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BIOENGINEERED CROPS AS TOOLS FOR INTERNATIONAL DEVELOPMENT: OPPORTUNITIES AND STRATEGIC CONSIDERATIONS

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SUMMARY

Crop bioengineering provides unique and dramatic opportunities for international agricultural development. However, we consider the technology not as a 'silver bullet' or panacea for crop improvement in the developing world but as an increasingly important tool that can be used to complement conventional methods of crop improvement. The number of bioengineered crops ready for commercial release in developing countries is expected to expand considerably in the next few years. But the multi-national life sciences companies that are leading the research, development and commercialization of bioengineered crops focus primarily on major crops that have high commercial value and extensive international markets. These companies also hold proprietary gene technology for many other crops of extreme importance to subsistence and resource-poor farmers but do not pursue product development and commercialization because of low anticipated returns. Such crops have traditionally been overlooked and are sometimes referred to as 'orphan crops' because of the relative lack of research and development applied to them. We propose a strategy for the development and delivery of bioengineered crops, including orphan crops, for developing countries. Consulting local public and private sector stakeholders to determine their highest priority needs for agricultural products is the first step. This ensures local stakeholder buy-in and that we do not invest in technology that is unlikely to be adopted. Next, the feasibility of developing and delivering the product is assessed. If the result is positive, the work is organized into 'product commercialization packages' (PCPs) that integrate all elements of the research, development and commercialization processes. The main elements of each PCP include (i) technology development; (ii) policy-related issues such as intellectual property and licensing, as well as gaining regulatory approval by the relevant national authorities; (iii) providing public information to producers and consumers about the benefits, risks and correct management of these new products; and (iv) establishing, or verifying, the existence of marketing and distribution

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mechanisms to provide farmers access to planting material. Our strategy involves integration of needs-based capacity building, socio-economic impact studies and product stewardship into each PCP. Whenever appropriate, opportunities are sought to create public–private partnerships to help leverage public funds, help absorb development costs and provide a broader distribution channel. To illustrate how our strategy is being translated into action we include, as a case study, examples of work by the US Agency for International Development-funded, Cornell University-led Agricultural Biotechnology Support Project II on the research, development and delivery of bioengineered fruit and shoot-borer-resistant eggplant varieties (*Solanum melanogena*) for South and Southeast Asia.

INTRODUCTION

Bioengineered crops are already contributing to agricultural productivity and sustainability in the more advanced developing countries. The multinational life sciences companies that are leading much of the research, development and commercialization of bioengineered crops currently focus primarily on a few crop/trait combinations that have high commercial value and extensive international markets. Many crops and traits of extreme importance to subsistence and resource-poor farmers around the world have been overlooked. The main aims of this article are: (i) to emphasize the critical importance of safely unlocking the full potential of bioengineering to cover a broader range of crop/trait combinations and better serve the needs of developing countries; and (ii) to propose a strategic approach by which this can be achieved safely and effectively.

BIOENGINEERED CROPS AS UNIQUE AND COMPLEMENTARY TOOLS

Bioengineered crops are plant materials that have been modified through genetic engineering. They are produced by insertion of a gene into an existing plant species, with the help of specific techniques, to enhance the receiving crop line or variety. The technology provides unique and dramatic opportunities for crop improvement. It can be used to produce crop varieties that would not be otherwise available and sometimes facilitates much faster and more precise ways of developing improved varieties. The technology allows selected individual genes discovered in one organism to be inserted directly into another – whether or not it is genetically related. Plant breeders had never, until the advent of bioengineering, been able to take advantage of genes from such diverse organisms as bacteria, fungi, animals and unrelated plants.

Bioengineered crops can be viewed as tools in the toolbox of agricultural biotechnologies. A summary of these and other biotechnological tools, with their uses, advantages and disadvantages, is shown in Table 1. In some cases biotechnologies such as tissue culture, marker-assisted selection and molecular diagnostics of plant diseases have already been used to good practical effect in developing countries, especially in Latin America and Asia. Bioengineering is among the less widely adopted technologies in developing countries, particularly in African countries with the exception of South Africa. Genomics, proteomics and bioinformatics are being used only by the most advanced developing countries.

Each tool has a current or potential use in addressing agricultural needs in developing countries. Some have multiple uses or are prerequisites for the application

Table 1. Tools of crop biotechnology.

Tool	Brief description and initial application	Advantages	Disadvantages
Short-term tools – for many crops and/or livestock; practical application within 0–5 years			
Tissue culture and virus elimination	*In vitro* culture of plant meristems can be used to both eliminate pathogens and rapidly produce large numbers of healthy plants. Virus elimination in potato was developed in the 1970s.	Rapid production of disease-free plants especially vegetatively propagated plants such as potatoes and bananas.	Skilled labour intensive, needs good management and controls to maintain disease-free status.
Marker-assisted selection	Using DNA-based markers for traits of interest enables selection of superior genotypes quicker and often cheaper. Being developed since the mid 1980s, routine application in plant breeding began in the mid–late 1990s.	Rapid elimination of lines lacking key traits. Enables stacking of genes for certain traits which cannot be distinguished by phenotype.	Requires good control over breeding populations to develop markers. Markers often specific to certain crosses and not applicable to others.
Doubled haploid production	Culturing immature pollen or embryos to produce homozygous plants in a single step. Known for many years in certain crops, but major work through the 1990s extended application to most cereals.	Rapid development of homozygous plants saves 2–3 years of selfing to produce true-breeding lines.	Expensive per plant, possibility of non-random segregation. Still not available for many crops.
Molecular diagnostics of disease	Genetic analysis of pathogens has resulted in the development of rapid and highly accurate diagnostic tests. Application to plant pathogens has been a reality for over 10–15 years and the information on pathogen diversity has been important to develop resistance management strategies.	Fast and highly accurate disease diagnosis results in proper measures to control both outbreaks and maintain pathogen-free status for quarantine purposes. Understanding pathogen diversity helps to develop robust disease resistance programmes.	The specificity of the tests means that care must be used to identify the causal agent of a problem (and not just opportunistic pathogens). The high sensitivity can sometimes be an issue if proper testing procedures are not followed.
Medium term – requiring 5–12 years to be adapted to address developing country challenges.			
Bioengineering or genetic engineering	Transfer of single (or a few) isolated genes into a plant cell and regeneration of a whole plant where the new gene(s) adds an important trait. First reported in 1983, first products released in the mid 1990s.	Specific addition of a trait from any source – not just those available by conventional breeding. Selective addition of a single trait without addition of other non-desired genes.	Long lead time to identify/develop genes of interest. Requires screening of many transgenic events to identify desired characteristics. Currently highly emotive and controversial, requiring large regulatory investments.

Table 1. Continued

Tool	Brief description and initial application	Advantages	Disadvantages
Long term – tools currently used mostly in medical research and often requiring more than 12 years to adapt to agricultural applications			
Genomics	Improvements to the equipment for genetic analysis now make possible the analysis whole genomes as opposed to single genes. This has the potential to extend the marker analysis beyond a few genes to many traits simultaneously. Developed over the last 5–10 years, these techniques are mostly being applied to human genetics due to the currently high costs per individual studied.	Combines all the genetic information to determine an ideal genotype instead of just a few genes. The study of whole genomes of populations of individuals can also reveal the genetic basis of different responses to both biotic and abiotic stresses – beyond the single gene affects which are currently being studied.	Requires a large amount of information per individual and thus expensive in agriculture where many individuals need to be analyzed. A lot of work needs to be done to develop useful applications to agriculture.
Proteomics	Proteomics is the study of the proteins expressed in particular tissue. The full protein spectrum of a particular tissue is analyzed at increasing levels of detail to identify not only the gene expression but also post-translational modifications which result in very different tissue differentiation from the same genome.	Analyzing the functional aspects of genes (i.e. the proteins and their activation) provides information about how genes operate to affect traits. This information enables rational design of modification to genes and genomes rather than simply identifying 'good' or 'bad' genes.	The level of complexity is very high and currently the protein spectrum in very few tissues (mostly human) has been analyzed in any detail. The promise of understanding the function and the relationships between proteins is still a theoretical one at this stage.
Bioinformatics	Not a technology *per se*, but a term describing the tools to handle the enormous amounts of data coming from the genomics and proteomics programmes. Already a vital tool to handle data, much of the software was developed during the human genome project in the 1990s.	Proper storage and manipulation of the data is vital to obtaining the information from the research work. Handling very large datasets makes possible the investigation of correlations which would not be possible manually.	Large amounts of computing power are needed as well as a large storage capacity. The algorithms to analyse the data are still at an experimental stage and there are still questions over doing experiments *in silico* which might not be relevant in the biological world.

of others; all of them are constantly evolving. For example, tissue culture was first used to eliminate pathogens and rapidly produce large numbers of healthy plants. But current applications include: (i) haploid production in plant breeding, in which homozygous lines can be produced in a very short period, and the time needed to develop a new variety is reduced; (ii) *in vitro* conservation, that facilitates long term maintenance of genetic resources; (iii) anther culture and embryonic techniques to

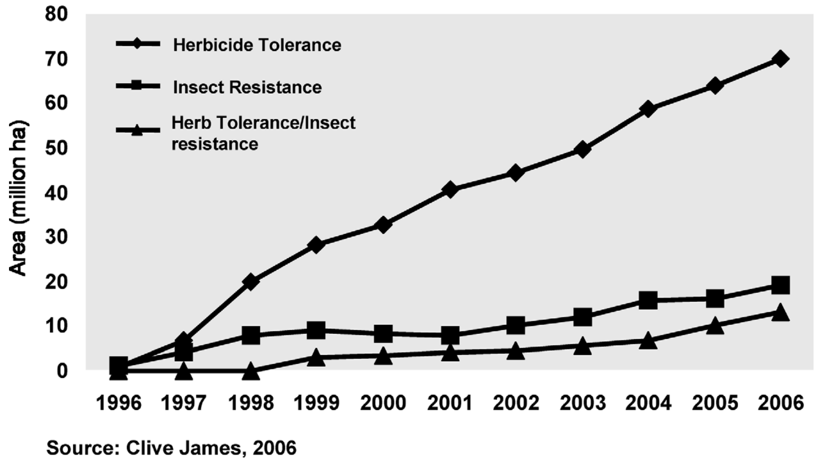

Figure 1. Graph of the area of bioengineered crops by trait since 1996. The area of virus resistant crops is not visible on this scale illustrating that there are – to date – only two traits that have been widely adopted (graphic reproduced with permission from International Service for the Acquisition of Agri-biotech Applications).

overcome reproduction barriers; (iv) conservation of genetic resources of root and tuber crops; (v) production of secondary metabolites with agricultural and medicinal interests; and (vi) mastering the conditions for genetic transformation and regeneration of bioengineered plants. As in the case of tissue culture, crop bioengineering and related biotechnologies (including genomics and bioinformatics) are evolving to a point where they merit serious consideration as mainstream tools for international development.

However, we consider bioengineered crops not as a 'silver bullet' or panacea for crop improvement in the developing world but, dependent on prevailing national or regional needs and circumstances, as an increasingly important complement to conventional agricultural approaches as well as non-bioengineering-based biotechnologies.

BIOENGINEERED CROP CULTIVATION TO DATE

The proportion of global area under cultivation of bioengineered crops increased annually during the period 1996 to 2006 (James, 2006). Over a third of the world's bioengineered crops are cultivated in developing countries, primarily in China, India, Argentina, Brazil and South Africa. Developing countries are expanding the area they devote to the cultivation of bioengineered crops faster than their more developed counterparts. Most of the commercial bioengineered crops currently cultivated around the world are either herbicide tolerant, insect resistant, or have a combination of herbicide tolerance and insect resistance (Figure 1).

The insect-resistant and herbicide-tolerant traits have been incorporated mainly into soya, maize, cotton and canola (James, 2006). These products are already beginning to play an important role in increasing agricultural productivity and

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sustainability around the globe. There are also small areas of potato, papaya and squash with genes for delayed ripening and virus-resistance inserted. Several forest tree species, such as conifers, poplar, sweet gum and eucalypts, have been bioengineered, but they have not so far been released for commercial purposes.

ENHANCED OPPORTUNITIES FOR THE USE OF BIOENGINEERED CROPS IN DEVELOPING COUNTRIES

Although current bioengineered crop variety releases are still very narrow in terms of crops and traits and the countries involved, many more crop-trait combinations are being investigated, with greater focus on virus resistance, quality, and, in some cases, tolerance to abiotic stresses. Over 40 transgenic events (Cohen, 2005) are under field-testing in developing countries.

Expanding the range of available traits

The long-term technological possibilities for bioengineered crops are limitless due to breakthroughs in genomics, proteomics and bioinformatics. Ultimately the association of DNA sequences with all biological functions of crops (as well as other life forms) will be defined. Plant genes responsible for all agriculturally important traits will be more easily identified, and isolated and transferred through biotechnology to target varieties (Tanksley and McCouch, 1997).

By facilitating access to desirable genes in plant germplasm collections, genomics, proteomics and bioinformatics will indirectly contribute to the improved conservation of biodiversity because collections that are put to better practical use are less likely to be abandoned due to budgetary cuts. Currently, only a small fraction of the world's plant germplasm is used for crop improvement, mainly because current plant breeding techniques to 'extract' the needed genes from plant collections are often too lengthy and expensive to be practical. Such enormous potential for crop improvement through the enhanced use of genetic resources cannot be ignored by any developing country that has serious crop-related constraints.

Moving beyond global major crops

It can be expected that the number of bioengineered crops ready for commercial release in developing countries will expand considerably in the next few years. But the multinational life sciences companies that are leading the research, development and commercialization of bioengineered crops focus primarily on crops that have high commercial value and extensive international markets. Many crops of extreme importance to subsistence and resource-poor farmers around the world have been overlooked. In addition to a small number of well-known major global crops such as maize, rice, wheat, soya, cotton and canola, many more crops are regionally or locally important for nutrition and income in poor regions (Nelson *et al.*, 2004). These include crops such as plantain and bananas; root and tuber crops such as cassava, sweet potato and yam; millets such as pearl millet, finger millet and foxtail millet; legumes such as cowpeas, groundnut and Bambara groundnut; and tree crops. Moreover, indigenous crops such as tef, quinoa and many types of vegetables, such as eggplant are critical for food security and nutrition on a regional or local basis.

Twenty-seven crops – often referred to as 'orphan' crops[1] because of the relative lack of research and development applied to them – were listed by Naylor *et al.* (2004) along with planting areas, production, value and dietary contributions. Within developing countries these crops cover some 250 million ha, with an additional 70 million ha planted to fruits and vegetables. In sub-Saharan Africa, for example, sorghum and pearl millet are more important than rice and wheat, both in area (41 million ha v. 9 million ha) and in contribution to diet. Roots and tubers are essential staples in Africa, where cassava is the third most important source of calories overall. Many of these crops are nutritious, valued culturally, adapted to harsh environments, and diverse in terms of their genetic, agro-climatic and economic niches.

STRATEGY FOR THE SAFE AND EFFECTIVE USE OF BIOENGINEERED CROPS IN DEVELOPING COUNTRIES

We present here the main strategic elements that we believe should be addressed in the development and delivery of bioengineered crops in developing countries. This approach was first conceptualized and adopted in 2001 in the context of our work on the Cornell University-led USAID-supported, Agricultural Biotechnology Support Project II (ABSPII at www.absp2.cornell.edu). In the following section our work on the development of bioengineered fruit and shoot-borer-resistant (FSBR) eggplant (*Solanum melanogena*) varieties for South and Southeast Asia is used as a case study to illustrate how our strategy is being translated into action.

Demand-driven product selection

Key factors: Consulting local stakeholders from the public and private sectors to determine which, if any, bioengineered crops are in demand is always the first step. This early consultation is essential for local stakeholder buy-in and avoids investment in technology that is unlikely to be adopted. The priority-setting is backstopped by economists who are recognized experts on research evaluation and priority setting. The process considers all of the key technical and non-technical components that affect farm-level acceptability and productivity among female and male farmers, and it balances country-specific, regional and even global needs. Information is collected from published sources and through structured discussions with scientists and other stakeholders such as producer groups of both men and women, private sector entities that might commercialize the products, consumers, public officials, extension workers and non-governmental organization (NGO) representatives.

[1] Following Naylor *et al.* 2004, we have chosen to use the word 'orphan' as opposed to 'minor' to describe those crops that receive little scientific focus or funding relative to their importance for food security in the world's poorest regions, although both terms are used more broadly in the literature. We refer to 'minor' crops as those other than the 'major' crops of wheat, rice, maize, soybeans cotton and canola. We want to stress the fact that minor crops and their orphan subset typically play major roles in nutrition and food production stability at local or regional levels.

The candidate bioengineered products each have specific gross and distributional (by location, gender, income level, farm size, consumer v. producer) effects, including economic, health and environmental impacts. The magnitude of these effects depend on: (i) technical factors including the nature, seriousness and scientific difficulty of the problems addressed, previous research investments, concurrent investments by others, integration with farm-level research and ownership of component technologies; (ii) rate and extent of adoption, which depends on agro-ecological factors, socio-economic constraints, and regulatory aspects; and (iii) market factors such as the price of the commodity, and the extent, location and structure of production, consumption and trade. Provisional priorities are subject to revisions as projects evolve.

Each candidate product is subjected to an analysis of its strengths, weaknesses, opportunities and threats (SWOT) and then ranked for its priority. SWOT analyses ask the following questions:

1) Technology development
   a) What is the stage of product development (e.g. planned, transformation in progress, regenerated plants)?
   b) Does the transgene perform as expected (does it actually work in the glasshouse/field)?
   c) Is the germplasm locally adapted (is it an existing cultivated variety)?
   d) How easily can the transgene be transferred to other varieties (is breeding an option to provide additional varieties with the same event)?
2) Policy
   a) Is there an intellectual property (IP) management strategy in place, or being developed, which ensures that issues relating to IP are adequately addressed throughout the product development phase and which avoids IP issues emerging late in the development or distribution stage?
   b) Has a freedom to operate (FTO) audit been performed and are the potential licensors identified (has the source and ownership of the components been determined)?
   c) Are there any existing licenses and is there any reason to expect that a commercial license will not be granted (are any of the licensors potential commercial competitors)?
   d) Are there any components in the construct that are unlikely to receive regulatory approval (unapproved selectable markers, transgenes of known toxicity)?
   e) Are there components in the transgene that have not received regulatory approval previously (i.e. will a full toxicity/allergenicity dossier have to be prepared)?
3) Distribution and marketing
   a) Is it known how farmers obtain planting material of the crop (is there an existing distribution network that can be utilized)?
   b) What is the plan for making the product available to farmers?
   c) Which partners will be included in distribution of the product?

  d) If there are private sector entities involved in distribution, how will they ensure access by all farmer groups (can the private sector make a profit without limiting access)?
4) Communication and outreach
  a) Will the product have a clear advantage to farmers and or to consumers (can this be used to encourage adoption)?
  b) How much information do the farmers/consumers in the target geographies have about the product or about transgenic technologies in general?
  c) How do farmers/consumers in the target geographies obtain their information (whom do they trust)?

Case study: It quickly became apparent during the priority-setting exercise for South and Southeast Asia that eggplant is an economically and nutritionally important crop in our target countries. It is widely cultivated and consumed in the subtropical and tropical regions of Asia and Africa. It grows in a wide range of climatic conditions and is a staple of human consumption. Its cultivation helps to generate valuable income for farmers and laborers. The national values for eggplant in millions of US dollars for India, Bangladesh and Philippines are 5904, 772 and 115 respectively[2]. However, the production of marketable eggplant is compromised due to numerous pest species that feed on eggplant. Of these, the most destructive is the eggplant fruit and shoot borer (EFSB) *Leucinodes orbonalis*. The larvae bore inside the terminal shoots, resulting in withering. The pest also bores into the young fruit and feeds inside, making the fruit unmarketable. Infestation can inflict about a 70% crop loss and fruit damage as high as 90% (Baral *et al.*, 2006; Dhandapani *et al.*, 2003).

Nearly all farmers rely exclusively on application of chemical insecticides to combat EFSB. This practice has resulted in widespread misuse of pesticides, causing a multitude of side effects that includes increased cost of production as well as exposure of farmers and consumers to pesticide residues. The excessive use of chemical pesticides has destroyed natural enemies of EFSB, resulting in a resurgence of the pest population.

No conventionally bred resistance to EFSB is available – attempts to crossbreed eggplant varieties with EFSB-resistant wild varieties have been unsuccessful – and, although some successes have been achieved through integrated pest management approaches (e.g. Baral *et al.*, 2006), their implementation can be impractical for small-scale farmers in remote areas. For these reasons ABSPII explored the possibility of developing and marketing bioengineered eggplants containing a transgene obtained from the soil-borne bacterium *Bacillus thuringiensis* (Bt) that provides resistance to EFSB (for details see 'Technology development, intellectual property rights (IPR) and licensing issues' below). A major advantage of this technology is that it reduces the use of chemical pest control, thereby reducing environmental risks. Through its safety tests, the US Environmental Protection Agency has found no human health hazards related to Bt use. The agency has exempted Bt from its standards for

[2]National crop values were calculated using national average production 1999–2002 from FAOSTAT and an indicative price for eggplant of $675/MT.

food-residue tolerances and groundwater concentration, from endangered species labelling and from special review requirements, indicating that cultivation of crops using Bt is safe for resource-constrained farmers in the developing world.

With this background, an ABSPII priority-setting exercise was conducted with local representatives of public and private sector stakeholder groups from our focus countries of India, Bangladesh and the Philippines. SWOT analyses for bioengineered EFSB-resistant eggplant (as well as for other candidate products) were conducted. These were based on information obtained either directly from the developer or by the ABSPII management team. The result for Bt eggplant was that high priority was assigned to the product. This was not only because of its verified technology and potential economic, health and environmental benefits but also because of the absence of road blocks due to IPR, favorable prospects for regulatory approval, strong local partnership organizations and the high likelihood of gaining public acceptance for the product.

Integrated, holistic planning and implementation

Key factors: All project implementation phases – from product selection to marketing and delivery – are conducted in the context of a 'product commercialization packages' (PCPs) approach that integrates all elements of the research, development and commercialization processes. The main elements of each PCP are illustrated in Figure 2 and include: (i) technology development; (ii) policy-related issues such as licensing the intellectual and technical properties associated with the product as well as applying for and obtaining regulatory approval by the relevant national authorities; (iii) providing public information to producers and consumers about the benefits, risks and correct management of these new products; and (iv) establishing, or verifying, the existence of marketing and distribution mechanisms to provide farmers access to planting material.

The level of activities for each quadrant of Figure 2 varies substantially with the particular bioengineered crop being addressed. There can be considerable differences in the specific research, development, and delivery issues associated with the different products and the locations in which the activities are to be conducted. For some products technology development might be the primary focus. For others, product development work might be complete – for example it might be possible for public or private sector institutions to donate the technology to the public good – and issues related to policy, information and outreach and/or marketing and delivery mechanisms might be of primary concern.

It is important in the planning and implementation of the work not to underestimate the resources needed to move a bioengineered crop from the research phase into the hands of the end-user. This vital point is often overlooked by public sector organizations such as universities and research institutes which, historically, have focused almost exclusively on the research phase. Figure 3 outlines the actual stages of product research, development and delivery that typically need to be addressed – it does not include the market assessment, feasibility studies and FTO reviews that need to be conducted before the product is chosen for development. In this illustration there are

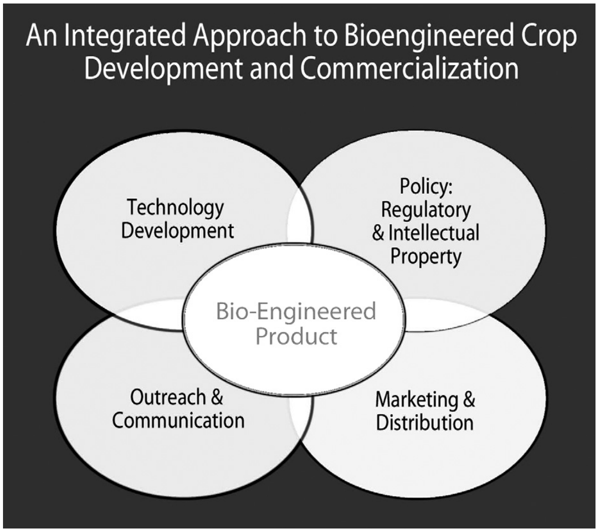

Figure 2. Main elements of an integrated product-driven research-development-delivery for bioengineered crops. Source: Agricultural Biotechnology Support Project II.

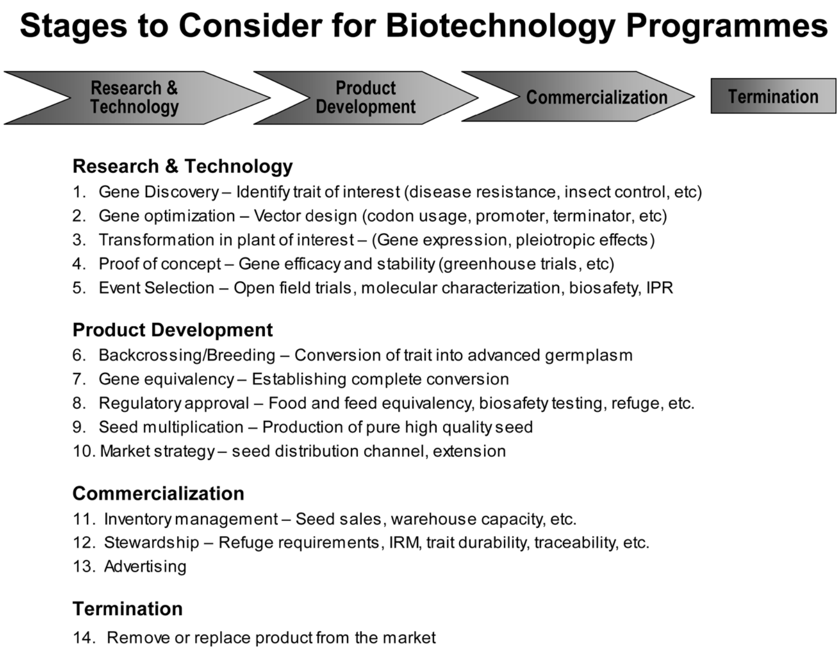

Figure 3. Stages in the research–development–commercialization/delivery continuum.

14 stages in the research–development–commercialization/delivery continuum, but only five of them relate to research. The cost of the other nine, non-research stages typically represents two-thirds of the total project.

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In countries where bioengineered crops are already approved and experience exists, the emphasis is best focused on the commercial delivery of products, either through private companies or efficient public sector systems. In countries with little or no experience in evaluating genetically engineered crops, strengthening product development expertise and sourcing existing products for field trials tends to be more important.

Case study: Implementation of the FSBR eggplant project addresses issues in all four main elements of the PCP approach, namely technology development, policy, outreach and communication, and marketing and distribution. Particularly groundbreaking achievements were catalysed by ABSPII in several critical, product-driven advances in policy-related activities. These included: (i) enhanced public–private sector partnerships resulting in public access to proprietary technologies for commercial use; and (ii) improved institutional environments for addressing related intellectual property and regulatory issues. ABSPII also played a pivotal role in this venture by funding all of the consortium partners for their R&D roles in the technology development of FSBR eggplant.

Building the team – importance of public–private sector partnerships

Key factors: Project implementation starts by building a team of people and organizations with the skills and experience to adequately address all stages leading to and including product delivery. These teams often need to include national and international players. Developing and industrialized country players are nearly always involved and, in many cases, the team includes private companies that know how to translate research into a product and then deliver it to the end-user. The private sector also has much to offer many developing countries in some areas of strategic research (e.g. genomics, bioinformatics and bioengineering) and, depending on the circumstances, provide technology or know-how on the basis of goodwill (and to help demonstrate in farmer's fields the benefits of the bioengineering approach) or for a share of the profits.

Case study: In the case of the FSBR eggplant work there was strong support from local stakeholders for a strategy that brings together public and private institutions to commercialize a high quality, consistent product for every segment of the society, thereby optimizing socio-economic gains from the project. Led by Hyderabad-based Sathguru Management Consultants Pvt. Ltd., this has been ABSPII's approach. Mahyco's Bt eggplant seeds will provide a solution to farmers currently engaged in cultivating hybrids. Meanwhile the public–private partnership will allow public institutions to access Mahyco technology. This, in turn, will help thousands of resource-constrained farmers to access high-quality open-pollinated (OP) transgenic seeds and thereby enhance their annual income (see 'Marketing and distribution' below). Since the market segments catered to by the private and public sectors are different, there are no commercial conflicts arising out of this partnership.

In India, public institutional partners include the Indian Institute of Vegetables Research (IIVR), Tamil Nadu Agricultural University (TNAU) and the University of Agricultural Sciences (UAS, Dharwad). These were chosen because they have capability and infrastructure for seed development and multiplication for end use distribution.

In the Philippines, the Institute of Plant Breeding at the University of the Philippines at Los Banos (IPB-UPLB) has a proven track record of producing and distributing foundation and certified seed of OP varieties and hybrids of various economically important crops including vegetables to resource-constrained farmers and other user communities. IPB-UPLB also distributes IPB-bred varieties and hybrids through franchising agreements with the private sector.

In Bangladesh, the primary private sector partner is East-West Seeds, a multinational vegetable seed producer with a leading market position in all major South East and South Asian vegetable seed markets. The main public partner is the Bangladesh Agricultural Research Institute (BARI) which has developed numerous eggplant varieties. Efforts are underway to strengthen the capability of the public institutions in Bangladesh to deliver the high quality seeds to farmers by encouraging the adoption of good manufacturing practices.

Technology development, intellectual property rights (IPR) and licensing issues

Key factors: Many of the advances in technology development associated with bioengineered crops, including Bt eggplant, have been made in the private sector. The absence of IPR regimes in many developing countries, combined with an inadequate understanding of the requirements and implications of IPR on bioengineering technology and concerns about the cost burden associated with IPR, are all factors that impede the roll-out of transgenic crops. A new concern is the potential for liability claims associated with unwanted transgenes in local crops. Uncertainty about how this will be resolved has resulted in a new reticence from technology owners to donate appropriate technology for developing country farmers.

A review of the FTO situation and establishing licensing relationships for the bioengineered product(s) should be conducted at the outset of the project as part of the feasibility study. This identifies where licenses will be needed so as to begin negotiations as early as possible. A tailor-made IP management and licensing strategy should be developed along with the scientific strategy to ensure that delays are minimized in the transfer of the improved product.

A major constraint to technology transfer in many developing countries is the lack of trained professionals who have the experience to understand the proprietary issues in biotechnology transfer. Other constraints, especially in the public sector, can include lack of clear policy and institutional support for IP from top management and the absence of a systemic approach to IP issues. The need may exist to institutionalize the management of IP rights by raising awareness of the issues throughout implementing organizations and developing clear procedures for the handling of materials and licenses.

Case Study: Mahyco, a private Indian company, was the first in India to develop a hybrid Bt eggplant with resistance to EFSB. The Bt gene it used (*cry1Ac*) produces the corresponding crystal protein (Cry1Ac3) which is toxic to many species of insects, including EFSB. Bt protein action is very specific. To become lethal, the Bt protein has to be ingested as it is activated in the high pH environment of the insect gut. The activated protein perforates the lining of the gut, which causes the death of the insect within a couple of days. Our product development approach has been to convert – through conventional breeding – the hybrid Bt eggplant developed by Mahyco into Bt eggplant varieties for India, the Philippines and Bangladesh.

At the outset of the project ABSPII played a central role in initiating and guiding negotiations on technology access and product development between Mahyco-Monsanto and each of the three partner countries. This dialogue led to a mutually beneficial contractual mechanism that provides FTO advantage to all the partners and complies with all IP licensing requirements. An audit of the product developed by Mahyco with support from Monsanto (which has licensed the use of *Cry1Ac* gene and other promoters that are applied in product development) revealed no FTO hurdles for Mahyco to license the technology to ABSPII partners.

Under the auspices of ABSPII, Sathguru partnered with Mahyco. The *cry*-gene technology was then licensed to several public institutes in South and Southeast Asia that were participating in the ABSPII convened public–private consortium (Medakker and Vijayaraghavan, 2007). The technology was sublicensed by Mahyco on a royalty-free basis to public research institutes in India IIVR, TNAU, UAS, Dharwad, in Bangladesh (BARI), and in the Philippines (the University of Philippines, Los Banos). Mahyco also sublicensed this technology to East-West Seeds, a private corporation in Bangladesh, on commercial royalty-bearing terms. To safeguard the licensor's interests, specific strategies for the stewardship and monitoring of the technology by the licensees were addressed and formulated early in the sublicensing process.

Regulatory file development

Key factors: Bioengineering is one of the most extensively reviewed agricultural advancements to date. There are no known substantiated harmful effects of bioengineered crops on human health or the environment. Most commercial bioengineered crops have been created in the USA and the EU and have been subjected to strict regulatory procedures. There are, however, some theoretical agro-ecological, economic and health risks associated with bioengineered crop production, marketing and use. Such risks are not unique to bioengineered crops and should, in actual fact, be considered for many new crop varieties produced by conventional means. However, the only country where the novelty of the product is the trigger for review is Canada – elsewhere the trigger for such review is the involvement of the genetic transformation event.

Given these possible risks, a regulatory package needs to be compiled to enable the commercialization of each bioengineered product. Obtaining regulatory approval for bioengineered products can be a major bottleneck and is likely to require a large portion of the resources for each project. For example, Pray (2006) estimates that in India, those costs exceeded $1 million for approval of Bt cotton and are expected to run around $500 000 for Bt eggplant. In the Philippines, recent studies estimate regulatory costs of $450 000 to $500 000 for Bt eggplant and $700 000 for Bt rice (Bayer, 2007;

Yarobe and Laude, 2007). A larger cost than the direct costs of meeting biosafety regulations are the foregone benefits associated with delays in product release (Bayer, 2007). Due to the high costs of regulatory file development it is advisable, to the extent possible, to utilize information from existing regulatory dossiers generated in other countries for the same or similar products. Depending on the focus country involved, this activity can be governed by national biosafety legislation and the authorities responsible for its implementation. Much of what is needed is codified; however, some of the work can involve negotiation and perceptions of risk based on the principles of substantial equivalence or the precautionary approach.

New data for the regulatory packages should be generated as much as possible within the focus country or region. An interactive relationship with regulatory authorities needs to be established – even at the outset of product development – and dialogue should be maintained throughout the time leading up to the formal submission of the regulatory package. In some cases, investments in institutional capacity are needed to gain approval for trials and to ensure successful performance. Preliminary trials with non-transgenic material may be required where the local organization has no experience with containment procedures.

Case study: The regulatory file development for Bt eggplant has been enabled primarily through the experience and expertise of Mahyco, the first Indian enterprise to commercialize bioengineered cotton hybrids in India. The company has gone through the full cycle of regulatory compliance for the Bt cotton and uses international best practices in regulatory file development and compliance. The studies on the cotton work by Monsanto, and Mahyco on the Cry1Ac protein and other biological material is of direct application to the Bt eggplant, and ABSPII and its partners have an agreement with the companies by which they have access to the data that were generated. This includes comprehensive biosafety and environmental safety studies (including gene flow assessments), allergenicity tests, acute oral studies, sub-chronic oral studies, primary skin irritation, mucous membrane test, soil microflora studies, entomological and food safety studies. Mahyco will also be conducting studies relating to sustainability of resistance management.

Interactions with the regulatory authorities in the three focus countries were initiated at the outset of the project. In India the two most important regulatory authorities overseeing the manufacture, import, use, research and release of genetically modified organisms (GMOs), including bioengineered crops, are the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Approval Committee (GEAC). The RCGM reviews all approved ongoing transgenic research projects, visits experimental facilities and issues clearance for import permits. GEAC is responsible for approval of activities involving transgenic products in research and industrial production from the environmental perspective. In addition to preparing the regulatory package for the Indian authorities, ABSPII and its partners are using many elements of the same package for review by regulators in Bangladesh and the Philippines, thus accelerating the approval process in these two countries.

In Bangladesh, the Ministry of Science and Technology has developed biosafety guidelines through an interim order (June 1 2000), which stipulates the mandatory biosafety procedures to be used for commercialization and release of bioengineered crops. In accordance with the guidelines, the Institutional Biosafety Committee, the National Committee on Biosafety of Bangladesh (NCBB) and the Field-level Biosafety Committee (FBC) are the co-ordinating and approving bodies for various stages involved in product validation and release of bioengineered crops. Mahyco and the ABSPII management team are assisting Bangladesh in developing capacity in these areas using Bt eggplant as a 'hands-on' example. The support of the South Asian Biosafety Program is also available to help accelerate institutional capacity building.

In the Philippines, the system for regulating all biotechnology activities was initiated in 1991. Since 2003, the Bureau of Plant Industry (BPI) has supervised the planned release of bioengineered crops in the country. Regulatory specialists from Mahyco are assisting the Philippine institution in the development of a regulatory file for the Philippine Bt eggplant in order to comply with national biosafety protocols. However, in order to be commercialized in the Philippines, the bioengineered eggplant is being subjected to mandatory risk assessment analyses. While current regulations allow for use of some relevant regulatory data generated in other countries, some of the data – particularly on environmental biosafety – are being generated within the country.

Marketing and distribution

Key factors: A marketing and distribution system needs to be in place or be planned early in the project. Early involvement of downstream partners, particularly private sector suppliers of seed and other agricultural inputs, helps to build the momentum for successful product adoption. However, additional considerations can arise. For example, there could be loss of markets, such as the EU, that ban or avoid bioengineered crops. Or there could be reduced efforts to seek alternative solutions if bioengineered crops are overemphasized. This could be accompanied by reduced competition in input supply resulting in fewer choices or higher prices for farmers. Also, disputes could arise in the product and distribution system when national policies on intellectual property issues, e.g. patenting of life, can differ from those of multinational suppliers. These disputes could also involve accountability and liability regarding food safety and biosafety concerns because of the lack of clear and broadly accepted internationally accepted technical standards.

Case study: Most eggplant farmers in India grow OP varieties (OPVs). The area planted with hybrid varieties is less than 30% of the total area. Growers who plant hybrid varieties tend to use more purchased inputs and have higher yields compared to growers who plant OP seeds. However, the use of OPVs tends to be more widespread because their seeds can be saved and replanted in future growing seasons. As a result, OPV seeds are much more available and affordable. The market price of hybrid seeds is five to ten times the market price of OPV seeds. Because of the existing price differential between conventional OPs and hybrids, and the zero premium being charged for the Bt trait in the OPs, it is still expected that most of the existing growers of hybrid eggplant will adopt the Bt hybrids rather than the Bt OP varieties, even though the latter would be priced much lower than the Bt hybrids. This is primarily due to production and yield differences between the two systems. Farmers growing OP eggplant are most likely to adopt the Bt varieties because of the cost factor. Growers of both types of eggplant can be expected to shift to the corresponding Bt versions because of the expected savings in pesticide expenses (Kolady and Lesser, 2006).

In India, the marketing strategy envisioned is based on the established vegetable seed marketing networks, which are mature and operate mainly through a dealer network for branded hybrid seeds (low volume/high margin) and the public distribution system mainly focused on OP varieties (high volume/low margin). Mahyco will market hybrids with the option to sublicense to other private sector organizations as well as to interested public institutions. The partner public institutions may opt to market varieties developed under this project through non-NGO networks in areas where they do not have strong delivery networks. The pricing of the product would vary between the hybrids and varieties and would also be based on the delivery channel. The hybrids and varieties to be marketed by the private sector would be market-competitive. The pricing of Bt varieties to be distributed through the public system would be based on a cost and overhead recovery model. This channel of distribution is intended to bring the benefits of technology closer to the economically weaker farming community. ABSPII will incorporate these market price mechanisms in the partner agreements so as to ensure clarity in marketing and pricing mechanisms for the Bt products.

For Bangladesh a similar marketing strategy is proposed. The public sector partners are partnering with Mahyco in transforming local popular varieties and are responsible for marketing them through established public sector distribution and marketing networks. Mahyco is sub-licensing the technology to select private sector enterprises for the transformation and marketing of hybrids.

In the Philippines, 75% of the eggplant seed market is hybrid. In addition to private enterprises such as the East-West Seed Company, UPLB itself is engaged in delivering hybrid seeds to resource-constrained farmers. Through its seed production unit, IPB or its constituent body will directly deliver hybrid seeds to resource-constrained farmers. Since the parents of the IPB experimental hybrids will be used as parent materials, the resulting product will be of high quality, attracting farmers' interest. For the remaining 25% of the eggplant farmers who plant OP varieties, IPB will also develop and deliver those varieties. Appropriate licensing agreements will be negotiated with the commercial seed growers who may participate in the distribution of the Bt eggplant at a later date.

The two streams of regulatory validation and marketing, one under the public system for the OPs and the other under the private enterprise system for the hybrids are expected to develop public confidence in the product and technology, and thereby encourage wider adoption in all the three countries.

Communication and outreach

Key factors: Without adequate public knowledge of biotechnology in general and the bioengineered products to be commercialized in particular the market for such products can be severely limited. A communication strategy is needed to provide regular, accurate information on the bioengineered product(s) to identified target groups in order to achieve product acceptance and to address stakeholder concerns as they arise. The strategy should include studies to assess baseline awareness of biotechnology in target groups, and thus serve as the basis for the design of awareness programmes and improve the likelihood of product acceptance.

Market access for bioengineered crops is dependent on attitudes of stakeholders such as local scientists, regulators, journalists, extension workers, farmers, retailers, religious groups and consumers, among others. Hence, information about the technology needs to be disseminated in a transparent and rational way that builds understanding, trust and the capacity to make informed decisions. It is also important to clarify who will be benefit from the technology. For example 'input traits' – such as the insect pest resistance in our eggplant case study – tend to benefit the farmer and agri-business, while the consumer sees no apparent benefits, only potential environmental and social risks. There is also a need for communication accompanying the distribution of bioengineered products to farmers especially as related to the issue of safe handling of such products.

Case Study: Beginning with project kickoff workshops, ABSPII organized periodic visits to the trial locations for scientists, science communicators, members of the media and farm leaders. The team has developed a question and answer sheet on Bt eggplant and has produced video training material for extension agents to use. All outreach material is being translated into local languages for distribution to farmers.

Capacity building

Key factors: It is important to include needs-based capacity building into each set of technical and non-technical activities. Much of the human resource and infrastructural capacity building initiatives in developing countries has focused on research, but there is an increase in efforts to build capacity in regulatory, intellectual property and communication issues associated with bioengineering. Less effort has been directed at other aspects of the continuum such as marketing and distribution. Only if the opportunities and challenges associated with all aspects of the continuum are addressed from the start of each project can success in terms of impact be assured.

Human resources capacity building should be built into the projects at all stages of the value chain to develop practical, 'real-life' experience for a critical mass of scientists and technicians, farmers, communication and outreach specialists, media personnel, risk assessment managers, policy makers and others. In this context, each project should carefully identify its human resource capacity building needs in terms of the numbers and specializations of personnel to be trained. Also, care should always be taken to promote continuity of the short-, medium- and long-term capacity building efforts.

Special emphasis is often needed on policy and regulatory matters including: (i) establishing IP frameworks for countries lacking them; (ii) training on IP issues relating to accessing technologies, product development and commercialization; (iii) enhancing the national or regional capacity to assist scientists and National

Agricultural Research Systems (NARS) on protecting and patenting inventions; and (iv) establishing a mechanism(s) for protecting and commercializing indigenous innovative technologies. Regarding infrastructure, efforts need to be made whenever possible to build on current assets.

In biosafety, critical capacity building issues include: (i) facilitating dialogue among those responsible for national biosafety and promoting policy linkages in relevant sectors impacted by a particular bioengineered product; (ii) nurturing the implementation of effective national biosafety mechanisms; (iii) facilitating networking in biosafety; (iv) strengthening capacity in biosafety risk assessment, risk management and biosafety communication; (v) developing rosters of regional scientific and socio-economic expertise; (vi) facilitating biosafety research to addresses gaps in risk assessment and risk management knowledge; and (vii) enhancing capacity in public awareness and advocacy.

Case study: Institutions such as TNAU, IIVR, UAS and IPB-UPLB have considerable experience in conducting transformation, introgression and molecular characterization. Mahyco's strength in advanced laboratory and scientific practices is shared with the teams from these institutions to facilitate their adoption of best practices in transgenic crop development and validation.

The Bangladesh institutions benefit immensely from capacity-building support from Mahyco. So far, Bangladesh has not commercialized any transgenic crop and their scientists' experience is limited to basic molecular research. The team from East-West Seeds and BARI visited Mahyco and participated in the initial development of the product in the Mahyco containment greenhouse. BARI scientists also visited TNAU. Mahyco scientists have since traveled to Bangladesh to train scientists and breeders at East-West Seeds and BARI in various facets of product development, including breeding practices, molecular characterization, regulatory protocols and compliance with biosafety guidelines.

Mahyco's regulatory specialists have provided hands-on training to Bangladesh scientists and project managers in the development of regulatory information and compliance with national biosafety protocols as prescribed by the Bangladesh regulatory authorities.

The experience of several project partners in IP licensing, as well as stewardship, has been shared freely with others within the team. Capacity in IP has been further enhanced by their participation in IP workshops, IP audit internships and IP reviews of lead institutions for product development.

Projected benefits and socio-economic impact assessment

Key factors: Socio-economic impact studies are built into each project from the start in order to provide feedback and strategic guidance to those engaged in research, development and delivery. Such studies also provide information that can be used as a basis for communication to all stakeholders in agricultural biotechnology including current and potential investors or donors. In particular, the benefits to resource-poor farmers should be thoroughly studied. Impact assessment on the products should consider such issues as labour use, adoption, farm-scale factors, profitability and risk, and environmental impacts among others. Macro-level effects on food security and food prices are also of relevance. Such studies provide not only justification for the activities, but can also be used to guide future investment.

Case study: A successful Bt eggplant would do much to reduce costs and overcome the negative impact of pesticide use on eggplant. Anticipated benefits to the farmer include:

- Access to better quality seeds through structured channels; an improvement over the present system where the majority of seeds supplied are not certified. Bioengineered seeds would be certified and distributed through structured channels.
- The option to choose bioengineered or conventional varieties (hybrids or OPVs) to best suit the geographical and socio-economic conditions of the farm community.
- Improved access to markets because the final product will be free from the fruit and shoot borer.
- Economic gains as a result of increased outputs, reduced crop protection costs and increased price because of better quality.
- Improved health as a result of reduced pesticide application. India and neighbouring countries have evidence of farmer health deterioration due to intensive spraying.
- Both farmers and consumers will benefit from increased nutrition intake due to wider consumption of eggplant, an important vegetable for resource-poor communities.

Since Bt eggplant will be the first food crop to be commercialized in India and Bangladesh, and one of the earliest food crops to be commercialized in the Philippines, there has been considerable interest from all stakeholder groups in conducting impact analyses. Formal ex-ante impact studies were conducted for Bt eggplant in India, Bangladesh and the Philippines by Mishra (2002), Krishna and Qaim (2008), Islam and Norton (2007) and Francisco (2006) respectively. Mishra (2002) projected benefits from adoption of Bt eggplant of US $411 million for India, US $37 million for Bangladesh and US $28 million for the Philippines before ABSPII initiated its activities. Consumers were projected to gain 57% of the benefits and producers reap 43% (http://scholar.lib.vt.edu/theses/available/etd-09072003-180026/). More recently, Krishna and Qaim (2007), contracted by ABSPII, evaluated the impacts of Bt eggplant in India and found the benefits from Bt hybrids to be about $108 million per year. The eggplant transgenic OPVs will add another $20 million in benefits. Consumers will be the largest beneficiaries, but farmers and the private seed company will also gain. Also contracted by ABSPII, Islam and Norton (2007) project that Bt eggplant in Bangladesh will result in $210 million in net discounted benefits over 15 years, with more than $36 million in non-discounted benefits during the first year of adoption by farmers. Francisco (2006) projects more than $36 million in net discounted benefits over 15 years in the Philippines. Health and environmental benefits are also derived from reductions in pesticide use of more than 50% in each country where Bt eggplant will be adopted.

Product stewardship

Key factors: In the context of this strategy, product stewardship is the responsible and ethical management of the bioengineered product from its discovery or development through to its ultimate use and beyond. Our strategy promotes a stewardship approach that starts with gene discovery, and includes plant development, seed production, seed marketing and distribution, crop production, crop utilization, through to product phase-out. The overall aim of the stewardship approach is to maximize the benefits, and minimize any risk, from using the bioengineered products.

Case study: The ABSPII team has developed guidelines and practices to ensure proper implementation and stewardship of the new varieties. As noted above, Mahyco has played a large part in ensuring a quality product by working with partner institutions on product development and breeding. All partners are active in the development of structured, high-quality regulatory file development that will stand the test of product validation. The team has also developed an integrated pest management IPM protocol.

The next phase is the training of extension personnel in public institutions and private seed companies in providing product stewardship at the farm level. The lack of expertise in many developing country public extension systems in providing guidance to the farmers in successfully producing and harvesting transgenic seed-based products is a constraint that needs serious attention. The public sector partners were partially selected based on their existing strength in extension services. ABSPII's local language multi-media resources is supporting extension agents and allowing them to communicate best practices at the farm level. Our partners also benefit from partnership with ABSPII's USAID-funded sister project, the Program for Biosafety Systems (PBS), which provides training for scientists and communicators on issues related to biosafety.

CONCLUDING REMARKS

We have attempted to highlight the enormous potential of bioengineered crops for providing solutions to important and previously intractable problems facing subsistence and resource-poor farmers in the developing world. We have also outlined a strategic approach that might be considered as a framework, or at least a starting point, for building developing countries' capacity to safely and effectively develop and utilize bioengineered crops, with an emphasis on orphan crops.

The case study presented on Bt eggplant for South and Southeast Asia illustrates an approach that is also achieving success and gaining credibility for other bioengineered crops in several geographies. These include ABSPII projects on virus-resistant papaya, virus-resistant tomato, disease- and insect-resistant banana, and late blight-resistant potato, and a project being launched by the Collaboration on Insect Management for Brassicas in Asia and Africa (CIMBAA – at www.cimbaa.org) on the development of insect-resistant cabbage and cauliflower. In each case advances in bioengineering are being made that will benefit the poor and hungry and that would be impractical through conventional plant breeding or non-breeding approaches.

Addressing the complex technical and non-technical issues associated with the research–development–delivery continuum for bioengineered crops requires a wide range and depth of expertise and facilities that extend far beyond the present or projected capacities of most individual institutions or even nations. Therefore, the full potential of bioengineered crops as tools for international development can be realized only if strong emphasis is placed on inter-institutional collaboration – including public and private sector organizations – at the national, regional and global levels. Only with such collaboration will the exciting potential of bioengineered crops be tapped for millions of poor and hungry people of this world.

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REFERENCES

Baral, K., Roy, B. C., Rahim, K. M. B., Chatterjee, H., Mondal, P., Mondal, Ghosh, D. and Talekar, N. S. (2006). Socio-economic parameters of pesticide use and assessment of impact of an IPM strategy for the control of eggplant fruit and shoot borer in West Bengal, India. *Technical Bulletin No. 37. AVRDC publication number 06-673. AVRDC – The World Vegetable Center, Shanhua, Taiwan.*

Bayer, J. (2007) *GMOs in the Philippines, the costs of regulations*. MS. Thesis, Virginia Polytechnic Institute and State University, Blacksburg, VA, USA.

Cohen, J. I. (2005). Poorer nations turn to publicly developed GM crops. *Nature Biotechnology* 23: 27–33.

Dhandapani, N, Shelkar, U.R. and Murugan, M. (2003). Bio-intensive pest management in major vegetable crops: An Indian perspective. *Journal of Food, Agriculture & Environment* 1:330–39.

Francisco, S. R. (2006). Ex-ante impact assessment of fruit and shoot borer resistant eggplant in the Philippines, *Draft Report, ISAAA and ABSPII.*

Islam, S. M. F. and Norton, G. W. (2007). Bt eggplant for fruit and shoot borer resistant in Bangladesh. In *Economic and Environmental Benefits and Costs of Transgenic Crops: Ex-Ante Assessment* (Eds C. Ramasamy, K. N.Selvaraj, G. W. Norton and K. Vijayaraghavan). Coimbatore, India: Tamil Nadu Agricultural University.

James, C. (2006) Global Status of Biotech/GM Crops in 2005. *ISAAA Briefs* No. 34–2005.

Kolady, DE and Lesser, W.(2006). Who adopts what kind of technologies? The case of Bt eggplant in India. *AgBioForum* 9:94–103.

Krishna, V. V. and Qaim, M. (2007). Estimating the adoption of Bt eggplant in India: Who benefits from public-private partnership? *Food Policy* 32:523–543.

Krishna, V. V. and Qaim, M. (2008). Potential impacts of Bt Eggplant on economic surplus and farmers' health in India. *Agricultural Economics* 38:167–180.

Medakker, A. and Vijayaraghavan, V. (2007). Successful commercialization of insect-resistant eggplant by a public–private partnership: reaching and benefiting resource-poor farmers. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (Eds A. Krattiger, R. T. Mahoney, L. Nelsen, *et al.*). MIHR: Oxford, U. K., and PIPRA: Davis, U. S. A. Available online at www.stemglobal.org/ipHandbook.pdf

Mishra, S. (2003). *Ex ante economic impact assessment of Bt eggplant in Bangladesh, the Philippines, and India.* MS. Thesis, Virginia Polytechnic Institute and State University, USA.

Naylor, R. L., Falcon, W. P., Goodman, R. M., Jahn, M. M., Sengooba, T., Tefera, H. and Nelson, R. J. (2004). Biotechnology in the developing world: a case for increased investments in orphan crops. *Food Policy* 29: 15–44.

Nelson, R. J., Naylor, R. L. and Jahn, M. M. (2004). The role of genomics research in improvement of 'orphan' crops. *Crop Science* 44:1901–1904.

Pray, Carl E., Bengali, P., Ramaswami, B. (2005). The cost of biosafety regulations: The Indian experience. *Quarterly Journal of International Agriculture* 44:267–289.

Tanksley, S. D. and McCouch, S. R. (1997). Seed banks and molecular maps: unlocking genetic potential from the wild. *Science* 277:1063–1066

Yarobe, J. M. and T. P. Laude, (2007). Costs and benefits of papaya ringspot virus resistant technology in the Philippines, *Draft report, ISAAA and ABSPII.*