Biotechnology products include antibiotics, insulin, interferon, recombinant DNA, and techniques such as waste recycling. Much older forms of biotechnology include breadmaking, cheesemaking and brewing wine and beer."

limitations on public GM crops and traits in 16 selected developing countries. *Next Harvest*© focuses on crop research data through 2003.

Recently, broader inventories have been compiled, especially that of FAO, which in 2003 launched an online database on Biotechnology in Developing Countries (FAO-BioDeC)[6] to monitor trends in the development, adoption and application of crop biotechnologies in developing countries. Other studies include Johansen and Ives (2001) and Alhassan (2003) for Africa, an Asian Development Bank report for Asia (ADB 2001) and a report on Latin America (Trigo et al. 2002). International Service for the Acquisition of Agri-biotech Applications (ISAAA)[7] prepares annual overview reports on the extension of global adoption of GM technologies and area planted worldwide

ISNAR reports (see for example, Falconi 1999; and, Komen et al. 2000 for summaries of findings) captured information on ongoing crop biotechnology projects and indicators of available capacity in a range of developing countries. Other reports include data and examples of GM crops for developed/developing countries, as cited in the Pew Initiative on Food and Biotechnology (Pew Initiative 2001), and the Nuffield Council on Bioethics (2004).

This study sampled programs and institutes in a limited number of countries so that a careful examination of data was possible. While useful for some purposes, sampling from a full range of initiatives in each country would not generate information with the level of detail and accuracy desired by ISNAR and partners. Extensive variation in the type and state of technology developed can mean differences in how data are collected and reported.

To ensure that relevant knowledge, experiences, and insight were captured in the study, an expert survey approach was used. Given the fact that the development of biotechnology

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[6] http://www.fao.org/biotech/inventory_admin/dep/default.asp
[7] Available for download at: www.isaaa.org

products is knowledge and resource-intensive, the survey was directed to pre-selected experts with unique expertise and knowledge due to their position and involvement in their countries. Another goal was served by this method: the development of a longer-term research partnership and involvement of key stakeholders in monitoring and assessing their own work.

Researchers and/or regulators in the 16 partner countries listed in Table 1 implemented the survey. In a joint effort with the International Food Policy Research Institute (IFPRI), the study team analyzed the information and consulted further with scientific and research leaders in their respective countries. Collection of information was coordinated with key national research organizations. A methodology was then developed for its analysis.

Fourteen of these countries were represented at a *Next Harvest* meeting, held in The Hague, in October 2002. At this meeting, participants examined preliminary data, standardized data entry procedures, and defined methodologies and validation for final collection and analysis (Luijben and Cohen 2002). With IFPRI's participation, further iteration and consultations were undertaken to update and finally validate all data for each country.

Experts collected data across five categories:

1. Information Collection. Continent, country and lead institute provided details on GM crop development. Table 1 shows the total number of events included in the final assessment for each country. This information also allows for within country and regional comparisons (See Section 9).

Table 1--Participating countries and numbers of transformation events used in this study.

Country	Transformation Events *No.*
China	30
South Africa	28
Indonesia	24
Argentina	21
India	21
Philippines	17
Egypt	17
Brazil	9
Bulgaria	8
Thailand	7
Zimbabwe	5
Pakistan	5
Costa Rica	5
Malaysia	5
Kenya	4
Mexico	3
Total	209

2. Description of crops under research, transgenes deployed, and the desired phenotypic trait. Crops were categorized and sorted following the FAOSTAT crop classification.[8] 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.[9] Where possible, detailed information at the gene level was obtained. If, for example, the trait being described was virus protection in papayas, the study team recorded the means by which the trait was conferred, (here a coat protein gene), and the specific virus against which the trait was developed (here, the papaya ring spot virus).
3. Types of genetic resources used for transformation were reported, enabling the team to determine whether these resources were developed by a public institution or private firm, and whether their original was local or foreign (imported).
4. The relation between regulatory processes and GM research. To accomplish this, data were collected by regulatory stage, emphasizing the most advanced events possible. Four

[8]http://apps.fao.org/faostat/form?version=ext&collection=Production.Crops.Primary&Domain=Production&language=EN&servlet=1&axis=item&xsl=areareflist

[9] 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

stages were used: experimental, confined field trial, scale-up, or commercial release. For experimental stage entries, experts were asked to identify only highly developed biotechnologies coming from laboratory, greenhouse, or glasshouse.

5. The type of collaboration developed (if any), and plans for dissemination of research outputs. Questions asked included the number of institutions involved, the type of collaboration developed and the plans for dissemination. The study team developed data collection and validation methodologies for information about specific countries, crops, and gene/technology combinations. This led to classification of data as unique transformation events. These single, unique transformation events represent a combination of crop, transgene, lead research institute, and the specific country of origin. This definition recognizes both the transformation event and its institutional context. Not all possible events are summarized here, as the study is designed to be illustrative of trends, not an attempt to capture each and every transformation event under testing or production in the participating countries.

As we have set a very high standard for the laboratory/greenhouse stages 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.

3. PIPELINES FOR GM CROPS AND TRANSGENES EMPLOYED

To date, our research includes 209[10] transformation events from 76 scientific institutes in 16 countries. Such institutions in China, South Africa, Indonesia, India, and Argentina accounted for over half of the events recorded (Figure 1). These countries maintain an ongoing commitment to biotechnology research, supported by universities and agricultural research institutes with good laboratory and agronomic capacity.[11]

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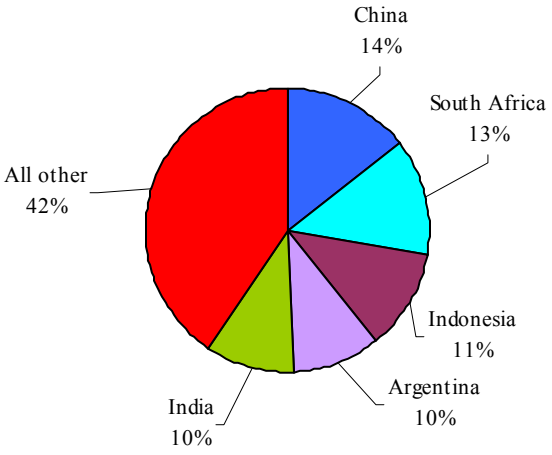
[10] Total number of events initially reported was 255. However, this number was reduced since some reported events were too premature in their development, or information could not be clarified, or because data was missing. Thus, the total number reported here are 209.

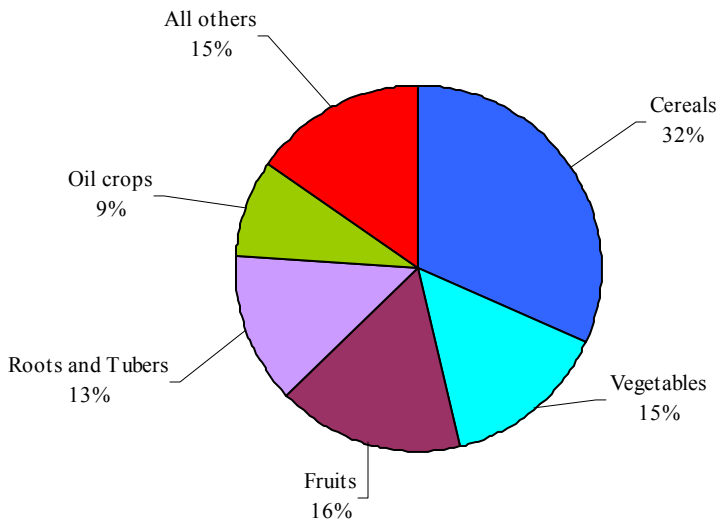
[11] The sources of investment and funding for this work are the subject of a parallel study (Falck et al. 2002), which will take into account many of the participating countries.

Figure 1--Percentage of transgenic events per country.



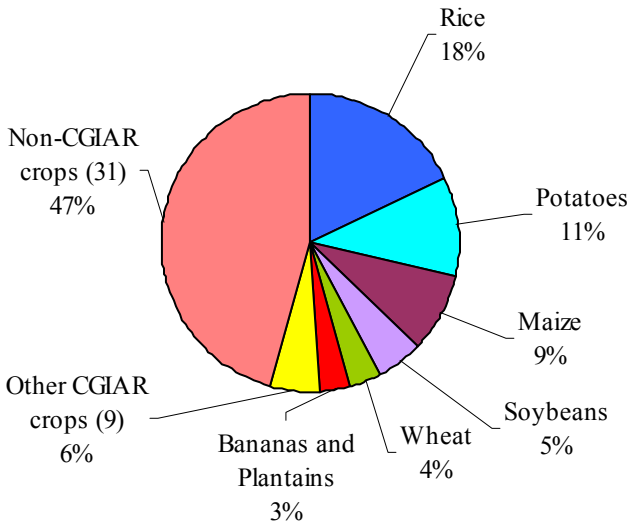
Transformation events organized by crop groups are shown in Figure 2. While transformation of cereals predominates, there are significant numbers of transformation events for fruits, roots and tubers, and vegetables, with each group representing a diverse set of crop species. Further, progress in transformation of indigenous crops, many captured in the "all others" category, including alfalfa, mung beans, beans, chickpeas, cowpeas, lupin, cacao and coffee, are also significant in number. The greatest numbers of transformation events to date are for rice (17.7 percent) potatoes (11.0 percent), maize (8.6 percent), and papayas (6.2 percent).

Figure 2--Percent transformation events by crop group



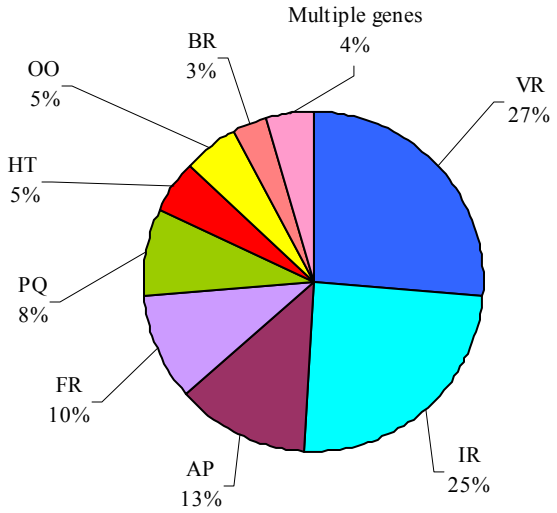
Transformation of crops organized by CGIAR Centers' mandates is shown in Figure 3. While public research efforts are responsible for transformation of 46 crops worldwide, only 15 of these crops are the subject of CGIAR Center and NARS research. Over half of all public transformation events (55 percent) are concentrated among these 15 crops. The remaining 45 percent of transformation events involve 31crops outside the CGIAR Centers' mandate, including cotton, vegetables, and fruits.

Figure 3--Comparison of events among participating countries with crop transformation at the CGIAR centers



The percentage distribution of events by phenotypic groups is presented in Figure 4. Over half of the 209 events included in the data set involved single genes that confer either viral or insect resistance to the host plant. In only a small number of cases (11 events) were multiple (stacked) genes being developed for phenotypic combinations, such as those that simultaneously confer insect resistance and herbicide tolerance.

Figure 4--Phenotypic distribution and percent of total events.



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

3. GENETIC RESOURCES

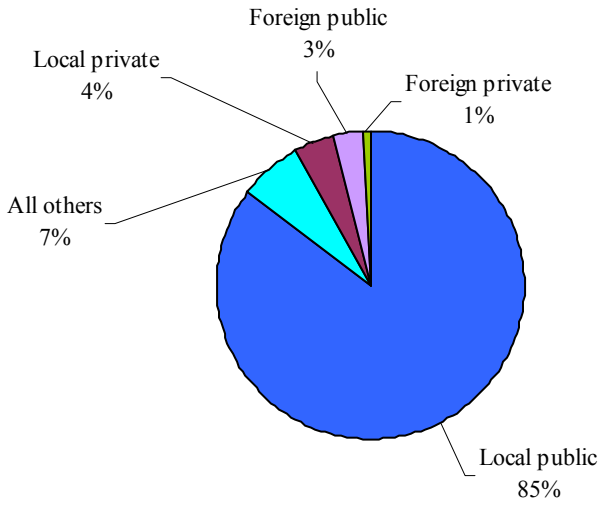
Novel genes are just one piece of the biotechnology puzzle. Equally important is access to genetic resources that possess acceptable agronomic performance characteristics and are suitable for transformation. In commercially-oriented biotechnology, genes are typically introduced into elite, or proprietary lines containing traits of local or national value, derived from years of conventional plant breeding. However, for public scientists in developing countries, access to proprietary genetic resources is limited by many factors. Private firms do not share

such material without licensing and remuneration. Such conditions, coupled with inadequate technology transfer agreements available for public research, may mean that the costs to farmers for such seed would be beyond their ability to pay.

To better understand the source and use of genetic resources, the survey asked experts if material used in the transformations was of local or foreign origin, and, whether it was from public or private sources.[12] Study results show that 85 percent of the genetic resources used for transformation were of local public derivation (Figure 5). Public genetic resources, usually thought of as locally adapted and well preferred by farmers, were identified for all 47 crops, including cotton. These genetic resources are usually free from any varietal or intellectual property claims. Their transformation is an indication of remarkable achievement, as our data is obtained only from well-advanced material, indicating the ability not only to transform, but also to express stable genes and traits, over several generations.

[12] Local genetic resources constitute landraces, varieties and finished lines produced or derived from developing countries; foreign (or imported) resources are those brought to a developing country by an external entity. Public materials are those from any form of public institution, and private are those from companies, as well as commodity organizations operating for and within specific developing countries.

Figure 5--Source of genetic resources, categorized as public or private, and as local or foreign.



Does the high percentage of local transformed material mean reliance or dependence on public genetic resources or, a deliberate independence from protected varieties or commercial germplasm? This question is not easy to answer, as both choices present benefits and costs, and different opportunities to the research institute. On the one hand, the ability to transform local, widely used public or indigenous genetic resources, among the 46 crops, provides the potential for greater public and farmer acceptance. Using well performing GM public germplasm means that farmers will not be prevented from saving seeds, nor will they be under the potential of monopoly pricing of seeds. The choice of using public or private genetic resources also depends on whether transformed lines are as productive and competitive as other available material (public or private), or if they were selected due to ease of regeneration.

Access to private or commercial genetic material is extremely limited, as only 9 percent of all transformation events used such material. The limited exchange of genetic materials between public institutions and private firms is reflected by the near-absence of collaborative

research projects between the public and private sector (See Section 9). For many crops, there are few productive alternatives to the genetic resources currently in use, as very little selection and adaptation is being done through either public or private research.

Once genes are stable in a particular background, backcrossing them with productive and accepted local genetic resources will ensure that transgenes are suitable for local situations. Companies will look for the best available lines of the backcrossing process, seeking plants that are adapted and productive for farmers. In Brazil, for example, extensive backcrossing by several companies and Embrapa is transferring genes for development (see Section 9).

Examination of benefits and cost may be needed to determine if the potential contributions of local genetic resources or locally adapted genes may need intellectual property protection. Benefit distribution and the extensive use and success in transforming local genetic resources, can form the basis for research agreements between public institutes and commercial GM producers. Creating clear benefit streams would also facilitate south-south transfer by minimizing the fear of economic loss, or germplasm used without sufficient agreement.

5. 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 stable research products derived from multiple generations, beginning in the laboratory and moving to the greenhouse or glasshouse. In this stage, the stable expression of the gene of interest is confirmed. In *confined field trials*,

expression of traits remains stable in small-scale, single or multi-location confined trials. These trials are designed to mitigate any environmental damage by their containment, thus their regulatory standards are different from those established for subsequent stages.

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.

Survey data show that a total of 127 events are at the experimental stage, while 44 are in confined trials, 22 in scale-up testing (mostly in China), and seven in the commercial release stage (Figure 6).[13]

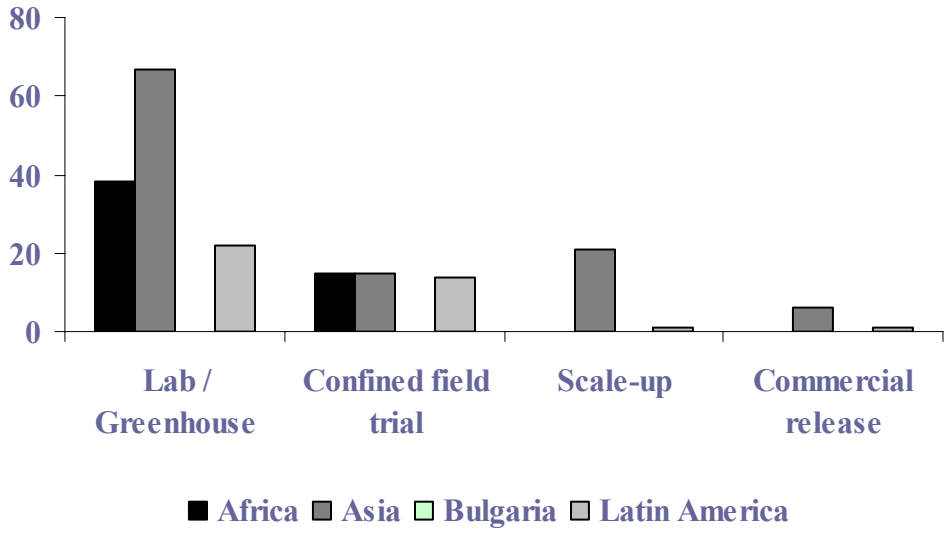
In all research pipelines, technologies or products are eliminated due to safety considerations or efficacy questions. For example, in pharmaceutical safety processes, 1 in 5 investigational drugs make it from human studies Phase I to commercialization (DiMasi, et al. 1999). However, in the case of GM crops, many countries have only interim guidelines or regulations in place, most of which do not allow for commercial approvals. Other countries, with commercial approval abilities, often lack confidence in their commercial decision-making. Such decisions are influenced by negative public opinion, pressure from anti-GM groups, and the current trade impasse over GM crops between the USA and Europe (Compés López and Carrau 2002). There may also be physical limitations such as growers inability to produce adequate seed amounts for large scale testing or for food safety testing.

[13] Nine transformation events could not be grouped among these stages, as these particular events were sidelined due to outstanding issues, some being agreement on intellectual property rights, or await further data before entry into the next stage of trials.

Those events in the confined testing represent the most promising public research for GM crops (Figures 2 and 4). These 44 events will decline in number during their rigorous evaluation and of those listed only seven countries have five or more trials in place. However, the public sector cannot just monitor confined trials for safety and efficacy. It must also guarantee seed supplies to evaluate product performance on a large scale, and include experiments designed specifically for safety evaluation. However, many of the events recorded have been in multiple years of testing and are waiting approvals for scale-up or pre-commercial trials. These larger tests could be done in partnership with private seed companies or with government seed production facilities. To accomplish this successfully, events should be identified as soon as possible, based on the most reliable field trial data possible.

We do not know the number of initial transformation events required to reach the event records in Figure 6. In fact, industry experience points to a ratio of transgenic events to useful released products of 100:1 (Quemada, personal communication 2004). Are the 44 events in confined testing, spread over many crops, traits and countries, sufficient to select superior GM material, increase seed, biosafety trials, and finally, advancement to commercial use? Implications of these numbers and ratios require analysis among participating countries and institutes, as it would allow institutes to assess their role from a development perspective and not for research alone.

Figure 6--Number of public events classified by regulatory stage and region



6. SAFETY, REGULATION, AND REQUIRED ASSESSMENTS

The most important benefit of biosafety regulation is ensuring that biotechnologies deployed in a country are safe and effective. In addition, a well functioning regulatory system can instill confidence in the public that the risk assessment used to evaluate newer technologies, including biotechnologies, are science-based, as presented under Article 15 and Annex III of the Cartagena Protocol on Biosafety (Convention on Biological Diversity (CBD)Secretariat 2000). While the Protocol provides a unifying approach to biosafety, it also states that the cost of the assessment is borne by the notifier (Article 15).

For this reason, the study explores the benefits and costs of regulation, especially those relevant to public institutions providing GM crops in the developing world. These institutions have little combined experience as “notifiers” and are only just beginning to understand the safety costs associated with those required for research and development. As all participating institutes place safety paramount, they wish to understand costs to the notifier 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. To initiate the exploration of safety and the costs of biosafety regulations, certain participants were able to give basic estimates of costs they face as they seek to fulfill safety requirements while developing their specific technologies and crops. In reviewing this data, some preliminary findings became apparent.

A study of Brazil by Sampaio (2002) estimates the compliance costs for regulatory approval of single events. These cost estimates include the initial green house and field screening, field testing for environmental impact, and food safety measured in US dollars. The average annual cost of compliance per event varied from US$ 140,000 for virus-resistant papaya, to US$ 800,000 for herbicide- resistant soybeans. The higher cost for herbicide resistant soybeans is mainly due to the requirement of performing complete animal studies. A study of Costa Rica by Sittenfeld (2002) estimated the average annual cost for virus-resistant rice at US$ 680,000. This estimate does not include costs associated with development of the technology.

Data presented from Brazil contains information for food safety testing needed for regulatory approval. While there were not many other examples of such tests, the need for food safety information, the policy and regulatory decisions affecting these requirements, and the severe lack of capacity for such in developing countries was also discussed (Cohen et al. 2003). For this reason, among others, the Cartagena Biosafety Protocol envisions the need for capacity building among regulatory bodies as a central activity (CBD 2001).

A study by Odhiambo (2002) estimated the cost for an insect resistant corn event in Kenya at US$ 160,000. The major component of which is the cost of containment structures. Sutrisno *et al.* (2002) presented data for insect resistant corn and cotton, herbicide resistant corn and soybeans in Indonesia. Their estimates show that average per year cost of regulation in

Indonesia ranges from US$ 390,000 to US$ 420,000. Quemada (2003) estimated that the total cost for the biosafety regulatory compliance of virus resistant potatoes in South Africa amounted to US$ 830,000.

These estimates rely on the state of knowledge and the current biosafety regulatory system in the respective countries as presented during the first *Next Harvest* conference in 2002. 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. Participants noted that there has been a shift of regulatory costs to earlier stages of the research process. This fact highlights the need to rationalize GM research efforts by being more selective as to projects and numbers of events so that safety requirements can be completed. Participants also noted the importance of ensuring that the cost structure and level of regulatory processes are adequate to assure safety, while not hindering the development of potentially beneficial technologies.

Table 2--Preliminary estimates of average per year per event costs of biosafety regulations among five countries

Country	Average per year regulatory Cost per Event (Million US$)	Crops	Source
Brazil[1]	0.14-0.8	Virus resistant papaya and potatoes, herbicide resistant soybeans	Sampaio (2002)
Costa Rica[2]	0.68	Virus resistant rice	Sittenfeld (2002)
Indonesia	0.039-0.042	Insect resistant corn and cotton, herbicide resistant corn and soybeans	Sutrisno, Herman, Moeljopawiro, Loedin (2002)
Kenya	0.16	Insect resistant maize	Odhiambo (2002)
South Africa[3]	0.83	Virus resistant potatoes	Quemada (2003)

Notes:
[1] Brazil does not include infrastructure investments. Variation in costs is related to safety assessment of events tested for food safety outside the country (e.g. glyphosate resistant soybean), or events for which research and development to the market are done in Brazilian laboratories.
[2] Costa Rica includes molecular characterization and epidemiology, transgenic field trials, biosafety, IPR, food safety deployment, gene flow.
[3] The data presented for South Africa is from a paper developed by Quemada (2003). Very preliminary data for South Africa was presented in the Next Harvest conference by Brink and Koch (2002). Estimate for South Africa's virus resistant potatoes are for the total regulatory span.

7. 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 209 events could not be included here, since detailed information on genes was not always available. Table 3 presents five of the eight phenotypes having the highest number of clearly identified genes or gene groups.

There are primarily three gene groups with sufficiently robust utility and suitability for wide use. The first gene group consists of C*ry* genes from *Bacillus thuringiensis* (Bt genes) that provide insect resistance. The second group consists of coat proteins of plant viruses used for virus resistance, and the third consists of genes conferring herbicide tolerance. 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.

Similarly, no group of genes has been shown to reliably confer bacterial resistance in the field, even though many investigators have studied the effects of antimicrobial peptides. Thus, there is only limited success in developing crops with traits other than insect resistance, virus resistance, and herbicide tolerance. The large number of single gene approaches means that researchers are testing numerous alternatives to achieve traits of interest, which may lead to identifying utility of other gene groups.

Five genes were labeled as confidential. Such confidentiality indicates that countries are becoming aware of the need to protect intellectual property rights in the earlier stages of development. These confidential genes could be publicly developed or received from the private sector under confidential agreements. In either case, they demonstrate that some research institutes are finding other than fully public means to use and develop novel genes.

When developing country scientists use genes made available for research, licensed, or derived from collaborative research, greater amounts of data are available to enable regulatory decisions. The more unique the gene and crop used for transformation, the additional data can be initially required during biosafety review. Of course, this means more time will be needed to

assemble such data, particularly if the genes are novel enough to warrant food safety testing for commercialization.

Among the genes or gene groups listed below, the C*ry* genes, coat protein genes, and herbicide tolerance genes can be expected to move through regulation with fewer requirements for additional data. This is because numerous safety reviews have been conducted on these genes in several countries. However, this does not rule out the need for tests to address specific environmental or biodiversity concerns, as results of such tests may not be transferable from one country to another.

The more unique or singular genes shown in Table 3 include 16 insect resistance genes, seven genes that are not coat protein approaches, and antimicrobial peptides or sarcotoxin, used for blast resistance. In contrast to well-known genes for herbicide resistance, the more unique genes will require more information for biosafety review, and have fewer options to benefit from data from other sources.

8. REGIONAL FINDINGS

By continent, researchers in four African countries (including North and Sub-Saharan Africa) completed 54 events, scientists in seven Asian countries produced 111, those in four countries in Latin America accomplished 30, and Bulgarian researchers produced eight (table 4). At the present time, the greatest number of events has been generated in Asia, though only the Philippines has approved a food crop for testing and commercial production. Our work among transition economies has just started; hence, we only have data from Bulgaria for East Europe. We group by continent to review similarities and differences among neighboring countries.

Table 3--Genes and gene groups clustered within 5 phenotypic groups

Phenotype Category	Gene or gene groups	Number of events	
IR			**51**
	Bt	35	
	GNA (Snowdrop lectin)	5	
	Pin	4	
	Trypsin inhibitor	2	
	Bt and Trypsin inhibitor	2	
	Gall midge(Gm2)	1	
	Confidential	1	
	Alpha amylase inhibitor	1	
VR			**55**
	Coat protein	48	
	Replicase	3	
	Nucleoprotein gene	1	
	Coat protein and Reporter genes	1	
	Coat protein and replicase	1	
	Antisense to TYLCV	1	
FR			**21**
	Glucanase, Chitinase	6	
	Glucanase, PGIP2	2	
	Confidential	2	
	Chitinase and AP24	2	
	Chitinase	2	
	Blast resistance	2	
	PGIP1 and PGIP2 - isolated at VOPI	1	
	Grape resveratrol	1	
	Glucanase, PGIP3	1	
	b32, PGIP2 (VOPI), and other selected anti-fungal genes	1	
	AP24,CH5b,GLN3	1	
HT			**11**
	PAT	4	
	EPSPS	2	
	BAR	2	
	AHAS	2	
	PsbA,atrazin	1	
BR			**8**
	Xa21	5	
	Sarcotoxin	1	
	Antibacterial	1	
	Antimicrobial peptides	1	

IR= Insect resistance, VR=virus resistance, FR=fungal resistance, HT=herbicide tolerance, BR=bacterial resistance.

These survey results by region capture several interesting points. First, while Asia is the most developed region in terms of having products across all stages of the research pipeline, the

region's success is directly tied to the degree of investments in research, and, the success that China (and to a lesser degree Indonesia and India) have had in insect resistant GM cotton approvals. Africa stands in sharp contrast to Asia, as once all events from South Africa are excluded, there is little GM crop research elsewhere. Latin America advancement in GM crop research lies in between Asia and Africa. Again, however, once Brazil, as the region's biotechnology research leader, is separated from the other Latin American countries studied, the amount of GM crop research declines in the region.

Table 4--Number of transformation events by region.

Continent	Country	Number of Events	Sub-totals
Africa	Egypt	17	54
	Kenya	4	
	South Africa	28	
	Zimbabwe	5	
Asia	China	30	109
	India	21	
	Indonesia	24	
	Malaysia	5	
	Pakistan	5	
	Philippines	17	
	Thailand	7	
East Europe	Bulgaria	8	8
Latin America	Argentina	21	38
	Brazil	9	
	Costa Rica	5	
	Mexico	3	
All		209	209

While research is underway elsewhere, it is clear that Asia has made a significant commitment to GM crop research (ADB 2001). The region hosts the largest number of countries engaged in GM crop research as well as the highest percentage of events in testing. Africa, with the exception of South Africa, is seriously lacking in capabilities and resources to consider such research (Alhassan 2003; UN ECA 2002), and in many cases, countries are just exploring the implications whether to consider research on, or import of, GM crops. Research capacity and

potential markets are evolving (such as insect resistant cotton), albeit subject to uncertainties regarding the use and trade of GM crops.

As shown in Table 5 below, Asia conducts research on the largest variety of crops and events, followed by Africa, particularly South Africa. Bacterial resistance is the most limited, while the single most important group is the expression of insect resistance in Asia. 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.

Table 5--Regional distribution of phenotypic traits by continent.

Continent	Crops (number)	AP	BR	FR	HT	IR	PQ	VR	Stacked	OO	Total
		Number of events									
Africa	20	8	1	7	4	11	5	18			54
Asia	30	11	6	6	2	39	10	27	4	4	109
East Europe	4	4	1		1			2			8
Latin America	12	3		8	4	1	2	8	5	7	37
All	46	26	8	21	11	51	17	55	9	11	209

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

South Africa presents an important case study. South Africa has devoted an appreciable amount of money to biotechnology research and development. Though the South African research program was relatively unfocussed in its early years, it has become more targeted and better coordinated with the enactment of the Biotechnology Strategic Plan and the BRICS (Biotechnology Research Innovation Centers), and under the pressure of reduced financial support for research in the Agricultural Research Council.

Furthermore South Africa's requirement that research proposals be linked to industrial applications or development partners is ensuring that agbiotech products are developed with relevance for end-users. More recently, the government initiated a three-year program to improve

Public Understanding of Biotechnology[14] that promotes informed decision making among the population (Koch, personal communication 2004). South Africa has an established biosafety process that reviews all activities with GMOs and has recently ratified the Cartagena Protocol on Biosafety.

9. REACHING THE FARMER

Participating countries were asked to share preliminary plans as to how GM crops will be disseminated to farmers. Results from the study indicate that in general, such plans have not been established—scientists have either not determined suitable mechanisms with which to reach farmers, or they intend to rely on the usual public sector methods of dissemination (Figure 7). Plans are further complicated by such factors as the uncertainty about the time lines for regulatory approvals and the difficulty scientists face in determining when to introduce GM crops and crop management techniques to farmers.

Some research institutes have sought partnerships to complete development of their GM research products, as one means to move research through the regulation process and onto public or private producers. However, few of these partnerships have developed, including those with the private sector. This reflects the paucity of working options available, and the difficulty of determining farmer acceptance when it is not possible to supply seed for observation and testing. Finally, such partnerships and time lines reflect only the estimated capacity of these institutes to offer/supply a product. The partnerships reported do not include time needed for acceptance, to engage farmers, and, to meet appropriate seed or plant material suppliers.

Who is responsible for establishing partnerships in these situations? In many cases, it goes well beyond the abilities of scientists, which may also account for the percentage of general

[14] http://www.pub.ac.za/

answers supplied. Research institutes need additional expertise to address the specifics above, maintain biosafety standards, and seek regulatory approval with responsible partners.

Economically advanced countries experience a rapid rise in the number of research partnerships involving commercial firms, universities, non-profit organizations, and public institutions (see for example, European Commission 2002). In plant biotechnology, public-private collaboration is usually emphasized in order to ensure that the products from agricultural research actually reach farmers' fields. Considering the time and costs involved in regulatory processes, it is essential that roadmaps toward product development and farmer interaction – and potential roadblocks – be conceived early in the R&D process. The local and international private sector would play a key role in this process, given their increasing experience in commercial development and eventual release of GM crops. However, examples of successful public-private partnerships in plant biotechnology are still rare (Spielman and Von Grebmer 2004).

Data collected in our survey reflect the general situation. Some form of partnership was recorded for 82 events or 39 percent of the total. Single, public R&D institutions conduct the largest proportion, 61 percent, of research. Of the 80 partnerships recorded, the majority (48 events) involved public-public collaboration, most often between public research institutions in the same country. In a number of cases, partnerships and technology transfers were undertaken on an international level, typically between public research and universities in Europe or North America.

Table 6--Types of institutional arrangements or collaboration used for this research

Institutional arrangement	Asia	Latin America	Africa	Bulgaria	All
Single public institution	71	22	28	8	129
Public/Public	25	9	13	0	47
Public/Private	1	7	7	0	15
Public/Foundation/Public	8	0	0	0	8
Public/Private/other	1	0	5	0	6
All other (no private collaboration)	3	0	1	0	4
Total	109	38	54	8	209

Private foundations, such as the ISAAA, are reported to be involved in 11 events, playing a brokering role in international technology transfer from the public or private sector. CGIAR centers were reported in three cases, confirming the CGIAR's limited role in GM crop development and the wide diversity of crops and genes being used (Figure 3, Table 3).[15]

Public-private collaboration was found in 21 cases (eight percent of all events) including a number of examples from African countries (Egypt, Kenya, and South Africa). The international private sector is involved in the majority of these cases, while local seed companies still play a minor role. Respondents were often not able to provide details of these public-private partnership arrangements, due to their confidential nature, but our limited information points to the use of contracts (research agreements, material transfer agreements) to govern public-private collaboration.

However, little is know of these partnerships in terms of relative strengths of each partner, and what conditions are critical for such partnerships to be of value to society (Spielman and Von Grebmer 2004). The key point is to assure equal footing between public and private

[15] Presentation of similar information from the CGIAR centers themselves may provide other and more extensive partnerships. However, there is only limited partnership information available at this time (Spielman and Von Grebmer 2004).

contributions. This is important in terms of genetic resources, as mentioned above, to ensure benefit, as well as for transgenes. The topic warrants further research to expand the knowledge and understanding of partnership arrangements and expectations.

A separate finding was that of all the types of partnership, no evidence was found of South-to-South collaboration. There are many reasons for this, including a lack of formal networking mechanisms, extremely limited resources, and a need for information on genes employed. As information becomes publicly available and new technology exchange mechanisms are created, such as the African Agricultural Technology Foundation (AATF)[16], more opportunities for South-South transfer may arise.

Brazil presents a unique approach. The case of Brazil contrasts to that of all other countries participating in the study. The number of transgenic events for Brazil indicates significant commercial involvement. Embrapa has been establishing partnerships with the private sector to explore commercial crop improvement, and this is the source of data used. These relationships are established through research contracts and later commercial contracts that set forth the terms and conditions for technology transfers to the private sector, the distribution of royalties and other arrangements.

Of the 46 transgenic events reported from Brazil, 37 were undertaken by commercial companies (local and international)[17], while nine events were produced by public research. These 37 events were primarily for insect resistance (IR) and herbicide tolerance (HT). These are well known traits for commercial research and investment. More than half of these events are in maize, followed by cotton, soybeans, and sugarcane.

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[16] http://www.aftechfound.org/

[17] These 37 events are not included in the total 209 events in this study as they are purely commercially and our focus is on the public research systems.

Public research spans five crops, with soybeans most important, followed by maize, potatoes, papayas and beans. Of the nine public events (included in the total 209), the phenotypic traits include primarily herbicide tolerance and virus resistance.

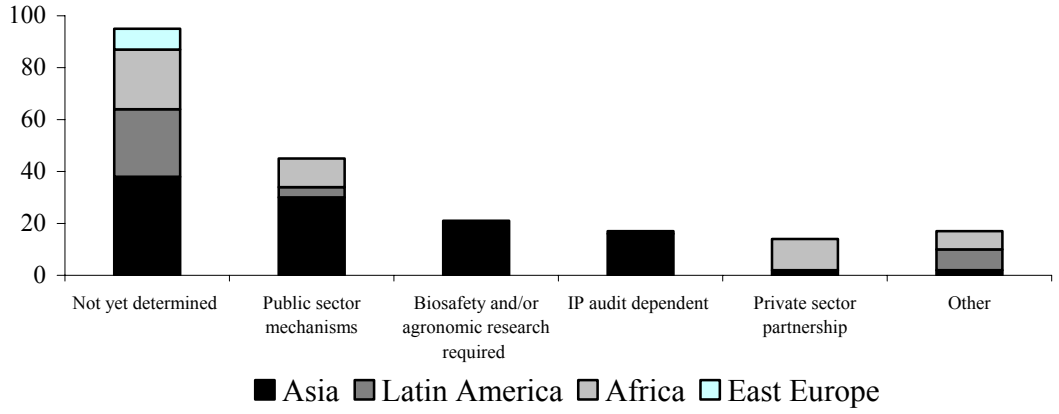
Embrapa can take advantage of commercial research opportunities, as there is a significant seed market potential in Brazil. This gives Embrapa more outlets for its technologies, and allows the Institute to indirectly take advantage of the additional sources of improved germplasm. In other developing countries, such stable, market-oriented, and seed distribution networks barely exist, or do not exist at all, creating almost sole dependence on the public sector for agricultural innovation. This is especially true for countries not allowing import, testing and possible approval of commercial transgenic crops. With sole dependence on public sector, and no ability to import GM crops for testing, farmers stand to lose in many different ways.

However, Brazil is also affected by judicial moratoria that resulted from complications associated with its biosafety and environmental legislation. While such private research offers local potential and benefit, it will not reach farmers while the current legal and political environment prevent GM crop testing and use. The impact is already evident in the number of events at the advanced testing stage, (36 of a total of 42 events), that are not moving to scale-up trials and or commercial approval stages.

The latest news from Brazil is that Congress should decide during the first half of 2004, on a new biosafety law that is supposed to give more freedom to researchers by removing excessive procedures while still imposing the safe evaluation of field tests. Glyphosate resistant soybean has been planted illegally since 1998, but in 2002 and 2003 the harvested crop was made legal by two specific laws. This has moved Brazil to the list of countries that now export GM-soybean, and this cannot be easily reversed. If nothing is done, insect resistant GM cotton

may follow the same path. These facts, and general changes around the world with respect to agricultural biotechnology and biosafety, are signaling the Brazilian Government and Congress that such a timely review of its GMO policy is needed (Contini et al. forthcoming).

Figure 7--Percent of events classified by nature of research partnerships



10. PUBLIC RESEARCH AND POLICIES FOR GM CROPS

ENVIRONMENTAL SAFETY: CROPS AND PHENOTYPES

Addressing concerns regarding environmental safety of GM crop introductions is essential. The summary data presented in this paper can provide a focus for expected environmental risk assessments. Common elements of current and future assessments, as determined for confined or commercial use, can be identified from such information, whether by crop, country, gene or phenotype. Ideally, this information would be shared among countries in conjunction with the development and implementation of the Biosafety Clearing House (BCH)[18], so that queries on risk assessments can be carried out based on accumulated experience.

As expectations for relevant risk assessments are developed, it would be possible to organize work with countries sharing common gene and crop experiences. This presents

[18] http://bch.biodiv.org/Pilot/Home.aspx

opportunities for South-South collaboration and data sharing, with the intent to minimize redundancies while maximizing exchange of expertise. The range of crops covered by our survey is very large, and so various assessments can be expected, depending on their specific characteristics such as: the plant's biological properties, their dispersal and ecological behavior, proximity to center of origin or diversity, and effects of the transgene on target and non-target species.

Experiences can also be shared with regard to experimental design, special environmental concerns (as per gene and crop), review of trials to date, and reasons for or against its advancement to commercial trials. This type of information, on the actual testing conducted, is not well known and often not documented in regulatory dossiers.

Our main concern is not to minimize the need for such tests, but to strive for consistency with their respective degree of containment and that testing is based on solid and comprehensive sources of information. Such background information and directions to applicants could clearly justify why a test is called for, how it should be designed, and the type of information needed. This increases regulatory proficiency and minimizes applicant's costs.

TRANSGENES: PROGRESS AND NEEDS.

As seen in Table 3, numerous transgenes are under development and testing for important phenotypic traits. Some of these genes are well understood and documented, while others are more unique and experimental. In either case, there is little consolidated information among developing countries as to gene/phenotype stability in the field. The conference participants recognized the need for consolidated information regarding genes, phenotypes, stability and expression in developing country situations.

Participants have greater familiarity with genes identified for insect and virus resistance, and herbicide tolerance (61 percent of total events). Others are more unique or of local derivation, or still very experimental. The widest variety of such genes was seen in the phenotypic categories of agronomic properties, fungal resistance, and protein quality enhancement. Included in these categories are genes for drought resistance, improved nutritional quality, salt tolerance, various combinations of glucanase and chitinase genes for fungal resistance, and applications of Xa21 for blight resistance, to name but a few. In addition, these genes are found in multiple crops, across many countries.

Collective knowledge on this array of transgenes can also be used to negotiate access and field-of-use agreements and to ensure intellectual property concerns and constraints are identified and resolved. While not covered in depth, these issues are preventing some of the gene technologies from moving forward in development (Figure 7). New forms of IP agreements can be approached through "humanitarian" use-type agreements, or IP donation facilities (Atkinson et al. 2003; AATF). Other factors, such as potential utility, the IP position of the technology owner, existence of competing gene constructs, and industrial marketing strategies can have a bearing upon licensing negotiations and conditions. Many of these GM crops have significance for within-country or regional trade, but not international. Reviewing IP concerns should take this into account, as these crops are not entering international trade, or shipment to countries where biotechnology patents are filed (Binenbaum et al. 2003).

Survey data was not collected for construct details, promoters, or markers. Meeting or exchanging data here is also possible, as many of the molecular characteristics are common as well. This affects the degree of safety anticipated at the gene level, and what, if any, are its

environmental consequences. When data is not available from any provider, then further environmental assessment trials are especially justified.

Finally, partnerships can help develop and provide information on the other 82 genes, or gene combinations, to increase understanding of modality and to ensure greater exchange of information for regulatory purposes. The sooner such opportunities are presented, the sooner gene stability, safety, and efficacy can be determined. However, as indicated in our findings on partnerships and multi-institute collaboration, such opportunities are limited.

RESEARCH AND POLITICAL UNCERTAINTY

This study shows how public institutes in the developing world advance GM crop research. Successful research has been recorded for 46 crops, with many waiting for further confirmation in field and scale-up trials. More advanced, or larger scale trials will let institutes know if their research is competitive when compared with available commercial opportunities. Farmer, or other field or quarantine testing, enables researchers and regulators to determine whether GM crops fill an important agricultural niche, or provide desirable traits in crops not of interest to the private sector.

However, this research is conducted during a time of political and legislative uncertainty that influences the regulatory system, and the potential use, risk, and advantages of genetically modified plants (Cohen and Paarlberg 2002). As discussed by Paarlberg (2000, 2001), a matrix of policies or actions determine a biotechnology acceptance gradient from precautionary to promotional. Of those determinants, this study focuses most specifically on biosafety regulation, actual GM crop approvals, and opportunities from confined field trials. Table 7 summarizes these comparisons. It reflects the fact that while progress is seen for approvals of GM cotton, relatively little progress is seen for advancing food crops.

Each participating country has confined trials underway, completed, or in multiple years of trials. However, eight of these countries have granted no approval for GM crops, while for eight other countries, primary approvals were made for GM cotton (Table 7). This table shows the year in which biosafety regulations and systems began, with each country having more than 12 years of experience, but with different end points, as in laws, regulations, or guidelines. The number of actual approvals and the year they were most recently granted serves as a measure of political or national acceptance or concern. If approvals are few and long between, it will be difficult to achieve timely advancement of publicly derived GM crops, thus limiting opportunities to interact with farmers.

Uncertainty comes not only from policy at the political level, but also from regulatory requirements at the research level. Additionally, but less visible it comes from the combination of genetic resources used for transformation and the particular gene inserted. When appropriate trials are delayed, or extra years added, whether due to breeding, testing, certification or regulation, new crops run the risk of being irrelevant by the time of approval.

For example, biotic stresses evolve and mutate, so that genes conferring useful resistance at one point in time may not in another, or resistance genes do not perform in the field, even though they provided resistance in experimental stages. Once virus resistant GM sweet potatoes received import and quarantine approval for Kenya, the Kenyan Agricultural Research Institute in confined field trials could rapidly test them where genetic protection proved insufficient. The longer such testing is postponed due to political or regulatory uncertainty, the longer events must be maintained in laboratories or screenhouses, delaying understanding and evaluation of their agronomic value

Table 7--Current regulatory status, approvals and testing of participating countries

Country	Commercial GM approvals for planting		National legal structure: law, regulation, or guidelines[1]	Approximate start of national regulatory development	Number of field trials approved	Number of Confined field trials from this study	GM crop area 2003
	No of events	*Crops*		*Year*	*Number*	*Number*	*Mill has.*
Argentina	7 [2]	cotton, maize, soybeans	Regulation	1991	367	5	13.9
Brazil	1	soybeans	Regulation	1989	339	6	3.0
Bulgaria	0		Draft Law presently national guidelines	1996	3		<0.5
China	1	Cotton[3]	Ministry of Agriculture Regulation, followed by State approval	1993	501[3]	3	2.8
Costa Rica	0		Regulation	1992	17	1	
Egypt	0		Draft law in preparation; currently: Law from Environment Ministry; Regulations (decrees): one for GM seeds and second for GM crops	1994		7	
India	1	Cotton	Regulations	1989		5	0.1
Indonesia	0	Cotton	Regulation	1993		0	<0.5
Kenya	0		Guidelines and regulations	1991	2	1	
Malaysia	0		Guidelines (law under development)			2	
Mexico	5	cotton, tomato, soybeans	Draft Law; Regulations and Standards	1995	241	2	<0.5
Pakistan	0		Guidelines under development			2	
Philippines	1	Maize	Regulation	1990		1	
South Africa	5	cotton, maize, soybeans	Law	1990	172	7	0.4
Thailand	0		Guidelines	1990		2	
Zimbabwe	0		Law	1990			
Total	21					44	<21.7

[1] Usually in the form of a Ministerial decree or similar instrument under existing phyto-sanitary or environmental law.
[2] Argentina has seven events listed here as we count the three HT/IR maize approvals as one type of event.
[3] This number was reported for China, from 1997 – 2002; while over 59 applications have been granted commercial approval, it is the GM cotton reported here that is approved for use by farmers. No transgenic food or oil crops have been approved to date (Jia and Peng 2002)
Sources: Agbios 2003; James 2003; NH data; UNIDO 2003; For field trials: CONABIA 1999 (Argentina), SAGARPA 2004 (Mexico), CTNBio 2001 (Brazil), OECD Biotrack 1999 (Bulgaria), Huang et al 2002 (China), and National Department of Agriculture (South Africa).

11. SUMMARY

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 continent and country to genes and genetic resources used for transformation. To do so, the paper summarized information for GM crop research conducted by public research institutes in 16 developing and transition economies. This information will help scientists, policy makers, and regulators understand their respective countries' public GM research and help address the question above. Further analysis—more in-depth and specialized examination of the key issues— will be conducted in direct consultation with the participating countries.

Research institutes covered in this study demonstrate capabilities across 46 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 (Nuffield Council on Bioethics 2004).

The public sector is a viable, but largely unproven, player in the bioengineering of local crops. While the participating institutes and scientists have developed many crop/phenotype combinations, which if found efficacious, and deemed safe, have not yet reached farmer's fields for trial and observation. This viability of research comes from capability and expertise in modern biotechnology created over the last decades and, equally important, the need for continued integration with conventional agronomic and breeding programs. This same capacity

also provides human resources for many of the regulatory decision-making bodies, insight into national councils, and ensures program continuity.

On the policy front, we see that regulatory systems and policies have been under development for over 12 years. Some of these systems have already conducted biosafety assessments, and have determined which crops are acceptable for trials and use. However, even with this progress, regulatory decision-making remains complicated, affected by conforming to the Cartagena Protocol for Biosafety, and, are subject to delays or moratoria. The fact that there are approximately 20 percent of the 209 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 arises for public GM crops because so many institutes work alone, without research or development partners. 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.

Moreover, this information can be used to organize 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.

The information reviewed in this study can also inform readers of parallel research in their own country, in other regions, and internationally. This can be valuable when selecting transgenes, considering regulatory requirements, and genetic resources available, or needed.

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 to address their needs and the needs of specific communities.

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, and more direct accountability. Such concerns are emerging issues in developing countries. The combined effect is delayed impact and uncertainty of the technologies, both of which are used by biotechnology's detractors nationally and internationally.

We have recognized policy, political and institute changes where efficiencies could be gained, while assuring safety and efficacy of GM crops. A combination of these changes and farmer testing of products from public research means a rapid assessment of success or failure. Clearly immense progress has been made on all fronts; but efforts are still needed to ensure that polices and institutes in the developing world stimulate the safe and relevant use of these new technologies for the poor.

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Table A-1--Biotech approvals for Planting in the developing world

Country	Trait	Cotton	Maize	Soybean	Tomato	Grand Total
Argentina	Count of events	2	4	1		7
	Glufosinate		1			1
	Herbicide tolerance	1	1	1		3
	Herbicide tolerance + insect resistance		3			3
	Insect resistance	1	1			2
Brazil	Herbicide tolerance			1		1
China	Insect resistance	1				1
India	Insect resistance	1				1
Mexico	Delayed ripening				1	1
	Herbicide tolerance			1		1
	Insect resistance	1				1
Philippines	Insect resistance		1			1
South Africa	Herbicide tolerance			1		1
	Insect resistance	1	1			2
Uruguay	Herbicide tolerance			1		1
Grand Total		6	8	5	1	20
Events count		6	6	5	1	18

Note: Events are counted as the unique combination of trait/country/crop. For example, the 3 biotech approvals for Argentina in maize HT/IR in Agbios database listed here are counted as 1 event.

Source: Authors calculations using Agbios data from "Global Status of Approved Genetically Modified Plants" in http://www.agbios.com/dbase.php?action=Synopsis, accessed 11/10/03

Table A-2--Events approved for planting in the developed world

Country/ region	Trait	Argentine Canola	Chicory	Cotton	Flax, Linseed	Maize	Melon	Papaya	Polish Canola	Potato	Rice	Soybean	Squash	Sugar Beet	Sunflower	Tobacco	Tomato	Wheat	Grand Total
Australia	CPB																		0
	CPB + virus resistant																		0
	Glufosinate		1																1
	Herbicide tolerance				1														1
	Herbicide tolerance + fertility		3																3
	Herbicide tolerance + insect resistance																		0
	Insect resistance				2														2
	Oil content																		0
	Oxynil																		0
Canada	CPB										2								2
	CPB + virus resistant										2								2
	Cyclohexanone					1													1
	Delayed ripening																		0
	ECB + glyphosate					2													2
	Glufosinate		3			2				1			1		1				8
	Herbicide tolerance		2			3				1			1						7
	Herbicide tolerance + fertility		3			1													4
	Herbicide tolerance + insect resistance					4													12
	Imidazolinone		1			1												1	3
	Insect resistance					2													2
	Oil content		1										1						2
	Oxynil		1																1
	Sulfonylurea					1													1
	Virus resistant																		0
European Union	Glufosinate																		0
	Herbicide tolerance			1															1
	Herbicide tolerance + fertility																		0
	Herbicide tolerance + insect resistance					1													1
	Insect resistance					1													1

Table A-2--Events approved for planting in the developed world (continued)

Country/ region	Trait	Argentine Canola	Chicory	Cotton	Flax, Linseed	Maize	Melon	Papaya	Polish Canola	Potato	Rice	Soybean	Squash	Sugar Beet	Sunflower	Tobacco	Tomato	Wheat	Grand Total
	Oxynil																		0
Japan	CPB																		0
	CPB + virus resistant																		0
	Delayed ripening																	1	1
	ECB + glyphosate					2													2
	Glufosinate		3			2							1						6
	Herbicide tolerance		1		1	2							1						5
	Herbicide tolerance + fertility		5																5
	Herbicide tolerance + insect resistance					4													4
	Insect resistance				1	1													2
	Lepidopteran pests + oxynil				1														1
	Oil content												1						1
	Oxynil		1		1														2
Netherlands	Herbicide tolerance + insect resistance																		0
Switzerland	Herbicide tolerance																		0
	Herbicide tolerance + insect resistance																		0
	Insect resistance																		0
United Kingdom	Herbicide tolerance																		0
	Herbicide tolerance + insect resistance																		0
United States	CPB									2									2
	CPB + virus resistant									2									2
	Delayed ripening																	5	5
	ECB					1													1
	ECB + glyphosate					2													2
	Glufosinate		3		1	2						1	4	1					12
	Herbicide tolerance		2	1	1	2							1	1					8

Table A-2--Events approved for planting in the developed world (continued)

Country/ region	Trait	Argentine Canola	Chicory	Cotton	Flax, Linseed	Maize	Melon	Papaya	Polish Canola	Potato	Rice	Soybean	Squash	Sugar Beet	Sunflower	Tobacco	Tomato	Wheat	Grand Total
	Herbicide tolerance + fertility	3				3													6
	Herbicide tolerance + insect resistance					5													5
	Insect resistance			2		2												1	5
	Lepidopteran pests + oxynil			1															1
	Oil content	1										1							2
	Oxynil			1															1
	Sulfonylurea			1	1														2
	Virus resistant								1				2						3
Grand Total		34	2	14	2	46	0	1	2	8	1	12	2	3	0	0	7	1	135
	Counting "events" only	16	2	12	2	22		1	2	4	1	9	1	3			3	1	79
	(Each country/trait/crop is count once only)																		14

Source: Authors calculations using Agbios GM database in http://www.agbios.com/dbase.php?action=Synopsis

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