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Telling Transgenic Technology Tales: Lessons from the Agricultural Biotechnology Support Project (ABSP) Experience

by

Carliene Brenner

A review of the ABSP Experience made available to ISAAA for publication.

No. 31 - 2004

NOTE TO READERS

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LIST OF ACRONYMS

AARD	Agency for Agricultural Research and Development, Indonesia
AATF	African Agricultural Technology Foundation
AGERI	Agricultural Genetic Engineering Research Institute (Egypt)
ARC	Agricultural Research Council (Egypt, South Africa)
ASARECA	Association for Strengthening Agricultural Research in Eastern and Central Africa
ASRT	Academy of Scientific Research and Technology (Egypt)
BFSC	Biosafety and Food Safety Committee
BSFTT	Biosafety and Food Safety Technical Team
Bt	*Bacillus thuringiensis*
CGIAR	Consultative Group on International Agricultural Research
CIP	Centro Internacional de la Papa (International Potato Centre) (Peru)
CMV	Cucumber mosaic virus
CRIFC	Central Research Institute for Food Crops (Indonesia)
FTO	Freedom to operate
GATT	General Agreement on Trade and Tariffs
GM	genetically modified
GMO	genetically modified organism
HRI	Horticultural Research Institute
IARC	International Agricultural Research Centre
IBC	Institutional Biosafety Committee
IFPRI	International Food Policy Research Institute
IPP	Intellectual property protection
IPR	Intellectual property rights
IABIOGRI	Indonesian Agricultural Biotechnology and Genetic Resources Research Institute
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
ISNAR	International Service for National Agricultural Research
ITB	Bandung Institute of Technology (Indonesia)
IUC	Inter-University Centres (Indonesia)
JICA	Japan International Cooperation Agency
KARI	Kenya Agricultural Research Institute
KIAT	Kantor Pengelola Kekayaan Intelektual dan Alih Teknologi (Intellectual Property and Technology Transfer Office), Indonesia
LMO	living modified organism
MSU	Michigan State University
MTA	Material transfer agreement
NARs	National agricultural research systems
NBC	National Biosafety Committee
NGO	non-governmental organization
OECD	Organisation for Economic Cooperation and Development
OTTIP	Office of Technology Transfer and Intellectual Property
PTM	Potato tuber moth
PVP	Plant Variety Protection
RIFCB	Research Institute for Food Crops Biotechnology

LIST OF ACRONYMS

SARB	Southern African Regional Biosafety Program
TAG	Technical Advisory Group
TRIPS	Trade-related Intellectual Property Rights
UPOV	Union pour la Protection des Obtentions Végétales (Convention for the protection of New Plant Varieties)
USAID	United States Agency for International Development
WTO	World Trade Organisation
ZYMV	Zucchini yellow mosaic virus

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The opinions expressed and arguments employed in this study are my sole responsibility and do not necessarily reflect those of USAID or of ABSP management.

Carliene Brenner
October, 2004

Telling Transgenic Technology Tales is the latest of a number of studies I have undertaken on biotechnology and developing country agriculture. The first effort, entitled "Biotechnology and Developing Country Agriculture: the case of Maize" (published by the OECD Development Centre in Paris in 1991), set out to assess the prospects, for a number of developing countries which are major producers of maize (Brazil, Mexico, Thailand, Indonesia), of incorporating new biotechnologies in maize production.

Since then, other studies, with different research objectives and analytical approaches, have covered a number of food and export crops and a number of countries in Asia, Africa and Latin America. The underlying, unifying thread of this work is a concern with technological innovation in developing country agriculture, and the kinds of institutional arrangements and policies needed to facilitate that process.

The advent of biotechnology has brought both hopes and fears to developing countries. It has brought hopes of enhanced pest and disease control for both plants and animals, reduced crop losses, accelerated plant breeding and, in principle, increased productivity and environmental sustainability. On the other hand it has brought fears, particularly with respect to GMOs, of risks to human and animal health and to the environment and of negative socio-economic impact. Developing country governments have nevertheless invested scarce public funds in biotechnology research. At the same time they have been slow to adopt and implement the biosafety systems which would enable them at one and the same time to take advantage of what biotechnology has to offer and guard against potential negative impact.

Despite widespread adoption of economic policies of liberalisation and privatisation in developing countries in recent years, there is still little private sector involvement in biotechnology research and local private seeds and agricultural inputs sectors are still relatively undeveloped. Countries therefore remain reliant on their public research systems to produce biotechnologies which respond to their specific needs and priorities.

A large share of the total funding for biotechnology research in developing countries – particularly transgenic research – is contributed by donors. A large share of project funding is also focused exclusively on research and scientific capacity-building, with little attention paid – and even less funding available – for the subsequent steps which are necessary for transferring the products of research from the lab to the farmer's field. It is somehow assumed that these "public good" technologies will be developed and distributed through public systems which, in the past have not been effective and which, currently, have even fewer resources at their disposal.

The notion of "public good" technologies is dear to the heart of the development community. However, if any of the "public good" technologies currently being developed – particularly transgenic technologies — are to be successfully and widely diffused, there is an urgent need to revise current approaches to project design and implementation.

Telling Transgenic Technology Tales tells the story of "near-market" biotechnologies developed under the ABSP project and draws on the lessons from that experience and other publicly-funded projects and programs to propose new approaches. The analysis also highlights the need for further research in three key areas:

- case studies of public/private sector collaboration in biotechnology research, product development and diffusion, to determine key elements of success or failure and to propose, where possible, new facilitating or "catalytic" mechanisms.

- studies of the key elements of national systems for biotechnology research, product development and diffusion in different developing countries, in order to determine the roles played by the public and private sectors, assess their strengths and weaknesses and suggest where funding and/or technical support might be targeted most effectively.

- case studies of the socio-economic costs and benefits of particular biotechnology innovations

I am grateful to have had the opportunity to conduct this study and trust that the findings will be of interest and use to the biotechnology and development community at large and, in particular, to donor agencies and all those involved in the design and implementation of publicly-funded agricultural biotechnology projects.

Carliene Brenner
October 2004

Purpose of the study

The USAID-funded Agricultural Biotechnology Support Project (ABSP), which was launched in 1991 and ended in June 2003, set out with a vision of developing and making transgenic crops available to developing country partners. At the time the project was initiated, no transgenic crop had yet been commercially released anywhere in the world.

ABSP was a pioneering project which has provided a wealth of lessons. Many of the difficulties encountered by ABSP are currently shared by other publicly-funded programs and projects aimed at the development and transfer of biotechnology in developing country agriculture. The essential purpose of this study is to analyse the ABSP and other experiences, to highlight the challenges to be addressed, and to propose new approaches to project design, management and implementation. (It does not take into account developments which have occurred under the follow-up projects ABSPII and The Commercialisation of Bt Potatoes in South Africa.)

Approach

The central hypothesis is that the successful introduction and diffusion of the new biotechnologies developed under ABSP, and indeed under any other publicly-funded biotechnology research program, will depend to a large extent on the strengths and weaknesses of the product development and delivery systems for publicly-funded research prevailing within developing countries. It is therefore crucial to take the key characteristics of those systems into account in the design and implementation of projects at the outset.

This study does not attempt to cover the ABSP program in its entirety. Instead, it takes the example of certain technologies developed under ABSP, which were chosen to illustrate the complexities of moving from research to product development and, finally, to commercialisation. Based on the concept of a national system which encompasses biotechnology research, product development, and technology diffusion, the analysis thus covers the three phases in the process of "moving from the lab to the farmer's field".

It focuses on "near-market" biotechnologies, defined as technologies which have resulted directly from research collaboration between ABSP partners, have evolved through basic and/or applied research, are progressing through product development and field-testing, through required biosafety and IPR procedures, and in principle should shortly be available for small- or large-scale production and distribution to farmers/producers and to consumers.

This study traces the development of two near-market technologies, in three different developing country settings. The technologies selected are: transgenic potato resistant to potato tuber moth (PTM) and transgenic and non-transgenic cucurbits resistant to virus and other diseases. The countries included are: Egypt, Indonesia, and South Africa.

In addition to the ABSP experience, this study draws on lessons from other publicly-funded projects intended to develop transgenic crops, together with well-documented biotechnology success stories, to propose new approaches to project elaboration.

Key lessons from ABSP

The ABSP project had a number of innovative features. First and foremost was the goal it set to make transgenic crops available to developing country partners. Secondly, it established innovative public/private partnerships and partnerships between private companies. Thirdly, it sought to link research with emerging policy issues specific to biotechnology: biosafety and IPRs.

During its first phase (1991-1998) the overall goal of ABSP was: "To mutually enhance U.S. and developing country institutional capacity for the use and management of biotechnology research to develop environmentally compatible, improved germplasm". Following a recommendation by its Technical Advisory Group (TAG), in the second phase (1998-2003) the objectives set were modified to give stronger emphasis to product development and moving closer to technology diffusion, viz: "To improve the capacity and policy environment for the use, management and commercialization of agricultural biotechnology in developing countries and transition economies".

ABSP had a number of significant, positive outcomes. It played a key role in raising awareness in developing countries, not only of scientific developments in agricultural biotechnology, but also of the need for appropriate biosafety and intellectual property protection policies and institutions to underpin the development and application of biotechnology innovations in their particular country contexts. This was achieved through various policy activities conducted both in the United States and in developing countries, as well as through communication and networking activities throughout the life of the project. Active participation of project staff in international meetings on agricultural biotechnology ensured that the project had a high profile within the international biotechnology and development communities.

However, analysis of the status of the two near-market technologies included in the study suggests that the final achievements of ABSP have been mixed. This is due in part to flaws in the original project approach and in part to developments over which ABSP had no control.

— *Research*

At the outset, ABSP research projects were initiated without extensive prior consultation in developing country partner countries. Priority was given to research identified as being of "global" relevance which, if successful, would have positive impact on developing countries as a whole. Initial research projects were essentially extensions of ongoing projects conducted at US universities, rather than resulting from a process guided by strategic planning, with coordinated inputs from all participants in both the US and developing countries.

The projects also suggest a research agenda which has been largely "science-driven", with little effort devoted to determining either the **needs** (in a social sense), **demand** (in an economic sense), or priorities in partner countries.

Under ABSP, developing country scientists were provided a rare opportunity for collaborative research on some of the significant advances made thus far in modern biotechnology. Some were also given the opportunity of in-house training in major US biotechnology companies. The scientific achievements of ABSP are impressive, both with respect to the training of developing country scientists and the acquisition of enabling research techniques which have been successfully transferred to participating countries. These include: the use of genetic markers for a number of crops; bioreactor micropropagation methods: improved tissue culture techniques; and new transformation methods for cucurbits, tomatoes, potatoes, and sweet potatoes.

— ***Policy activities***

The linking of collaborative research to biosafety and IPRs was one of the innovative features of the ABSP project. Biosafety and IPR policy issues were addressed from two different angles: (1) issues associated directly with specific technologies being developed through collaborative research and therefore at research project level and (2) from the perspective of capacity-building in developing countries, and therefore at institutional or national level.

In terms of issues related to specific technologies, time-consuming, capacity-intensive, and costly biosafety procedures remain to be resolved for all the transgenic products which have been developed within the program, and, more specifically, for the two technologies on which this study has focused. No provision was made in the ABSP budget for contributing to the costs of complying with the necessary regulatory procedures for the risk assessment complex of the "near market" technologies, even though the ABSP Annual Impact Report dated July 2000 acknowledged that "………depending on the stringency of the commercialization procedures, it will be difficult for a public-funded effort to meet the regulatory costs".

Similarly, IPR issues associated with the biotechnologies developed under ABSP have not yet been resolved. For example, freedom to operate (FTO) beyond research is not assured in some of the collaborative research projects and, particularly, with respect to the two technologies closest to the market: the Bt potatoes and transgenic cucurbits. (Recent progress has been made with respect to the Bt potatoes in a follow-on project funded by USAID.)

On the other hand, the achievements of ABSP with respect to biosafety and IPR policies have been notable in terms of capacity-building and in facilitating institutional innovation in those policy areas in developing countries. In particular, ABSP has been instrumental in facilitating the establishment of the Office for Technology Transfer and Intellectual Property (OTTIP) at AGERI in Egypt, the Technology Management and Commercialization Office under the Ministry of Agriculture and Land Reclamation in Egypt, and the Intellectual Property and Technology Transfer Office (Kantor Pengelola Kekayaan Intelektual dan Alih Teknologi – KIAT) in Indonesia, under the Ministry of Agriculture.

During the life of ABSP, biosafety undoubtedly became an issue which would require more time, effort, and both human and financial resources than could have been envisaged at the outset of the project. Neither USAID nor ABSP management could have been foreseen the strength of opposition which developed on the part of non-governmental organizations (NGOs) and, in Europe, on the part of consumers, to the introduction of GM foods. Developing country policy-makers are confronted not only with internal opposition to GMOs in general, and to imported GMOs in particular, but also the possibility that trade barriers could be put in place by countries of the European Union against agricultural imports "contaminated" by GMOs.

This opposition has had a number of consequences. Many developing country governments are reticent to introduce GMOs and have consequently taken an extremely cautious approach in developing and, more importantly, approving and implementing biosafety guidelines or legislation.

— ***Beyond research: product development and technology diffusion***

Commercialization was implicit in the objectives of the ABSP project from the outset, but became more explicit following the October 1998 Report of the Technical Advisory Group (TAG). The TAG report proposed that, in order to achieve that objective, emphasis should be shifted away from research to the delivery of research products, and that a commercialization specialist be included in the management team.

Despite the delays brought about by the need to establish new biosafety capacities and procedures in partner countries, a number of products generated by the research were tested, first in the United States and, subsequently, in developing countries. At least confined testing, initially with material from MSU but later with local cultivars, was conducted in each of the three countries included in this study. And, in the case of the Bt potatoes and both transgenic and non-transgenic cucurbits, field-testing has been conducted over a number of years.

More than 40 Bt potato lines have been field-tested in Michigan, Egypt, and South Africa over the life of the ABSP project. Not only have they performed well agronomically, they have also expressed excellent resistance to PTM both in the field and in storage. The transgenic cucurbits have proven their efficacy in field trials in Egypt, as has the non-transgenic material transferred to several developing countries.

Moving forward to product development in the sense of field-testing provided a valuable opportunity in developing country partners for "hands-on" experience in developing capacity for risk assessment and management. It should also have provided an early opportunity for developing country partners to establish and consolidate links with local public agricultural institutions (for example, those which provided test sites and/or conducted agronomic and field evaluations), public or private seed companies, local farmers or farmers' groups, and NGOs, with a view to future product development, production, and distribution. Only in the case of the non-transgenic cucurbits developed by Cornell have product development links been made. The cucurbit team at Cornell has been successful in collaborating with private seed companies in Egypt, Indonesia and South Africa, at least for the testing of its material, and has transferred material to a growing number of other countries. To date, only one seed company has entered into a licensing agreement for the use of Cornell lines, but it is anticipated this will be followed by other revenue-generating agreements.

Paving the way towards commercialisation should have implied a more comprehensive approach to technology transfer, encompassing technology transfer **beyond** research and **beyond** field-testing, to the development and production of a biotechnology product, and the final delivery (or diffusion) of that product in the farmer's field or to the final consumer. This would have required additional, complementary skills, particularly in marketing and/or socio-economics and sound knowledge of local markets. It may also have required identifying and enlisting additional partners – including private sector partners – in the project.

Clearly it was not the mission of ABSP per se to commercialize products generated by the program. ABSP could nevertheless have played a more effective role in encouraging partner countries to develop the linkages, partnerships and expertise required to move the technologies generated by its collaborative research from field-testing to product development to commercialization and diffusion.

— ***Private sector partnerships***

Private sector partnerships were another innovative feature of ABSP. They took three forms. In the first instance, collaboration between two private companies, DNA Plant Technology in Oakland, California, and Agribiotecnologia de Costa Rica (ACR) in Costa Rica, focused on investigating the potential of embryo regeneration using DNAP's proprietary bioreactor technology to increase the production of pineapple, coffee, palms, and banana. Private companies (Monsanto and Garst Seeds) were also the source of proprietary genes, and contractual arrangements were concluded for their use in research. In-house training for developing country scientists in companies involved in research collaboration under the ABSP project (Pioneer and Monsanto) was the third form of partnership.

No concerted strategy was developed, however, for approaching private companies either in the United States or in developing countries to determine their interest or otherwise in the development, production or distribution of the transgenic technologies being developed by the ABSP project research. And no concerted approach was developed for negotiations with private companies beyond research.

In contrast to the situation with respect to the two transgenic technologies analysed, the cucurbit team at Cornell has been successful in collaborating with private seed companies in each of the three countries included, at least for the testing of its material. Had greater effort been concentrated on the registration of Cornell's non-transgenic cucurbit lines in Egypt, Indonesia or South Africa, and licensing arrangements already established, this may have constituted a promising network for the subsequent commercialisation of transgenic products.

ABSP/private sector partnerships were innovative in that they have contributed critical elements of the technologies developed through collaborative research. However, except in the case of collaboration on transgenic maize between Pioneer in the United States and AGERI in Egypt, the private sector partners demonstrated little interest in maintaining a stake in the further development of these technologies in developing countries.

— *Management*

Given its broad thematic and geographic coverage, the heterogeneity of its partners, severe budget cuts in the first phase of the project, personnel changes in ABSP and its partners, shifts in emphasis between the first and second phases, changes in USAID policy, and dramatic changes in the general public's perception of transgenic technologies during the life of ABSP, the management of this complex international program presented some daunting challenges.

The fact that local or regional USAID Missions were encouraged to "buy into" the ABSP project had both positive and negative impact. On the positive side, the contribution of the USAID Cairo Mission to AGERI of around $7 million during the term of ABSP, enabled AGERI to undertake research and other activities on a scale which could certainly not have been contemplated from ABSP core funding. Conversely, this generous funding created a situation where it was virtually impossible for ABSP management to exercise any authority over AGERI, whether with respect to the directions and output of collaborative research or to product development and commercialization.

In retrospect, the expectations for ABSP voiced in the original proposal – product development within 3-5 years — were unrealistic. This should have been realized early in the life of the project, the more so when the budget was severely cut. However, the objectives set were neither readjusted nor more sharply focused as it became apparent that making significant progress towards commercialisation during the second phase of the project was, at the least, problematic. On the contrary, by the end of the project the objectives (both geographic and scientific) became more diffuse rather than more focused. In Phase II, a "new generation" of policy support activities began and the geographic focus was extended to the Eastern and Southern Africa regions.

The management structure of ABSP originally included a Technical Advisory Group (TAG), subsequently replaced with an External Board of Directors. The fact that the TAG met on only a few occasions meant that research projects continued with little systematic evaluation of scientific results and progress and with no clear time frames set for product development.

Neither the TAG, the External Board, nor the Internal Board appeared to have met with sufficient regularity or frequency to have provided adequate direction, guidance and support to ABSP top management. No provision was made for « go no-go » decisions with respect to different program activities: nor was provision made for the inclusion of new marketng or other skills as the focus shifted – in principle – away from research towards product development and commercialisation.

Several changes occurred in the structure and composition of the ABSP management team at MSU – particularly with respect to its Director(s) – in the 12 years of its existence. After the first joint Managing Director resigned, subsequent Directors were no longer faculty staff. However, ABSP top management established and maintained excellent working relations with the International Agricultural Institute, the host institution at MSU. These good working relations were helpful in enabling ABSP to survive a drastic budget cut in its second year, and to weather subsequent budget cuts and delays. The MSU Office of Intellectual Property (OIP), founded the year after

ABSP began, provided timely IPR expertise which ABSP needed to negotiate contracts between private companies and developing country partners which complied with Federal regulations but at the same time met company requirements.

Other members of the small core staff remained throughout the life of the project, thus ensuring continuity. During briefing visits to MSU, staff members have described the enriching learning experience it was for them, as part of ABSP, to interact so closely with individual scientists from developing countries, and, on field visits to partner countries, to understand better the institutional and cultural environment of partner countries. Clearly, each individual staff member has felt closely involved and highly committed to the project.

* * *

Despite its many and sometimes ground-breaking achievements, at the end of the ABSP project in June 2003, that is after almost 12 years and investment in the order of $13 million, no technology developed under ABSP has yet completed the product development phase, and the outlook for the diffusion of the two near-market biotechnologies analysed in the study is uncertain. This is in part due to shortcomings in the ABSP approach and its implementation. At the same time, it must be acknowledged that moving the transgenic biotechnologies closer to the farmer is currently constrained, not so much by the intrinsic qualities of the technologies, which have generally performed well in field-testing, as by the broad enabling environment in developing countries. This includes weaknesses in the links from public research to the farmer as well as policy or regulatory obstacles. Review of other publicly-funded agricultural biotechnology projects involving transgenic crops suggests that many are already facing — or will shortly face — the same kinds of constraints as those of the technologies developed under ABSP.

New approaches to narrowing the gap between research and the farmer's field

Insights from ABSP and other publicly-funded projects, as well as reviews of well-documented success stories of the development and commercialisation of agricultural biotechnology products, highlight the urgent need for new approaches. These would need to take the following issues into account: developing country policies and regulations; the changing roles and responsibilities of public research institutions in developing countries; the changing role of scientists in developing countries; the scope for public/private sector collaboration; and project approach, design and management.

— ***Developing country policies and regulations***

Government policies and national regulatory frameworks in developing countries are crucial components in supporting, facilitating, or impeding the development and diffusion of agricultural biotechnology, particularly when publicly- or donor-funded and developed within their own public research institutions. One of the most important aspects of such policies is the formulation of a national biotechnology policy or strategy so that promising, priority areas for public research can be identified and product development and distribution systems strengthened. Of the three countries included in the study, South Africa is the only one to have developed a national strategy.

Governments also have a responsibility not only to draw up clear, workable national biosafety guidelines or laws but, more importantly, to ensure they are implemented. They have a similar responsibility for the formulation and adherence to clear rules of the game for IPRs. Governments have an important role in providing, through public institutions, technical support facilities and services for field-testing, seeds testing and multiplication, quality control, etc. It is also important that they ensure policy coherence among different ministries, to avoid conflicting rules and regulations, for example, between public health, environment, and agriculture ministries.

Clearly, there is a continuing need for capacity- and institution-building in developing countries, particularly with respect to the elaboration and implementation of regulatory frameworks for biosafety and IPRs. Perhaps, more importantly, there is a strong need for additional case studies of the benefits and costs of specific biotechnologies – and particularly transgenic crops – so that countries can make objective, science-based decisions regarding the introduction and diffusion of new biotechnologies in their particular country context.

The scope for intervention in the evolving policy and regulatory environment in developing countries is, at best, limited. It must therefore be acknowledged that political support, or at least the support of relevant high-level decision-makers, can be crucial for the success or failure of donor-funded biotechnology projects.

— ***Changing roles of public research institutions in developing countries***

ABSP and other experiences of publicly-funded research provide sobering lessons for public research institutions, including universities, in developing countries which, in the past, have often been insulated from accountability. Many of these institutions remain heavily dependent on donor funding and, in the current overall climate of scarce public funding and growing pressure from their governments to produce tangible results, are faced with new challenges. These include, for example, the need to be better attuned to the needs and views of farmers and of the private sector, and to be able to demonstrate that their research is appropriate and relevant to their country's needs. This implies the need, if product development is envisaged, to enlist potential private partners at the outset, to seek marketing/commercial/economic advice where relevant, and to include this expertise in project teams. Institutions may also be under pressure to increase their share of income-generating activities by providing services or performing commissioned research, possibly for producer groups or for the private sector, as a means of becoming more financially sustainable and less dependent on external funding.

Particularly for those institutions conducting research on transgenic crops, it is necessary that they enhance their capacity to incorporate regulatory compliance not only in research planning but, where appropriate, in moving towards product development. Provision for these items, until now largely neglected, needs to be taken into account in budget estimates for research.

— *Changing role of the scientific community in developing countries*

Developing country scientists in public institutions, particularly those involved in advanced biotechnology research, need to be aware of the implications of the changing environment in which they are conducting their research. Within their own institution, they have a responsibility to be familiar with biosafety and IPR requirements. New institutional IPR policies can also mean they will be able to profit from their own innovations. Scientists have an important role to play in interacting and communicating with the non-scientific community, the private sector, policy makers, and civil society. They may also need, in order to ensure the future of their research, to communicate the message that biotechnology is not necessarily synonymous with GMOs, and to point to well-documented positive socio-economic impacts.

— *The scope for public/private sector collaboration*

The lessons from publicly-funded biotechnology initiatives to date suggest that much of the research under way has been proposed by scientists from the perspective of what science might have to offer in solving a particular problem affecting plant production. Certainly it has not been undertaken from the perspective of actual demand in an economic sense, or of a clearly-defined need in a social sense. The prospects for involving private companies depend very much on market prospects, and, given the negative short- to medium- demand outlook for some of the outputs of this research – for example, transgenic cassava — the prospects of enlisting private sector collaboration are extremely limited.

While there is a strong case for public/private sector collaboration in the development of biotechnology in developing country agriculture, there are few well-documented successful experiences from which to obtain guidance. In most developing countries, there is little experience of public and private sector collaboration, and consequently little on which to build mutual trust and confidence.

To become involved in product development and commercialization, private companies require, first and foremost, assurance of clear short- or longer-term market potential. In many developing countries, private sector activity is limited and technology markets undeveloped, so that it may be necessary for publicly-funded incentives to "kick start" the creation of a new technology market. Governments may also need to devise fiscal and/or other incentives for local biotechnology start-up companies or for public/private joint ventures for biotechnology with local or foreign firms.

Most private companies in developing countries are interested only in "finished products" and are not prepared to meet the substantial costs of fulfilling the range of biosafety procedures required in order to bring a product to commercialization. (For example, the estimated cost for the food and feed safety and environmental impact studies for Bt potato in South Africa is in the order of $900,000). Investment in the crucial product development phase thus emerges as a major impediment to public-private sector collaboration in the commercialization of the products of publicly-funded biotechnology research.

As illustrated in the limited number of biotechnology success stories so far documented, farmers and farmer cooperatives, producer groups, and NGOs may all have roles to play in forging the links between product development and technology diffusion. Indeed, farmers will be the ultimate arbiters of the success or failure of a new biotechnology. It may be necessary to create new links between different public and private interests, or new combinations of market and non-market mechanisms, at this crucial final phase. Funding and/or technical support may be needed during the period necessary to "bridge the gap" until the new technology has proven its scientific, economic, and social viability. Where extension services are still public sector activities, they too can play an important role as intermediaries, not only with farmers, but also with private companies, for example, through ensuring the presence of local seed and other companies when new technologies are being demonstrated or field-tested.

— *Project approach, design and management*

ABSP and other experiences in the publicly-funded national and international reseach communities suggest that linking current biotechnology research approaches to the "market" is unrealistic. The training of scientists in biotechnology research and methods, and capacity-building in the regulatory procedures and institutions which underpin the development and introduction of biotechnology are realistic, attainable objectives. However, the attainment of more ambitious objectives, such as moving from the lab to the farmer and, in development community parlance "targeting poor farmers", is much more problematic, particularly with respect to transgenic technologies.

Where it is intended that biotechnology research should lead to the production of a tangible biotechnology product and to the delivery of that biotechnology product in the farmer's field, the lessons of ABSP and other publicly-funded projects highlight the need for: (1) assessment of potential demand for the intended product in specific local markets, together with socio-economic impact assessment and (2) in-depth knowledge of the national system for biotechnology research, product development, and technology diffusion. This kind of analysis would, *inter alia,* assess the strengths and weaknesses of the seeds, agricultural inputs and agricultural services sectors and provide insights into the kinds of obstacles – apart from regulatory difficulties – likely to be encountered. It would also clarify the roles played respectively by the public and private sectors in the production and final distribution of agricultural technologies. It would then be possible to make informed judgments as to whether potential exists for private sector production and distribution (market channels), whether non-market channels could be envisaged, or whether transitional arrangements would need to be devised.

If it is considered that successful research has short-term market potential (that is, could be diffused through market channels), efforts could be made to involve private sector partners, either early in the research effort, further downstream at the product development phase, or subsequently in the production and diffusion of the new technology. If there is no obvious potential market demand, transitional diffusion mechanisms engaging both public and private partners (public extension systems, farmer or producer groups, NGOs) might be facilitated by "technology brokers", such as the International Service for the Acquisition of Agri-biotech Applications (ISAAA) and the African

Agricultural Technology Foundation (AATF), or by "product champions" who will become advocates for pursuing the technology through the innovation process.

The successful experiences to date highlight the importance of plotting the appropriate strategic links from research to the farmer's field from the outset. These links need to encompass policies and regulations, public institutions and private companies, assets/disciplines/skills, and people.

In defining the scope of a project, there is an obvious need for broad consultation with all potential partners, public and private, and with relevant expertise. It is then possible to identify who will provide the range of complementary expertise/assets necessary, to define their roles, and to decide how responsibilities and benefits will be shared among all the partners. It is also then possible to decide how budget resources might best be allocated among the different partners involved during the different phases in the innovation process: research, product development, and technology diffusion.

Only after extensive consultation and preparation is it possible to define clear, attainable objectives, including the appropriate point of intervention in the different phases, as well as the type of research to be conducted: basic, applied, or adaptive. It is then also possible to set realistic time-frames with benchmarks for research and product development.

Even after lengthy consultation and preparation, it may be necessary to make difficult choices and to accept inevitable trade-offs in setting objectives. Similarly, it must be acknowledged that, as was evident in the ABSP project, the enabling environment for the introduction of new biotechnologies may evolve, either globally or within partner countries, in ways that are impossible to foresee. For that reason, provisions should be made for go, no-go decisions, so that unpromising or unsuccessful avenues of research, or what emerge as incompatible relationships or conflictual situations, may be terminated.

— ***Management***

The ABSP experience emphasizes the difficulties of managing complex, ambitious projects involving a multiplicity of individual partners, partner institutions, and countries, and highlights the need for truly committed, sensitive, competent leadership. It also raises questions regarding an appropriate management structure for a project of its magnitude. Clearly, appropriate management structures are an important element in the success or otherwise of such projects. Here, the challenge is to ensure effective management of the overall project and its various elements, and at the same time devise a management structure as simple and transparent as possible, where roles and responsibilities are clearly defined, authority to take decisions is clearly allocated, and where top-level management is provided with both guidance and support.

The ABSP experience also points to the need for continuity and stability in management, particularly for long-term projects. When there are changes in top management, it is important to retain a core of management entity members so that relations with developing country partners can be maintained, the learning process can be documented, and the project "memory" kept intact.

Considerable effort also needs to be devoted to communication and information-sharing among all partners involved. This is important in order to inculcate a sense of involvement in and commitment to the project, and to build trust and confidence among a diversity of public and private partners of different cultural and professional backgrounds.

— ***Strategic options and issues for donors***

At this particular point in time, a large share of the research on GM crops conducted in public research institutions in developing countries is funded by donor agencies, whether through multilateral or bilateral funding, through support to the IARCs or to specific national programs or projects in developing countries. This state of affairs raises the important issue of returns to investment. The combined experience of ABSP and other publicly-funded biotechnology projects involving research on transgenic crops suggest the following key alternative sets of strategic options and issues for donor investment:

1. Continued focus on funding of research on transgenic crops

Donor agencies contribute a large share of funding for the ongoing research on transgenic crops conducted in the public research systems in developing countries. Bridging the gap between this research and the farmer's field appears in many instances to be compromised, at least in the short term. The reasons are twofold: firstly, the systems in place for linking publicly-funded research to product development and the farmer are weak or undeveloped; secondly, opposition to GMOs remains strong.

In addition, the time frames originally envisaged for moving from the lab to the farmer need to be revised and extended, to at least between 10 and 15 years.

Returns to a strategy of continued funding of research on GM technology may be considerable in terms of scientific capacity-building, but unless greater attention is paid at the outset to identifying the research needs and priorities of developing countries, there is a risk of irrelevant research output.

2. Reallocation of funding to achieve better balance between research and subsequent phases of the innovation process

Funding could be distributed more evenly between research outputs and development, with more effort directed towards product development. This might include the funding of a range of product development activities beyond small-scale field trials, and/or fufilling necessary biosafety requirements, leading to a finished biotechnology product.

Funding might also be directed towards supporting the creation of new market (private sector) mechanisms for product development and technology diffusion, for example, through incentives for local companies. Alternatively, it might be directed towards supporting the creation of new public/private sector (market and non-market) channels for product development and diffusion, involving public institutions, farmers, NGOs, and local companies, possibly through technology "intermediaries" or "product champions".

Funding of the product development area is crucial for the transgenic technologies currently being developed in public research systems in developing countries. Such a strategy would be unlikely to yield short-term returns to investment but should yield considerable benefit in the medium-term. Indeed, without additional investment, in the product development phase, the future of "public good" technologies appears bleak.

3. Funding of non-GMO biotechnology research

A strategy of funding biotechnology research not involving GM technology would have the advantage of relatively early returns to investment in terms of product development and, possibly, better prospects of linking research output to the market. It would, of course, also have returns with respect to scientific capacity-building.

At the same time, it should serve the purpose of building confidence in the agronomic, environmental, and socio-economic benefits of biotechnology products. This would, in principle, consolidate the links necessary for the introduction of transgenic technologies in the short-term future.

In this case, however, countries would be under less pressure to establish and implement sound biosafety policies and institutions.

INTRODUCTION

The USAID-funded Agricultural Biotechnology Support Project (ABSP), initiated in 1991, set out with a vision of developing and making transgenic crops available to developing country partners. At the time ABSP was launched, no transgenic crop had yet been commercially released anywhere in the world. Nevertheless, hopes ran high that these new technologies could be developed, transferred, and diffused in developing countries, if not during the first, at least within the second phase of ABSP.

Since the first transgenic crop was commercialised in 1996, the global area planted to these crops has increased rapidly, and in 2003 rose to 67.6 million hectares. These crops are grown by 7 million farmers in 18 countries (ISAAA, 2003). Despite this apparent success, during the same period biotechnology in general, and genetically-modified organisms (GMOs) in particular, have become the subject of continuing acrimonious public debate, particularly in the countries of the European Union, over possible risks to human or animal health or to the environment. Public disquiet has at the least slowed, but more often halted, even more widespread introduction of transgenic crops.

During 2001, a final evaluation of this complex project was conducted by an international team of reviewers[1]. This evaluation analysed the achievements and shortcomings of the project and pinpointed key lessons to be drawn over the life of the program which it was possible to take into account in the design of subsequent USAID-funded projects: ABSPII and The Commercialisation of Bt Potatoes in South Africa. As the report was intended primarily for use by USAID it was not widely circulated. It has since been acknowledged that ABSP constitutes a pioneering learning experience from which others might benefit. The purpose of the present study, which updates and expands on the earlier findings, is therefore to take a more comprehensive analytical approach, and to make the valuable insights to be gained from the ABSP experience available to a wider audience.

It is hoped that the lessons from ABSP will be instructive for the diversity of organisations and individuals working in the broad field of biotechnology and development and, in particular, for those involved in publicly or privately-sponsored initiatives directed towards enabling developing countries to benefit from what agricultural biotechnology has to offer.

The ABSP project has provided a wealth of lessons regarding the complex and lengthy process of developing transgenic crops and moving towards commercialisation. Many of the problems it encountered are currently shared by other publicly-funded programs aimed at the development and transfer of biotechnology in developing country agriculture. The sum of these experiences presents a strong case for new approaches to project design, management and implementation.

[1] Dr. Ann Marie THRO, USA; Dr. Maria José SAMPAIO, Brazil; Dr. Ana SITTENFELD, Costa Rica; Carliene BRENNER, France.

OBJECTIVES

The study will focus on analysis of the ABSP experience to illustrate the challenges to be addressed by publicly-funded and implemented programs aimed at developing and delivering biotechnology products in developing countries.

The principal objectives of the study are therefore:

- to determine how successful ABSP was in meeting its overall objectives
- to review the role of ABSP in promoting institutional development and innovation in partner countries
- to examine the effectiveness of the public-private sector partnerships initiated under ABSP
- to highlight some of the difficulties and pitfalls encountered, particularly with respect to the ultimate commercialisation of biotechnologies developed by public research
- to propose, in the light of lessons from both ABSP and other experiences, new approaches to the design and management of similar, collaborative projects

APPROACH AND ANALYTICAL FRAMEWORK

In contrast to the approach taken in undertaking the final evaluation, this study does not attempt to cover the ABSP program in its entirety. Instead, it takes the example of certain technologies developed under ABSP (which terminated in June 2003), chosen to illustrate the complexities of moving from research to product development, and, finally, to commercialisation. Put differently, the analysis encompasses the whole process of "moving from the lab to the farmer's field".

It therefore focuses on what are termed « near-market » biotechnologies, defined as technologies which have resulted directly from research collaboration between ABSP partners, have evolved through basic and/or applied research, and are progressing through product development and field-testing, through required biosafety and IPR procedures, and, in principle, should shortly be available for small- or large-scale production and distribution to farmers/producers and to consumers.

The study focuses on two near-market technologies, in three different developing country settings. The technologies selected are: transgenic potato resistant to potato tuber moth (PTM); and transgenic and non-transgenic cucurbits resistant to virus and other diseases. The countries included are: Egypt, Indonesia and South Africa.

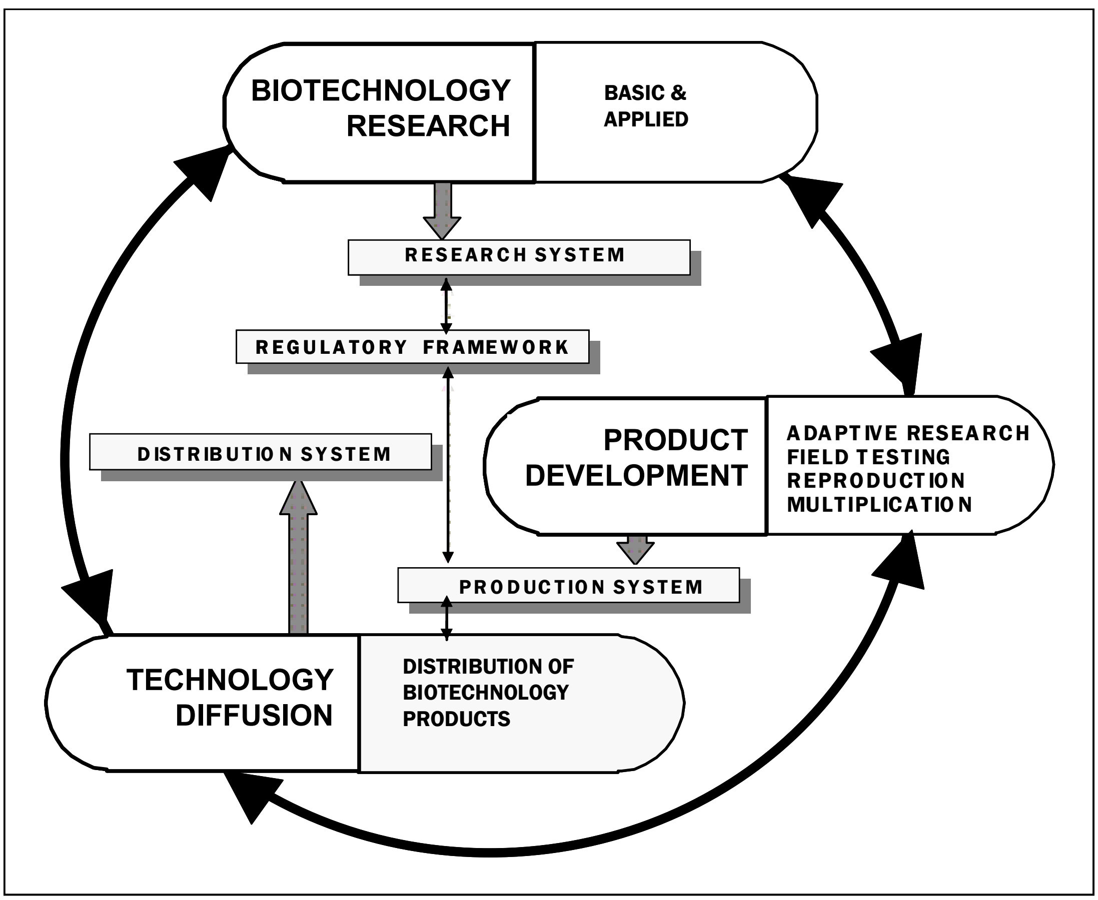
The central hypothesis is that the successful introduction and diffusion of the new biotechnologies being developed under ABSP, and, indeed, under other publicly-funded biotechnology research programs, will depend to a large extent on the strengths and weaknesses of the product development and delivery systems for publicly-funded research prevailing **within** developing countries. It is therefore crucial to take the key characteristics of those systems into account in the design and implementation of projects at the outset.

One of the lessons learnt from earlier research on publicly-funded agricultural biotechnology undertaken by the OECD Development Centre (Brenner, 1996) was that the « distance » between research, product development, and commercialization – or from the laboratory to the farmer's field – depends on a number of crucial links and interactions among public and private sector entities, both national and international, and between government policies and market forces.

The concept of a national system for biotechnology innovation that encompasses **research**, **product development,** and **diffusion** can provide a means to better observe linkages that need to be made beyond research, illuminate the complexities of the process, and pinpoint where bottlenecks are likely to occur.

Figure 1 below presents a stylized schema of such a system in which biotechnology would be integrated. This system encompasses biotechnology research, product development, and diffusion (or distribution), as interactive and linked. These three sets of activities function within the confines of a particular policy, financial, production, and regulatory environment. The biosafety and intellectual property aspects of that regulatory framework have emerged as crucial in the case of agricultural biotechnology.

Figure 1. National System for Biotechnology Innovation



The conceptual framework above corresponds in many ways to the national systems of innovation approach proposed by OECD (OECD, 1999) and by F van Waarden et. al. (2001) or to the "enabling environment" proposed by Robert Tripp (2003). The Van Waarden approach encompasses basic research, applied research, product development, production, quality control, and marketing. Rather than a linear presentation, Figure 1 proposes a virtual circle in which, ideally, there is two-way interaction between the various elements which constitute the system. It is also important to keep in mind that the system links people, competences, public and private institutions, and policies, and that these different elements may interact at different levels: personal, institutional, national, regional, and/or international.

For purposes of illustration, the different phases of the research, product development, and technology diffusion process are presented here as sequential. In reality, they may overlap. For example, it may be difficult to make a distinction between applied and adaptive research. Information gathered during product development may provide feedback to research as well as to the distributors of the technology.

In an increasingly globalised world, no country is technologically self-sufficient, and different elements of technology, both tangible (equipment) and intangible (knowledge), are likely to be obtained from a diversity of sources, both internal and external, and in a national, bilateral, regional, or international context. Table 1 outlines some of the key elements, in terms of asset complementarities, contributed by different public and private entities, ranging from local to international level.

Table 1. Asset complimentarities in agricultural research

Institution/Firm	Scientific and Knowledge Assets	Other Assets
Multinational Research Firms (Life-Science Firms)	Genes, gene constructs, tools, related information resources Biotechnology research capacity	Access to int'l markets and marketing networks Access to int'l capital markets Access to philanthropic funding Economies of market size Decision-making speed and flexibility
International Agricultural Research Centers (CGIAR)	Germplasm collection and informational resources Conventional breeding programs and infrastructure Applied/adaptive research capacity	Access to regional/global research networks Access to bilateral/multilateral donor funding Generally strong reputational integrity
National Agricultural Research Systems (NARS)	Local/national knowledge and materials Conventional breeding programs and infrastructure Applied/adaptive research capacity	Seed delivery and dissemination programs and infrastructure Generally strong reputational integrity
Local firms	Local/national knowledge and materials Applied/adaptive research capacity	Seed distribution and marketing infrastructure

Source: Adapted from Byerlee and Fischer 2001.

Nevertheless, all technology developed through international collaborative research will be transferred through and conform with **national** regulatory systems: phyto-sanitary, biosafety, and intellectual property protection (IPP). This applies to all phases of the innovation process.

The term "technology transfer" means different things to different people. Indeed, this has been an important factor in the ABSP project. In Figure 1, technology may be transferred in different forms, and through different mechanisms, at all phases during the process of innovation: from research to final technology diffusion. Thus, technology transfer should occur not only from the research system **to** farmers, but also from farmers **to** the research system. Table 2 illustrates different kinds of mechanisms used, at different phases, for the transfer of genetic technologies, for both market and non-market transactions.

Of course, **research** is not necessarily intended to result in an end product, and biotechnology research may be seen, for example, as contributing an enabling technique, as in the use of genetic markers in plant breeding. On the other hand, it may indeed result in an end-product, for example, in the form of a virus-resistant seed. For the purposes of this study, where appropriate, a distinction is made between a **technique** used in the course of research and a **technology** as an end-product. Table 1 relates to transfers of technology both as an input into the research process and as an end-product.

Research and **product** (or technology) **development** are intimately linked, and so it is often difficult to determine where development begins. For example, when a technology product or process is "imported" and requires "adaptation" to local agro-ecological and production conditions, or to local germplasm and cultivars, adaptive research is an integral part of technology or product development.

Table 2. Technology transfer mechanisms for genetic technologies

	Form of technology transfer	Phase in innovation process
Market transactions	Purchase of technology (new seed variety, planting material)	Diffusion
	Licensing of product or process (diagnostic kit, technique)	Research, development, diffusion
	Joint ventures	Research, development, diffusion
	Trade secrets (inbred, parental lines)	Research, development
	Collaborative research	Research, development
	Bio-prospecting agreements	Research, development, diffusion
	Materials transfer agreements	Research, development
Non-market transactions	Training and technical co-operation	Research, development, diffusion
	Collaborative research	Research, development
	Materials transfer agreements	Research, development
	Technology "donations"	Research, development
	Seed exchange among farmers	Diffusion

Source: Adapted from Brenner 1998.

Development encompasses all the activities which help convert the results of successful laboratory research into a tangible technology product, such as a genetically-modified seed or disease-free planting material. Such activities may include: adaptive research; small and large-scale field testing; production and multiplication of seeds or planting material; and setting up a demonstration plot or pilot plant.

Conforming with the necessary regulatory procedures, particularly for biosafety and intellectual property rights (IPRs), is an integral part of research, product development, and technology diffusion. In moving through product development, while scientists may continue to be involved, additional, complementary skills and competences are required: plant breeders, agronomists, seed producers.

In Figure 1, **technology diffusion** represents the third and final step in "moving from the lab to the farm". In this final phase of introducing a new agricultural innovation, while some of the individuals and institutions concerned with product development may continue to be involved marginally, new persons, competences, and organizations are required to distribute the product to the farmer. This "final" technology transfer can take place either in a market context, that is, where private commercial companies sell the product; through public extension systems and/or NGOs, or through a combination of public and private organizations.

Both public and private entities, contributing different kinds of assets and inputs, are likely to be involved at the various phases illustrated in Figure 1. The kinds of public and private sector entities involved are listed in Table 3.

Table 3. Public and Private entities in research, product development, and technology diffusion

Agricultural research	Product development	Technology/Diffusion
PRIVATE		
Non-commercial: Foundations, NGOs **Commercial:** Life science, biotechnology, seed, and agro-chemical companies Producer associations and co-ops Plantation companies Commodity boards	Foundations, NGOs Life science, biotechnology, seed, and agro-chemical companies Producer associations and co-ops Plantation companies Commodity boards	Foundations, NGOs Life science, biotechnology, seed, and agro-chemical companies Producer associations and co-ops Plantation companies Commodity boards
PUBLIC		
Ministries of agriculture, livestock, education, S&T, etc. National research councils and institutes Universities	Public research institutions Universities Parastalals (seeds, feed, animal health)	Public research institutions Universities Parastalals (seeds, feed, animal health)

In the most technologically-advanced countries, there is a strong tradition of interaction and feedback among the various links within the national research, product development, and technology diffusion system, both public and private. For a number of reasons, these links are often weak in developing countries. Private markets for technological innovations are often undeveloped, structures and mechanisms set up by the public sector to facilitate technology transfer and diffusion (for example, extension systems) have generally not proven efficient in the past and, in many countries, are being dismantled or privatized under pressures to decrease public spending. Furthermore, contacts between public research institutions and the private sector, are in many cases, either tentative or non-existent.

ORGANISATION

The two near-market biotechnologies developed under ABSP will be analysed against the background of the framework depicted in Figure 1. The analysis is based on:

- A review of relevant published and unpublished literature
- Documentation generated during the life of the ABSP project
- Field visits to Egypt, Indonesia, and South Africa, and interviews with public and private persons and institutions directly or indirectly involved in the ABSP project (Annex 1.)
- Interviews and discussions with ABSP management at MSU and with USAID officials in Washington

The study is organised as follows. In the first chapter, a brief overview of the ABSP project is provided. This is followed in Chapter II by short country profiles of Egypt, Indonesia, and South Africa. Chapter III traces the two "near-market" technologies, from the initial research phase to their present status, in these three countries. In Chapter IV, the key lessons learnt from ABSP are outlined. In the fifth and final chapter, a number of issues emerging from the ABSP and other experiences are discussed, new approaches to bridging the gap between research and the farmer's field are proposed, and key strategic options are outlined.

Chapter I

OVERVIEW OF ABSP

This chapter presents a brief overview of the ABSP project, focusing, firstly, on its origins and the United States Agency for International Development (USAID) approach to project design and elaboration, followed by objectives of ABSP, management structure and budget, and its various activities.

Origins

USAID has been funding biotechnology initiatives since the 1980s. Its first involvement was in funding the Tissue Culture for Crops Project (TCCP), based at Colorado State University. Research sponsored under the TCCP sought to produce crops (wheat, rice, and sorghum) tolerant to a number of stresses, including salinity, drought, and acid/aluminum soil conditions. Research efforts, conducted by teams of scientists and plant breeders in US universities, national agricultural research systems (NARs), and international agricultural research centres (IARCs), relied primarily on somaclonal variation, tissue culture, and *in vitro* selection to produce novel sources of genetic variation. However, as these approaches had failed to achieve the outcomes envisaged, in 1989 USAID began a review of alternative possibilities to support biotechnology.

As a basis for designing a new program, USAID followed the procedure commonly used in launching major US research initiatives, calling upon the National Research Council of the National Academy of Sciences of the United States to assist in identifying broad priorities for consideration in an international biotechnology program. A panel of experts, all scientists, from US universities, the US private sector, the United States Department of Agriculture (USDA), the Rockefeller Foundation, IARCs, and one representative from a developing country NARS (Thailand), was then appointed with the task of establishing priorities in plant biotechnology which could benefit agriculture in developing countries in the relatively near future, that is, within 3-5 years.

The deliberations of the panel, which met in Washington in September 1989, were published in a report entitled *Plant Biotechnology Research for Developing Countries (1990).* Certain features of the report are worthy of mention. One important feature was that it considered institutional aspects of biotechnology research and development as important as the technical aspects, and, specifically, recommended assistance to developing countries in developing and implementing appropriate biosafety regulations. It also recommended that USAID should take the lead in promoting international cooperation in intellectual property rights (IPRs) among both public and private US research organizations, donor agencies, the IARCs, and developing country governments in addressing IPR issues.

Another important feature was the emphasis on training and networking. Training was considered important not only for biotechnology *per se*, but also in the complementary agricultural sciences, plant and animal breeding, agronomy, and pathology. Networking was envisaged as networks of developing country scientists linked to counterparts in the IARCs and in industrialized countries through electronic means and periodic workshops.

In terms of scientific priorities, the panel proposed three broad areas: tissue culture, micropropagation, and transformation; plant disease and pest control: and the genetic mapping of tropical crops. No specific mention of public and private sector collaboration was made in the Panel's recommendations, although partnership with the private sector was emphasized by USAID Director for Agriculture William Furtick in his introductory remarks.

Following publication of this report in 1990, USAID elaborated a program intended to combine biotechnology research, training, and management with broader aspects of technology transfer, including policy. A call for competitive bids (Request for Applications: RFA No. W/FA-91-004 Agricultural Biotechnology for Sustainable Productivity, Project No.936-419) was then issued, which comprised two distinct parts, one to be led by a US university and one by the private sector. The call for proposals was issued on June 17, 1991, with the very short closing date of July 23, 1991 for the submission of applications. The ABSP project was designed to support a program of research and development, testing, commercialisation, and product distribution, for a period of six years, at a cost of more than $6 million in core funding. Participatory funding from missions and regional bureaus was to be encouraged and was estimated at $3,500,000, making a total of approximately $9.5 million.

The cooperative agreement for the project, initially entitled Agricultural Biotechnology for Sustainable Productivity (subsequently changed to the Agricultural Biotechnology Support Project), was awarded to Michigan State University (MSU) in 1991. The original project proposal states : "This project will combine management, networking, research, and technology transfer to improve agricultural sustainability in LDC's". The longer-term goal was to enhance agricultural productivity in developing country agriculture in a sustainable way. This implied, in particular, reducing levels of pesticide application and, consequently, protecting the environment. The research was to include and, indeed, to focus on transgenic approaches to problems which had not been possible to resolve hitherto by conventional methods.

The private sector component of the project was awarded to DNA Plant Technologies (DNAP) of California, to collaborate with a private partner in Costa Rica, Agribiotecnologia, on the development of micropropagation techniques for coffee, banana, and pineapple. This project was folded under the umbrella of ABSP and Michigan State's management. While part of ABSP and MSU's management, this component was designed as a single project with a limited time frame. USAID support thus ended in 1995.

At the outset, the overall goal of ABSP was:

"To mutually enhance U.S. and developing country institutional capacity for the use and management of biotechnology research to develop environmentally compatible, improved germplasm."

Dr. Mariam Sticklen, initially Joint Director of ABSP with Dr John Dodds, played a major role in the elaboration of the proposal submitted to USAID. In an interview at MSU in May 2003, Dr. Sticklen explained her vision for the ABSP program. Her idea was to focus on crops of importance to the limited number of countries originally chosen as partners, a choice conditioned in part by the private partners who had elected to become involved in the project, and in part by the countries which were already comparatively advanced in setting up biosafety guidelines or regulations. In her view, the great advantage of working with private sector partners was that they would be able to contribute proprietary technology and also facilitate rapid commercialisation.

It was planned to focus in the beginning on tissue culture and micropropagation of bananas and pineapple and in-vitro propagation of trees (with DNAP) as the technologies generated could be commercialised in the **short-term.** The research focus would then move to potato and cucurbits, and possibly tomato, which it was hoped could be commercialised in the **medium-term**, that is, by the end of 6 years. This would then leave the more risky research, transgenic corn, for the **longer-term**.

Following submission of the proposal, the reviewers made a number of comments and requested clarification on technical and other issues. Firstly, they questioned the reliability of the time frames envisaged for research and product development. In a written response Dr Sticklen reiterated that transgenic potato and transgenic cucumber and melon should be ready for commercialisation within 3-5 years.

The response to reviewers' concerns regarding prospects for commercialisation was that "if the biosafety of these transgenic plants is confirmed, there will be tremendous market potential for these crops" (potato, rice and maize as food crops, and cucumber/melon as cash crops). Although rice was one of the crops included in the original MSU proposal, it was subsequently withdrawn because the Rockefeller Foundation had already initiated its Rice Biotechnology Network.

In October 1998, as part of a review of the progress of the project, the Technical Advisory Group (TAG) proposed a modification of goals for Phase II of ABSP. Thus, in the second phase, the objectives were: "to improve the capacity and policy environment for the use, management, and commercialization of agricultural biotechnology in developing countries and transition economies". The objectives set during the first phase of ABSP (1991-1998) therefore differed somewhat from those of Phase II (1998-2003), with stronger emphasis in the second phase on moving closer to commercialisation.

Management

ABSP was initially structured as a consortium of public institutions and private companies in the United States together with developing countries. At the time the project was launched, MSU took the management lead in a consortium of 3 US universities, the others being Cornell University and Texas A&M. At the outset, the developing country partners chosen were: Indonesia, Kenya, and Ecuador.

At the time ABSP was implemented, it was headed by a full-time Innovational Managing Director, who was also responsible for Communication and Networking; and a half-time Institutional Management Director, who was responsible for Research and Institutional Management. In addition to the Directors, the management structure included a Technical Advisory Group (TAG) appointed by USAID "to monitor and evaluate the progress of the project". An institutional advisory group or Internal Board of Directors was also set up, composed of MSU Department Chairs, the Director of the MSU Institute of International Agriculture, representatives of Texas A&M and Cornell universities, and one representative per developing country with ABSP activities. This group was " to meet at an interim and final stages ….. to regularly monitor technical and managerial conduct of the project", review reports sent to USAID, provide oversight and guidance, and advise the research projects and ABSP management.

In line with the revised objectives it set for Phase II, in 1998 the TAG recommended a revised management structure, intended to facilitate the transition from the research phase to application and delivery. As a consequence, during Phase II, management included a Director and an Associate Director. Also during Phase II the TAG was replaced by an External Board of Directors, envisaged as having a stronger role than the TAG. The new Board was to meet annually to review work plans, the strategic direction of research and policy activities, review effectiveness of specific program elements, and provide reommendations to USAID and ABSP. Its membership included: the private US biotechnology sector, US regulatory agencies, international development agencies, environmental groups, and the food industry. The MSU Internal Board of Directors continued, but with MSU membership only, and a new role – liaison between ABSP and the host organisation, MSU .

It is to be noted that a provision was made in the original proposal for the recruitment of a commercialization specialist and a biosafety specialist. The commercialization specialist was to "work jointly with all parties concerned (including the private sector) to develop a commercialization project for genetically engineered crops". However, no such position was filled during the life of the project. A biosafety specialist was recruited as a consultant to ABSP.

The first phase of ABSP ran for 6 years, and, in 1998, a non-competitive extension was granted to continue the project until 2002. A further extension was subsequently granted to June 2003.

Over time, ABSP included as many as seven developing country NARS and six other United States university partners (not members of the management consortium): Cornell University, University of Wyoming, Virginia Tech University, University of Texas at Dallas, Arizona State, Ohio State, and the Scripps Institute International Laboratory for Tropical Agricultural Biology. Private sector partners have included: DNAP, ICI Seeds, Pioneer HiBred, and Monsanto in the United States; Fitotek Unggul in Indonesia; and Agribiotecnologia de Costa Rica (ACR) in Costa Rica.

During the life of ABSP, a growing number of countries and institutions became involved in its policy-related activities. This was in contrast to the number of developing country institutions involved in collaborative research with the United States partners, which dwindled, so that, when the project came to an end in June 2003, the Egyptian Agricultural Genetic Engineering Research Institute (AGERI), the South African Agricultural Research Council (ARC) Vegetable and Ornamental Plant Institute (VOPI), and the Tata Energy and Resources Institute in India were the only developing country institutions actively collaborating.

Research

The overall scientific goals of ABSP included the transfer of genes to provide host plant resistance to major pests and diseases in several crops of importance to developing countries.

More specific project objectives were as follows :

- To develop disease-free, high quality planting material of tropical crops, specifically banana, pineapple, coffee, and palm
- To assemble vectors containing insect and virus-resistant genes
- To genetically engineer potato, sweet potato, and maize for resistance to virus and insect pests in developing countries
- To genetically engineer cucurbits with a virus coat protein for development of resistance to potyviruses
- To transfer scientific knowledge and techniques to developing countries through postdoctoral fellowships
- To demonstrate pest resistance of transgenic crops and integrate this into sustainable agricultural systems via collaborations

During the life of ABSP, research projects included :

- commercial micropropagation of tropical crops
- development of cucurbits with multiple virus and disease resistance using a combination of molecular genetics and conventional breeding approaches
- development of Bt transgenic potato germplasm resistant to potato tuber moth
- development of gemini virus-resistant tomato
- development of transgenic maize resistant to the maize stem borer
- investigation of *Bacillus thuringiensis* toxin receptor
- drought and salinity tolerance in wheat

- development of virus resistance in sweet potato
- high beta-carotene mustard oil

Policy activities

— *Biosafety*

The ABSP project was implemented at a time of growing public debate worldwide on the possible risks of biotechnology, whether with respect to biological diversity, or to food or environmental safety. These debates were fuelled in Europe by food-related crises, which have made consumers particularly sensitive about food safety issues. Environmental non-governmental organisations (NGOs) in Europe and in developing countries have also been extremely vocal in taking issue with the new technologies derived from genetically-modified organisms (GMOs). As a consequence, in the public debate, biotechnology has become synonymous with GMOs, although they are only one of the many products of biotechnology.

Fears surrounding GMOs have been both assuaged and stimulated with the entry into force of the Cartagena Biosafety Protocol, to which most developing countries are signatories.

The integration of science with policy development was one of the innovative objectives of ABSP, and so activities related to building awareness and capacity in biosafety began in 1993. These activities have involved many countries which were not partners in research collaboration, and have included, in addition to training and biosafety policy development, financial support for the building of the basic infrastructure for greenhouse containment testing.

Many scientists from developing countries have attended biosafety courses, seminars, and workshops, and, in some cases, have undertaken in-house training with private companies in the United States. By encouraging these scientists, who were to become leaders in their institutions, to attend different biosafety events, ABSP helped to build a vital bridge between capacity-building and policy development.

The first activity took place in 1993 when ABSP organised a four-week biosafety internship program, in which scientists and regulatory personnel from Kenya, Indonesia, and Egypt participated. The program enabled participants to witness “hands-on” applications of biosafety procedures used in the safe handling of transgenic plants in laboratories, greenhouses, and fields. Interns met with regulatory personnel at the state and federal agencies in the United States responsible for transgenic field testing permit applications, food safety, and other risk assessment issues. They also visited and interacted with personnel from the US Department of Agriculture – Animal and Plant Health Inspection Service (USDA-APHIS), Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Michigan Department of Agriculture, Michigan State University, Asgrow Seed Company, ICI Seeds, and the National Biological Impact Assessment Program (NBIAP).

This was followed in May 1993 and January 1994 by two regional workshops. These workshops, which addressed policy, risk assessment, and field testing issues related to the management and safe handling of transgenic plants, brought together biosafety, science, and regulatory personnel from Latin America, United States, Africa, Middle East, and Asia.

In August 1996, in cooperation with Virginia Tech, ABSP organised a two-week program in biosafety which gave participants a thorough grounding in all aspects of biosafety for the environmental release of GMOs, including the theory and practice of risk assessment and management of agricultural biotechnology applications. Practical experience was gained through case studies.

The training of developing country participants has been instrumental in several countries in the development and drafting of biosafety guidelines, in the setting up of national or institutional biosafety committees, or in the adoption of national legislation on biosafety .

In its second phase, ABSP extended its biosafety efforts to regional activities , forming a partnership with the Southern Africa Regional Biosafety Program (SARB) and with the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA).

In 2002 ABSP also published a « workbook » on Biosafety and Risk Assessment in Agricultural Biotechnology, which attempts to synthesize the knowledge and experience gained during several years of activity. The workbook is designed to complement technical biosafety-assessment training courses in developing countries.

— ***Intellectual property rights (IPRs)***

In the same way as for biosafety, the ABSP project conducted a number of initiatives related to IPRs. At the time the project was launched, major changes in intellectual property protection were occurring worldwide. These changes were closely linked to developments in biotechnology and to efforts led by the United States in the General Agreement on Trade and Tariffs (GATT), predecessor of the World Trade Organisation (WTO), to extend intellectual property protection to areas hitherto excluded. These efforts focused, in particular, on biological innovations and on GMOs. Multilateral negotiations led to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which entered into force on 1st January 1995. This Agreement covered all the main areas of intellectual property, including micro-organisms. Provisions were nevertheless made in the Agreement for plants and animals other than micro-organisms, as well as essentially biological processes for the production of plants or animals other than non-biological and microbiological processes, to be excluded from protection. However, in the case of plant varieties, countries would be required to provide intellectual property protection "either by patents or by an effective *sui generis* system or by any combination thereof ».

Although most developing countries were signatories to the TRIPS Agreement. At the time ABSP was initiated, developing country partners had very little experience and, in most cases, little appropriate institutional and/or technical infrastructure for the intellectual property protection of biotechnological innovations. There was, therefore, growing concern among developing countries that their genetic resources – and biodiversity – could be exploited against their will, or without their knowledge, as a result of extended IPRs.

Within the ABSP project, the issue of IPRs needed to be addressed at two levels, both within the collaborative research program, and as part of capacity- and institution-building in partner countries. Within the research program, proprietary technology in the form of genes and promoters had been obtained from Monsanto company and from what is now Syngenta and agreements were signed with these companies (or their predecesssors) for the use of the technology for research purposes only.

As part of the capacity-building objective of ABSP, courses, seminars, and internships on IPRs were developed. Developing country demand for these courses became so strong that, in 1996, the internship course was "spun-off" to MSU and has since been offered as a regular, annual course. The ABSP project has sponsored participants in these courses from Costa Rica (1), Egypt (4), Kenya (2) Morocco (5), Indonesia (6), South Africa (1), India (2), and Ethiopia (1).

Another important outcome was a handbook containing the basic materials taught in the MSU IPR course. This book, published by CABI in 1998 as one of its series on Biotechnology in Agriculture, includes 15 case studies authored by developed and developing country collaborators (Erbish and Maredia, 1998).

IPR activities conducted under ABSP have resulted in institutional innovation, firstly with the development of Indonesia's Plant Variety Protection Law. ABSP also played a key role in the establishment and implementation of technology transfer and IPR offices in Indonesia – KIAT – linked to the Agency for Agricultural Research and Development and, in Egypt, OTTIP, linked to AGERI.

ABSP has been able to call on MSU's Office of Intellectual Property legal expertise when needed, and has also used Prof. John Barton of Stanford University as a consultant to assist several countries in designing and implementing IPR legislation. Another interesting feature of the project is that it has supported the filing of two patents during the development of research agreements.

In an effort to distil the experiences of the ABSP project, a "Basic Workbook in Intellectual Property Management" has been prepared by Dr. F. Erbisch, former Director of the MSU Office of Intellectual Property (OIP). The workbook is intended as a training manual and is now available on the following web site: http://www.iia.msu.edu/iprworkbook.htm.

Communication and networking

Information, communication, and networking activities were also an integral part of the original RFA for ABSP. One activity specified at the outset was the continuation and expansion of IPBNET, the International Plant Biotechnology Network. During Phase 1, this was achieved through a widely-distributed newsletter called BioLink. This was one of the first available information sources for public sector researchers in developing countries, which conveyed the message that biosafety and IPR issues were essential considerations in the conduct of their research.

In Phase II, BioLink was replaced by « Linkages », a scaled-down project information newsletter with more limited circulation. The ABSP website also provided easy access to information on all facets of the ABSP program.

In addition to organising numerous country-specific, regional, or international meetings on different biotechnology-related themes, ABSP also funded the participation of developing country representatives at regional or international biotechnolgy meetings, and financed membership to the US Bio-Industry Association or subscriptions to CABI's AgBiotech Net as part of its communication activities.

* * *

The ABSP project had a number of pioneering features. First and foremost, was the goal it set to make transgenic crops available to developing country partners. Secondly, it established innovative public/private partnerships and partnerships between private companies. Thirdly, it sought to link research with emerging policy issues specific to biotechnology: biosafety and IPRs.

Because it was innovative, ABSP provides valuable lessons from which to learn. In the following chapters, the research and development paths, as well as progress towards commercialisation, will be traced for two of the "near-market" biotechnologies developed through the project.

Chapter II

COUNTRY PROFILES

Brief profiles of Egypt, Indonesia, and South Africa are presented in this chapter. The profiles highlight both differences and similarities in these three countries with respect to agriculture and agricultural research in general. They also focus on the relative importance in each country of potatoes and cucurbits among vegetable crops and describe elements of the research, product development, and diffusion system in which transgenic potatoes and virus and pest-resistant cucurbits would be introduced.

EGYPT

Agriculture

Agriculture in Egypt has a number of unique characteristics (Bowman, Rogan, 1999). Perhaps the most striking is that Egypt has virtually no rainfall, and so agricultural production is entirely dependent on the waters of the Nile, the world's longest single river. For thousands of years, the rhythm of Egyptian agriculture was dictated by the natural flooding of the Nile, which gave rise to three seasons : flooding, planting, and harvesting.

While the timing of the Nile flooding was predictable, its volume was not. Since the times of the Pharaohs, ways of controlling the water have therefore been another unique feature of Egyptian agriculture. The art of river engineering during the Ptolemic period (305 BC – 30 BC) involved not only the development of canal irrigation systems, but also the invention of lifting devices – the water wheel and Archimedean screw — which made it possible to produce two crops per year. Irrigation improvement and extension have continued into modern times, so that, by the 1920s perennial irrigation systems provided water to 80 per cent of Egypt's 5 million feddans of irrigated land.

The completion of the Aswan Dam in 1970 was a further major step in controlling the water from the Nile. However, it also stopped the flow of nutrient-rich silt to Egypt's farmland, creating greater need for agricultural inputs in the form of animal manure and mineral fertilizers.

A final unique feature of Egyptian agriculture is that only about 5 per cent (3.2 million hectares) of the total land area of 1 million square kilometers is cultivated. This means that, at 0.05 hectares per capita, Egypt has one of the world's lowest per capita levels of agriculturally productive land.

Ancient Eypt provided a surplus of food as well as ornamental flowers and non-food products for export. Indeed, agricultural exports helped fund the construction of the Egyptian marvels that remain today. For thousands of years, Egyptian farmers have grown a wide diversity of agricultural products : grains and legumes, fruits, and vegetables. Figs, grapes, pomegranates, melons, cabbage, cucumbers, garlic, leeks, lettuce, onions, and radishes were already popular in ancient Egypt.

This diversity of products has been produced in two distinct agricultural zones : the Nile Valley and the Nile Delta. The green ribbon of farmland in the Nile Valley stretches 700 kilometers from the Aswan Dam to the Delta. Seven branches of the Nile feed the triangular Delta region. Other areas of agricultural land include the Fayyum, desert oases, and reclaimed land.

Today, Egyptian agriculture is a combination of the ancient and the new. In some cases, the use of farm implements and animals has scarcely changed since ancient times, and there is little evidence of technological change. In others, including a number of large corporate farming operations, advanced technology has been introduced.

In Egypt, agriculture still accounts for 20 per cent of GDP and 20 per cent of total exports, and still employs 34 per cent of the labour force. At the same time, despite progress towards self-sufficiency in some key food crops (for example, wheat, where imports have declined from between 75 and 80 per cent in the 1980s to 61 per cent in 1999/2000), Egypt depends on imports for more than half its food needs.

Agriculture policy

In 2001, Egypt's population was around 69 million and its population growth rate estimated at 1.76 per cent. There are therefore strong pressures, despite the constraints imposed by limited water and land resources, to increase agricultural production.

Major changes in Egypt's agricultural policy have been introduced since the 1980s. Some of the significant steps taken under the agricultural reform policy include: gradual removal of government controls on farm output prices and the removal of farm input subsidies; removal of government constraints on the private sector in importing and exporting agricultural crops; imposition of limitations on state ownership of land and the sale of new land to the private sector; adjustment of the land tenancy system; and confining the role of the Ministry of Agriculture to agricultural research and extension.

The strategic goals of the new agriculture policy include:

- Optimizing crop returns per unit of land and water consumed
- Enhancing sustainability of resource use patterns and protection of the environment
- Bridging the food gap and achieving self-reliance
- Expanding foreign exchange earnings from agricultural exports

In contrast with the situation in many developing countries, investment in the agriculture sector has increased in Egypt in recent years, from 8.48 per cent of total national investment in 1995/96 to 14.4 per cent in 2000/2001. Agricultural irrigation and drainage accounts for a large share of this increase, with research, institutional support, and agricultural extension the other targeted areas of investment.

Potatoes and cucurbits in Egypt

— *Potatoes* (Guenthner et. al. 2002)

Production and consumption trends

First grown commercially in the late 1800s, the production and consumption of potatoes in Egypt have steadily increased over the years.

Potato is cultivated essentially in four regions of Egypt, three of which are continguous in the Nile Delta, and one which is also part of the Nile Valley. Until the 1990s, potatoes were grown on thousands of small farms in the traditional old lands of the Nile Valley and Delta regions, all supplying the same wholesale markets. With the development of new lands and the emergence of large farms, specialization in production has increased. In general, the smaller growers on the old lands use traditional practices, while the large growers and those on new lands have introduced new technology and production practices. Some large farms, including some owned by global processing firms, now specialize in production, either for the export market or for potato processing.

During the period between 1971 and 1996, potato production increased from less than 0.5 million metric tons to a record of more than 2.6 million metric tons. In the same period, yields increased from around 17 metric tons per hectare in the early 1970s, to more than 23 tons per hectare during the 1999-2001 period. In the past few years, production has remained more or less stable at around 1.8 million metric tons.

Domestic consumption per capita increased from about 7 or 8 kilos per year during the 1960s and early 1970s, to more than 20 kg/yr since the late 1980s. Demand has continued to increase since the 1990s, particularly for processed potato products.

Potato tuber moth (PTM) is a serious pest in Egypt. Despite recommended control practices which are followed by Egyptian potato growers throughout the entire cycle from sowing to harvesting, PTM continues to be a major, even devastating, pest for Egypt's summer potato crop.

Exports

Egypt has an advantage in the global potato trade due to its ability to harvest new potatoes from November until the end of June. During the 1990s, its potato exports grew from 136,000 metric tons to around 420,000, representing around 13 per cent of Egypt's total potato production. The bulk of potato exports were to the European Union, principally to Germany and the United Kingdom. Most of Egypt's fresh potato exports are marketed at the time when EU tariffs are lowest, that is from 1st January to 14th May. During this period Egyptian freshly-harvested potatoes compete with

European potatoes which have been in storage since the autumn harvest. Many consumers prefer the thin-skinned, new potatoes during that market window, and so Egyptian potatoes are often able to command a premium price.

— *Cucurbits*

Production and consumption

Cucurbit species, which have high nutritive value, have always been an important part of local diets in Egypt. Popular cucurbit species include a number of high value crops such as watermelon, melon, cucumber, squash, and pumpkin. Cucurbits, in general, account for around a third of total vegetable production and occupy about a fourth of total cultivated vegetable area.

Around 46,000 hectares of watermelons, 28,000 hectares of squash, pumpkins and gourds, 20,000 hectares of cantaloupes and other melons, and 18,000 hectares of cucumbers are produced annually.

Infection by viruses, including several potyviruses such as zucchini yellow mosaic virus (ZYMV) and cucumber mosaic virus (CMV), is a major production constraint in cucurbits. Productivity is also constrained by environrnental dehydration-related stresses such as drought and salinity.

Exports

A large share of cucurbits produced in Egypt are consumed domestically, but exports of melon and water melon exceed $1 million annually.

Elements of the national system for research, product development and diffusion

— *Agricultural research*

Egypt has a relatively long tradition of agricultural research. The first school of Agriculture was established in 1869, and the first Directorate of Agriculture in 1875. Research on cotton in Egypt was initiated in 1898 during British occupation. The establishment of several other agricultural research institutes followed during the first 20 years of this century, while Egypt was still under British rule. Since then, and particularly after 1960, Egypt has built one of the largest agricultural research systems in developing countries (Pardey, eds. 1991).

Until 1971, agricultural research was conducted within the various departments of the Ministry of Agriculture. The research departments were then reorganized into a single research body, named the General Authority for Agricultural Research, which was reorganised and renamed the Agricultural Research Centre (ARC) in 1983. As the principal agency within the Ministry of Agriculture and Land Reclamation responsible for research, technology generation, and transfer to Egyptian agriculture, the ARC comprises 16 research institutes, 6 central laboratories, and 46 experimental research stations, and employs more than 2,500 Ph.D. researchers.

Total funding for agricultural research in Egypt, including both national and external contributions, reached L.E. 242,2 million per annum, amounting to 1.21 per cent of the national agricultural income during the fiscal year 1991/2. The major external contributors are the United States, individual European countries, the European Union, Canada, Japan, UNDP, and FAO.

The need to increase agricultural productivity within a diversity of farming systems has highlighted the need for closer collaboration among national agricultural research bodies. In an effort to foster such collaboration, research and extension councils have been established in four different targeted agro-ecological zones in Egypt. Each zone is served by a regional council representing universities, regional research and extension stations, and national research centres: the Agricultural Research Centre (ARC), the Desert Research Centre, the National Research Centre of the Ministry of Scientific Research and Technology, and the Water Research Center of the Ministry of Public Works and Water Resources.

— *Biotechnology*

Biotechnology policy and research

The Academy of Scientific Research and Technology (ASRT) has overall responsibility for coordinating biotechnology research activities at the national level. Although some industrial, environmental, and public health biotechnology research is conducted, the major focus is on agriculture. Similarly, although a number of universities (Menoufia University, Cairo University, and Ain Shams University) conduct biotechnology research, a single institution has developed into an internationally recognized "centre of excellence ". This is the Agricultural Genetic Engineering Research Institute (AGERI).

The broad priorities fixed for biotechnology research in Egypt relate to :

- Producing transgenic plants resistant to indigenous biotic and abiotic stress
- Reducing the use of agrochemicals and pesticides and their environmental risks
- Improving the nutritional quality of food crops
- Reducing dependency on imported agricultural products, both seeds and crops

Priorities for biotechnology research are set as a function of the 5-year Plan for Agriculture.

Biosafety

Egypt was one of the first developing countries to develop biosafety guidelines, the Ministry of Agriculture and Land Reclamation (MALR) having issued 2 decrees in 1995, the first which established a National Biosafety Committee (NBC), and the second which adopted biosafety regulations and guidelines. Procedures were then established for the review process and procedures established for field-testing. Procedures for commercial release were adopted in 1998. Once approved by the National Biosafety Committee, applications are forwarded to the Seed Registration Committee, which grants approval to begin three year (or three season) quality and performance evaluation. Only on completion of these trials will a conventional or GM variety be approved for commercial release.

In 1999, a joint review of biosafety policies and procedures in Egypt was conducted by AGERI and ISNAR (ISNAR, 2000). This review made a number of recommendations which included, first and foremost, the revision or re-issue of biosafety guidelines; establishment and funding of a Secretariat for the NBC; the institution of mechanisms to disseminate information to the biotechnology community at large; and development of a pro-active plan for building public awareness.

Intellectual property rights

A number of changes have occurred in Egypt's national system for the protection of IPRs in recent years. Although not a member of the Union pour la Protection des Obtentions Végétales (UPOV), Egypt does allow Plant Variety Protection, and recent changes have been made in its intellectual property law.

In parallel with research and development of GMOs in Egypt, changes have also been made with respect to IP policy within the ARC which, in 2002, adopted a Technology Management and Commercialization Policy. This new policy allows for the financial benefits of IPRs taken out on inventions produced within any of the institutions of the ARC to be shared with the inventor in the ratio 80 per cent for the institution and 20 per cent for the inventor.

Public and private sector roles in research, product development, and technology diffusion

To date, most of the agricultural research in Egypt has been conducted in public research institutions. The Horticulture Research Institute, one of the institutions under the umbrella of the ARC, conducts research on a large number of horticulture crops, including potatoes and cucurbit species. In the past, the Horticultural Research Institute has imported varieties of cucurbits, including watermelon, cantaloupe, cucumber, and squash, and conducted research to adapt them to Egyptian production conditions. It has also been involved in adaptive research on potato, for example, by introducing potato cultivation to desert areas. Little information is available on the research activities, if any, of the growing number of private companies involved in the production and export of horticulture products in general and cucurbits, and potatoes in particular.

The Horticulture Research Institute is also involved in seed production and continues to play an extension role by working with farmer cooperatives, conducting field days, or playing an intermediary role through demonstrations by large farmers. It thus provides links between research, product development, and technology diffusion.

— *the vegetable seed sector*

One of the recent important policy changes affecting technology diffusion was the 1993 decree, which reorganized the seed sector (ISNAR, 2000). This decree separated seed certification, quality control, marketing control, and law enforcement activities from seed production activities. The way was thus opened for private sector involvement in what had previously been an almost exclusively public sector activity. While the ARC retains overall responsibility, the Central Administration for Seed Testing and Certification (CASC), created in 1995, is responsible for seed quality control, legislation, and policy enforcement. CASC is the designated seed certification authority and performs lab and field testing for certified seed and lab testing for uncertified seed.

The Central Administration for Seed Production (CASP) administers and advises ARC on requirements for foundation and registered seed and plants. CASP also supervises and contracts with seed growers to multiply seed. As a result of these changes, Egypt now has a growing number (60 in the year 2000) of registered seed companies for seed production, import, and export.

In the cases of both cucurbits and potatoes, seed represents a relatively high share of total production costs. In the case of potatoes, seed costs have been estimated at 48 per cent for small farms and 31 per cent for large farms. In recent years, a growing share of seed is imported (55,000 tons) and the cost of potato seed imports is estimated at $US 33 million annually. Informants in Cairo report that locally-produced seed would cost much less.

* * *

In the period 1995-1999, 24 applications for contained or open field trials were reviewed by the National Biosafety Committee (NBC), and 23 permits were issued. Egypt now has several transgenic technologies in the research, product development, and commercialization pipeline, but none has yet been approved for commercial release.

INDONESIA

Agriculture

Indonesia is the largest archipelago in the world, comprising at least 47 different ecosystems. The Indonesian archipelago consists of several thousand islands, covering a total area of almost 2 million square kilometers, around 28 per cent larger than Alaska. Five islands (Kalimantan, Sumatra, Irian Jaya, Sulawesi and Java) account for 92 per cent of the country's land area. Java is by far the most intensively cultivated farming area.

With a population of around 210 millions, Indonesia is also the fourth most populous country in the world.

Indonesia's agricultural sector is dominated by food crops, including rice, maize, cassava, soybean, peanuts, and sweet potatoes, which account for around half the annual harvested area. The second most important sector is that of smallholder estate crops, including coconut, rubber, coffee, and oil palm, which account for around one third of the harvested area. Large estate crops, primarily oil palm, rubber, and sugar cane, account for around 10 per cent of the total harvested area.

The majority of farms are relatively small, averaging less than 1.0 hectare per holding. Agriculture is very labour-intensive and most farmers plant rice in the wet season. Where farmers have access to irrigation, they typically grow rice again in the dry season, or secondary crops such as maize or vegetables.

Until recently, in national development plans the Indonesian government regarded agriculture mainly as a support for the manufacturing and service sectors. Policies therefore positioned agriculture as a supplier of cheap food and industrial raw materials, as a price regulator, and as a source of cheap labour. However, since the financial crisis of 1997, policies regarding the agriculture sector have been reversed to the point where it is now regarded as a prime mover for the national economy.

As a consequence, the strategy for agriculture has been directed towards adding value, and agribusiness has become not just a new approach to agricultural development, but a strategy for Indonesia's economy as a whole. As part of the reforms which have reoriented the agricultural development model, decision-making has been decentralized to provincial and district levels to ensure that farmers' perceived needs are better taken into account.

Potatoes and cucurbits in Indonesia

Vegetables are an increasingly important item in the Indonesian diet. Lowland (below 1,000 metres) tropical vegetables, which include cucumber, melon, chili, pumpkin, swamp spinach, shallot, and eggplant, are grown principally in the coastal areas. Highland temperate vegetables, which include potato, cabbage, tomato, carrot, onion, leeks, and garlic, are grown primarily in the mountainous areas characteristic of the central areas of the archipelago.

In terms of harvested area, Indonesia's most important vegetable crops are chili, shallot, yardlong bean, cabbage, potato, Chinese cabbage, cucumber, and tomato. However, in terms of value, chili, shallot, potato, cabbage, tomato, French bean, leeks, carrot, and cucumber are the most important.

— ***Potatoes***

Production and consumption trends

Since the achievement of rice self-sufficiency in 1984, public efforts in Indonesia have been directed towards encouraging farmers to diversify crop cultivation. Potato is considered a strategic commodity because it is suitable for agro-ecological conditions in the cool highland areas of Indonesia. Since

1992, the Development of High Quality Seed Potato Multiplication System Project has been under way in an effort to develop a multiplication and distribution system for high quality seed potato to improve potato productivity. This has been conducted through the Ministry of Agriculture as part of technical cooperation with the Japan International Cooperation Agency (JICA).

From around 26,000 hectares in 1981, the total potato-growing area in Indonesia has expanded to around 65,000 hectares, with average yields of between 15 and 20 tonnes per hectare. The main potato producing areas are North Sumatra, West Java, and Central Java provinces, which together accounted for 80 per cent of total production in 2002. Between 1998 and 2002, the domestic consumption rate of potato grew at an average of 7.26 per cent per annum. Growth in demand has increased, in particular, for processing potatoes.

For Indonesian potato farmers, the potato crop is currently considered high input, high risk, and high output. Imported seed tubers are expensive, and the lack of elite potato propagules and improved Indonesia potato cultivars adaptable to specific environments are major constraints. Annual demand for seed has been estimated at 95,000 tonnes per season, of which 10 per cent is currently met by foreign suppliers.

Production is also constrained by lack of appropriate post-harvest and storage methods to reduce losses, especially for seed tubers.

Disease is another risk factor. The major diseases and pests of Indonesia are: potato viruses (PVX, PVY, PLR V), late blight, bacterial wilt, bacterial soft rot, root knot nematode, potato tuber moth (PTM), and green peach aphids. If the risk factors were reduced, potato would become a highly profitable crop.

Exports

Among total exports of fresh vegetables from Indonesia, potato exports have become a growing source of foreign currency earnings. In 2000, fresh potatoes were exported to south-east Asian countries, Saudi Arabia, Lebanon, and Sweden. Frozen potatoes were exported to Japan and several south-east Asian countries.

— ***Cucurbits***

Production and consumption trends

The most important cucurbit crops in Indonesia are cucumber and melons. A market survey by East-West seeds in 1999 assessed harvested area for cucumbers at 48,121 hectares, with a seed rate of 1 kg/hectare. With around two-thirds of farmers buying new hybrid seeds each year, there was an estimated annual cucumber seed demand of 32 metric tons. Similar estimates for melon indicated a harvested area of 2,150 hectares and a seed rate of 0.5 kg/ha. All farmers plant hybrid varieties, suggesting an annual melon seed demand of 1.1 metric tons.

Cucumber is grown by small-scale farmers, especially landless farmers who rent land to grow the crop. It is commonly consumed cut into small pieces and added to a main dish, and is consumed by all income groups. Virtually all cucumber grown in Indonesia is consumed domestically.

Melon, grown in the lowlands of Indonesia, includes both watermelon and other types of melon. In 1999, an estimated 2,150 hectares were planted to melon, which is grown primarily by small-scale farmers.

A study which has assessed the profitability of melon production (Mather et al, 2002) suggested that it is quite profitable and generates a significant amount of employment, most of which is hired labour. However, melon production is also risky due to severe pest and disease constraints. Thus, the high level of input costs and production risks represent barriers to entry for many Indonesian farmers.

In constrast to cucumber, melon is consumed primarily by Indonesians with relatively high income levels who can afford to pay its high price.

The zucchini yellow mosaic virus (ZYMV), which is transmitted by aphids, and downy mildew (a fungus) are both important constraints to higher cucumber yields in Indonesia. According to the Research Institute for Vegetables, viral diseases – especially ZYMV - reduce both farmers' yields (by 15 to 20 per cent) and the crop quality. Little information is available on the impact of pests and diseases on melon yields, but Indonesian informants report that viral diseases are a major constraint to higher yields and account for yield losses of around 15 per cent.

Elements of the research, technology development, and diffusion system

— ***Agricultural research***

Indonesia has a relatively long history of agricultural research. The first agricultural research initiatives were undertaken, in what was then called the Dutch East Indies in the early 1800s, with the establishment of tropical botanical gardens. The most important of these, set up in 1876, was the State Botanical Garden at Bogor. Its research program, which gained international recognition, involved the acquisition, screening, and field testing of new plant material, which was then released to private estate corporations. Eventually, these estate companies invested in and undertook their own, often crop-specific research, which was complemented by a variety of public research agencies established by the colonial administration during the early 1900s. This basic institutional structure, involving a mixture of public- and private-sector research initiatives, remained virtually unaltered for several decades (Pardy, eds. 1991).

The research effort became fragmented during the period of political turbulence and instability which marked the years following World War II. Shortly after General Suharto came to power and established food self-sufficiency as a national priority, the first steps were taken towards the creation of a national agricultural research system, under the Agency for Agricultural Research and

Development (AARD). Agricultural research, both in terms of investment and the number of researchers, grew steadily between the early 1960s and 1980. Indeed, Indonesia was among the largest of the NARs, with more than 1000 researchers in the period 1981-85. (Pardy, eds. 1991)

AARD has been restructured several times since its creation in 1974, and most recently to "create, engineer and develop new innovations needed to foster an agribusiness system which supports the agriculture sector to become a reliable sector in national development".

The IAARD is the umbrella organisation for agricultural research within the Ministry of Agriculture. Research is conducted by 7 major second-tier institutions focusing on the broad areas of socio-economics, soils and agro-climate, engineering, food crops, horticulture, estate crops, and livestock. In turn, each of these units manages several research institutes which conduct research in these fields.

The major reorganization of the research, technology development, and diffusion system in Indonesia which occurred in 1995 arose from a concern that the linkages between research and extension were inadequate in transferring new technology to small farmers. In response to that concern, research efforts have been decentralized and some of the regional substations of the Central Food Crop Research Center (CRIFC) upgraded and given mandates to play a leading role in research on specific commodities. At the same time, technology assessment centres were established in each province to create links between research, extension, and on-farm testing of new technologies. These changes reflect the growing capacity and widening agenda for agricultural research.

— *Biotechnology*

Biotechnology policy and research

In 1983, Indonesia formulated a strategy and policy document: the National Program of Development of Biotechnology. In 1985, the Indonesian government established a National Committee for Biotechnology at the State Ministry for Research and Technology to implement this biotechnology strategy. At the same time, it also established three Inter-University Centers on Biotechnology (IUC): one for medical biotechnology at the University of Gajah Mada, one for industrial biotechnology at Bandung Institute of Technology, and one for agricultural biotechnology at the Bogor Agriculture Institute. These were to become "centres of excellence" in biotechnology research. The project for the IUC for agricultural biotechnology was financed through the World Bank loan for 7 years at US$ 7.8 M.

In 1988, all the institutions involved in biotechnology were evaluated by the State Ministry for Research and Technology through the National Committee of Biotechnology in order to determine their stage of development. The evaluation included the Research and Development Center for Biotechnology at the Indonesian Institute of Sciences (LIPI), the IUCs, Agencies for Research and Development for the Ministries of Agriculture and Health, and the Agency for Assessment and Application of Technology. As a result of this evaluation, three centres were selected in 1990 to play the major role in their respective areas. These centres are:

- The University of Indonesia, Jakarta, for medical biotechnology
- Central Research Institute for Food Crops (CRIFC) of the Ministry of Agriculture, for agricultural biotechnology
- Agency for Assessment and Application of Technology, for industrial biotechnology

In 1995, AARD was reorganized to strengthen biotechnology research. The Biotechnology Division of CRIFC and the Bogor Research Institute for Food Crops were merged to become the Research Institute for Food Crops Biotechnology (RIFCB). Biotechnology research projects involving food crops, industrial crops, and estate crops were thus pooled under the supervision of RIFCB.

Further changes were made when it was decided to create, under the umbrella of the AARD, the Indonesian Agricultural Biotechnology and Genetic Resources Research Institute. IABIOGRI manages a number of its own research projects, but also serves as the site for efficacy and environmental safety testing for genetically engineered crops produced by other public institutes and private companies.

The most recent development is that Indonesia is now attempting to define a national biotechnology strategy. At the time of writing, the Bandung Institute of Technology has been charged with this task, which is being undertaken in collaboration with the Biotechnology Consortium of Indonesia, an informal grouping of institutions, universities, and companies involved in biotechnology.

***Biosafety* (DAI, 2003)**

National biosafety guidelines were passed by ministerial decree in Indonesia in 1997. Environmental impact and food/feed safety issues are assessed by a Biosafety and Food Safety Technical Team (BSFTT), which reports to a Biosafety and Food Safety Committee (BFSC) presently under the Indonesian Agency for Agricultural Research and Development (IAARD) in the Ministry of Agriculture (MOA).

Under Indonesia's existing regulations, parties interested in the commercialization of a transgenic crop first apply for approval from the Directorate General that has jurisdiction over that particular crop. The Director General then requests the BFSC to provide a recommendation regarding safety of the new plant. The BFCS recommendation is based on input from BFSTT, which conducts experiments in containment facilities and in isolated field tests (three locations in one season). BFSTT is also required to assess food/feed safety based on data submitted by the applicant. If the BFSTT assessment is favourable, the BFSC may then provide a positive recommendation to the Director General, who approves the entry of the transgenic plant into the multi-location variety testing system. For field trials which are purely for research and product development, the applicant applies to the BFSC, which also relies on input from the BFSTT, and grants approval for the field trial.

Food and feed safety issues are, in principle, considered in the recommendations made by the BSFTT and in any consequent ruling by the BFSC that the transgenic crop is safe. However, the draft food and feed safety guidelines have not yet been approved.

IPRs

In Indonesia, a plant variety protection law which meets the requirements of the 1991 UPOV Convention has been enacted, even though Indonesia is not a UPOV member. Because the pending PVP law has not yet been signed, the PVP office is not yet operational. At present, the patentability of genes under Indonesian law is also unclear. In the meantime, PVP is implemented by the variety release system, which grants variety names and provides protection via a trademark mechanism.

The government of Indonesia has established an Intellectual Property Rights and Technology Transfer Office under IAARD (KIAT) to address intellectual property protection, licensing, and technology transfer issues. KIAT has successfully helped IAARD to license crop varieties, which it has developed, to local seed companies.

Elements of the national research, product development, and technology diffusion system

An estimated total of US $278 million was spent on agricultural research in Indonesia in 1998/99 (Fuglie, 2002). Of that, around 45.5 per cent was provided by the central government from tax revenues, contributions of state-owned estates for estate crop research, and forest concession levies. Foreign aid accounted for another 25.5 per cent, and private companies for around 26 per cent. Linkages between IAARD and universities, and IAARD and the private sector, in conducting agricultural research have also been strengthened with the support of loans from the World Bank and the Asian Development Bank (ADB).

While the share of the private sector in agricultural research remains small, it has increased considerably in recent years. Most of the private sector research is confined to varietal testing and improving seed propagation methods. However, some private seed companies began to develop breeding activities in Indonesia in the late 1980s, in hybrid maize and vegetables.

— *the vegetable seed sector*

The Indonesian seed industry was long dominated by government agencies, or state companies which produce and multiply seed, and, until recently, also distributed improved seed to farmers. However, the liberalization of agricultural policy has opened the way for private sector activity, particularly for horticultural crops.

While a growing number of private firms market vegetable seed in Indonesia, the vegetable seed sector is highly diverse. Some firms produce and market seed of several different vegetables, while others specialize in just a few vegetables. A few firms breed varieties specifically for Indonesian conditions, but most import varieties from abroad. Some firms focus essentially on open-pollinated varieties, while others produce and/or market both open-pollinated and hybrid varieties.

As indicated above, a program has been under way for some years to improve the quality of seed potatoes and to develop an effective system for multiplication and distribution of certified potato seed.

* * *

Five imported transgenic technology products developed by multinational companies have completed field testing and environmental regulatory review in Indonesia, but are awaiting local assessment of food safety. Indonesia approved transgenic cotton for commercialization in 2000, but authorization was granted on an annual basis, and planting restricted to a small area in South Sulawesi. The Agriculture Ministry renewed the authorization for a further year in 2002, but, for reasons which are not entirely clear, Monsanto decided in July 2003 to suspend its sales of Bt cotton in Indonesia. No transgenic food crop has yet been approved for commercialization.

SOUTH AFRICA

Agriculture

The republic of South Africa, which has a total population of around 44 million people, covers an area of 122.3 million hectares. Gauteng, the smallest province, is the most densely populated, with 422 people per square kilometer; while Northern Cape Province, the largest, has a population density of only 2 people per square kilometer.

Varying climatic zones and topography permit the production of almost any kind of crop, so that South Africa is self-sufficient in many of its major crops. Agricultural production is fairly evenly balanced between the production of field crops (30 per cent of total agricultural value), horticulture (26 per cent), and livestock products (43 per cent). The dominant field crops are maize, wheat, and barley; the dominant estate crop sugar cane, the dominant horticultural crops citrus, deciduous fruit and potatoes, and the dominant livestock products are poultry, beef, and dairy.

Farming was first introduced into South Africa around 800 A.D. by early Bantu-speaking people, who cultivated sorghum and millet with iron hoes, and raised goats, sheep, and cattle. Settlement by Europeans began with the establishment of the Dutch East Company in the 1600s. By 1650, white farmers began to settle new areas and had introduced wheat, oats, and barley.

During the 19th century, the Cape colony expanded eastwards into Xhosa territory. Between 1830 and 1880, following the introduction of the ox-drawn iron plough which brought new land under cultivation, a prosperous African peasant class emerged in the Transkei, Ciskei, and Basutoland, competing successfully with under-capitalised settler farmers.

However, the situation of black farmers deteriorated from early in the 20th century, first with the

Natives Land Act of 1913, which restricted land ownership by black farmers to designated reserves. As more and more Africans lost access to their land, rural poverty became common.

During the 1930s and 1940s, a Co-operatives Societies Act was passed, and commodity boards (including a Potato Board) were set up. Controlled prices and marketing were introduced for some commodities, and levies were imposed on production to help finance research. From the 1960s, the agriculture sector expanded considerably, due largely to the mechanisation and modernisation of large-scale farms owned by whites.

Farm size and ownership currently differ greatly among races and areas. Only 1 per cent of black farmers own more than 10 hectares of land, 22 per cent own between 1 and 2 hectares, and 50 per cent of black farmers own less than one hectare. Commercial, white farmers use about 80 per cent of the potentially arable land. Farms are classified as large commercial, small commercial, small-scale, and resource- poor.

Following the installation of the new African government in 1994, the South African territory was reorganized, with 9 provinces where there had previously been 4. The incorporation of what were previously termed homelands has meant a major reorganization, and, in some cases, amalgamation of agriculture departments.

In 2001, South Africa developed a strategic plan for agricultural development, which places particular emphasis on the development of smallholder agriculture through land reform, access to credit, and market opportunities. The marketing sector has been deregulated to bring it in line with the social and economic democratisation of the country and with international trends. Within the strategic plan, priority has been awarded to ensuring that agricultural research, the transfer of technology, and education and extension are more responsive to markets.

Potatoes and cucurbits in South Africa

— ***Potatoes***

Production and consumption trends

Potato is the single most important vegetable product in the Republic of South Africa, with total production of 1,650,333 tons produced during 2001. The estimated gross value for the 2001 potato crop was R 2,014 million. Although cultivated on only 0.03 per cent of arable land, on average potatoes contributed over 2 per cent of the gross value of all agricultural products in South Africa in 2001 (Jordaan & van Schalkwyk 2002).

Potato is a relatively new crop in South Africa, the first growers' association having been formed in 1924. Since then, it has become a well-organised industry covering all aspects of potato research, production (including table and seed potatoes, potatoes for processing), seed certification, and product control, processing, consumption, and exports. Potatoes South Africa is today an active producers' organization.

Over the years, local research and breeding at ARC-Roodeplaat has provided new, improved cultivars adapted to South African production conditions. Due to the high risk of importing tuber-borne diseases, the import of conventional seed potatoes is not permitted. However, *in vitro* material and mini-tubers from approved institutions can be imported for the development of new varieties in South Africa.

The five main varieties cultivated in South Africa are: BP-1 (49 per cent), Up to date (18 per cent), Mondial (9 per cent), Bufflesport (6 per cent) and Vanderplank (4 per cent). In some provinces, potatoes are produced the whole year round, and potatoes are produced by both small-scale and large, commercial farmers.

This continuous growing season provides South Africa with a constant supply of fresh potatoes to both fresh markets and processing plants. The majority of production is in four provinces (Mpumalanga, the Northern Province, Eastern Free State, and the Western Free State), which provide 60 per cent of total potatoes produced.

Because potato is grown all year round, storage is not required on most farms. Commercial growers tend to store them in the ground for short periods after the end of the growing season. Diffused light storage is used for seed storage where it is economically feasible. Processors and fresh markets maintain cold storage for inventory control purposes.

Potato consumption has increased steadily in recent years, increasing from around 10 kilos per capita in the early 1960s to some 30 kilos in 1999.

A number of diseases and pests are major problems for South African potato growers. Diseases include: common scab, bacterial wilt, and late blight, which is a devastating fungal disease. Common viral diseases include Potato Virus Y (PVY), Potato Virus X (PVX), and the potato leaf roll virus (PVL V). PTM is also a destructive pest, although infestation varies among the different potato growing regions.

Exports

Most potatoes grown in South Africa are consumed locally. In 2000, 3 per cent of total potato production was exported, mainly to neighbouring countries such as Zimbabwe, Mozambique, and Angola.

— ***Cucurbits*** (Mather et.al. 2002)

Production and consumption trends

South Africa's annual fruit production (2000) is valued at around US $1 billion. Of that, the aggregate value of musk melon and sweet melon is approximately US $21 million. Vegetable production is valued at approximately US $603 million, with the aggregate value of marrows (zucchini), cucumber, and butternut squash valued at approximately US $64 million.

The production and consumption of vegetables in South Africa has in the past been highly segregated by race. This is due both to differences in consumer preferences between races, as well as to the enormous disparities between the resource levels of white and black consumers and producers. Whites traditionally produce and consume vegetables such as potatoes, tomatoes, onions, carrots, lettuce, and cucumbers, while blacks traditionally produce and consume pumpkins, cabbage, spinach, and some types of squash.

White farmers market their produce through large urban wholesale markets or directly to retailers (supermarkets, greengrocers, etc.). While some black farmers market their produce through the large urban wholesale markets, most sell them to smaller local markets or informal hawkers.

Black farmers face a number of constraints to producing non-traditional fruits and vegetables. Firstly, they have poor access to credit and land resources, and production costs are high. Secondly, packaging and transport costs are high. Thirdly, marketing presents particular challenges. For these reasons, with the exception of pumpkin and butternut squash, the majority of black farmers are not engaged in the production and marketing of higher-value fruits and vegetables.

In South Africa, five principal viruses attack cucurbits: zucchini yellow mosaic virus (ZYMV), watermelon mosaic virus (WMV), cucumber mosaic virus (CMV), papaya ring-spot virus (PRSV), and, more recently, the Moroccan strain of watermelon mosaic virus (WMV-M). Yield loss due to viruses is variable, depending both on the type of cucurbit and the timing of the attack.

The principal fungi which threaten cucurbits in South Africa include downy mildew (DM), powdery mildew (PM), fusarium (melon) wilt, anthracnose, and gummy stem blight (GSB). As a means of control, farmers apply either insecticide or fungicide, both of which may be carcinogenic.

Elements of the research, product development and technology diffusion system

- ***Agricultural research***

The Agricultural Research Council (ARC) is a parastatal organization, and one of nine Science Councils in South Africa. The ARC is the principal agricultural research institution in South Africa, currently responsible for approximately 60 per cent of all agricultural research in South Africa. It serves as research arm for both the National Department of Agriculture and the 9 Provincial Departments of Agriculture. ARC's role is the promotion of agricultural research, technology development, and technology transfer, to support the optimization of the role of agriculture in the national growth and development of South Africa.

ARC comprises 13 research institutes located in or around Pretoria, Potchefstroom, Bethlehem, Rustenburg, Stellenbosch, and Nelspruit. The research institutes also have research and demonstration trials at about 40 research farms at strategic sites throughout the country. In addition to the ARC, agricultural research is also undertaken at the University of Pretoria, Stellenbosch University, University of the Free State, and the University of Natal.

In accordance with current policy for agriculture, it is proposed to raise investment in agricultural research, education, and extension, from its current low level of 1.04 per cent to 3 per cent of agricultural GNP. Particular attention will be paid to:

- Promoting collaboration between the ARC, University Faculties of Agriculture, Provincial Departments of Agriculture, agribusiness, and other agricultural research institutions to refocus on strategic priorities, innovation, and adaptive research.
- Establishing a National Agricultural Research Forum to integrate, coordinate, and link agricultural research and industry with international agricultural research organizations and extension services
- Re-evaluating the funding basis to promote partnerships between agricultural research institutes, universities, and the private sector

— *Biotechnology*

Biotechnology policy

South Africa is one of the few countries in the world to have elaborated a National Biotechnology Strategy. Implemented in 2002, the strategy identifies the need to develop Biotechnology Regional Innovation Centres (BRICs) to facilitate commercialization and develop biotechnology companies in South Africa. To date, four BRICs have been established.

As part of the national strategy, a Biotechnology Roadmapping Project is currently under way. This initiative will identify the strategy for the development of a number of technology platforms/clusters over the next 5-10 years.

South Africa has a long involvement in traditional biotechnology. It has one of the largest brewing companies in the world, as well as a long-standing wine-making history. It has strong capacity in applications in fermentation, bacterial expression, tissue culture, and plant breeding. It therefore has a solid base for the necessary technical background and human/infrastructural capacity for the more recent developments in biotechnology, such as DNA marker technology, gene isolation, and the production of transgenic organisms.

Although South Africa has developed genetic engineering techniques and capacity over the past twenty years, commercialization is very recent. Few local products have been developed, even though approximately R 100 million is annually spent on biotechnology research and development.

Approximately 55 companies in South Africa are involved in biotechnology, and locally commercialized products are mostly in the plant and medical sectors. The number of field trials for GMOs has increased rapidly from 12 in 1995 to 45 in 1998. Examples of biotechnology products being developed locally include fungus-resistant strawberries, insect-resistant sugar cane, virus-resistant potatoes, and fungus-resistant maize and sorghum.

Biosafety **(Brink, 2003)**

South Africa has well-established and operational biosafety and regulatory structures in place, within the Department of Agriculture. The first field trials for transgenic crops were undertaken in 1990, under interim safety legislation. Between 1990 and 1999, an interim biosafety assessment and decision-making process was in effect, with the South African Committee on Genetic Experimentation (SAGENE) serving as focal point. This process was superseded by provisions in the GMO Act, which was implemented in December 1999.

The national biosafety framework requires risk assessment at all levels of GMO development and commercialization. It requires an independent scientific review of biosafety, which details risk management and biosafety communication requirements. Public input on applications is sought, and non-safety considerations are allowed in decision-making. National decision-making is undertaken by a multi-departmental committee which includes human health, agriculture, environmental impact, socio-economic, and trade considerations, as well as impact on labour.

— ***Intellectual property rights***

Similarly, South Africa has had IP legislation in place for many years, and has considerable experience with patenting and plant variety protection.

It is interesting to note that, at the time of writing, although a proposal to that end was made a few years ago, the ARC still does not have its own institutional IPR policy. This is not the case, for example, at Stellenbosch University, where scientists share the benefits of IPR royalties or revenues.

Public and private sector roles in research, product development and technology diffusion

In the past, public research institutions in South Africa have played an important role in horticultural research in general, as well as in product development and technology transfer through the extension system. In the past, a voluntary levy (which may shortly be made compulsory) paid by potato growers has helped finance potato research.

Potato is a crop for which the research, product development, and diffusion process is highly-developed and well-organised, with well-established links between the public research system (VOPI in particular) and other elements of the potato industry. This system has served consumers and commercial farmers well in the past, but will in future be required to facilitate access to new technology for poorer, smaller potato producers.

The situation is different with respect to cucurbits. Very little research on cucurbits is now conducted by South African public research institutes, and little information is available on the research activities of the private sector.

— *the vegetable seeds sector*

Private companies have long played an important role in the vegetable seeds sector, particularly for commercial, white farmers. Today, the South African vegetable seed sector is essentially private, dominated by 5 firms: Hygrotech, Stark Ayres, Mayford, Alpha Seed, and Selector. The first three account for approximately 88 per cent of the formal vegetable seed market.

* * *

South Africa was the first African country to commercialise transgenic crops. The first GM crop, Bt cotton, was initially tested in 1990 and was commercially released in 1997. Transgenic maize was approved for commercial release in 1998, and transgenic soybean in 2003. These new biotechnologies were developed and transferred by multinational companies. No locally-developed transgenic crop has yet been commercialized.

Chapter III

TWO NEAR-MARKET BIOTECHNOLOGIES DEVELOPED UNDER ABSP

This chapter traces the two near-market biotechnologies selected for analysis: (1) transgenic potato resistant to potato tuber moth (PTM) and (2) cucurbits resistant to multiple viruses and diseases. Each technology is traced from its origins in the ABSP project, through product development, to prospects for commercialization or final technology diffusion to the farmer's field, in Egypt, Indonesia and South Africa. It is to be noted that the analysis does not take fully into account the most recent developments of the ongoing follow-up project funded by USAID entitled "Commercialization of Bt Potatoes in South Africa" (Brink, 2003).

Technology 1: Transgenic potato resistant to PTM (Bt potato)

Research

The genetic engineering of potato for resistance to PTM was one of the biotechnologies included in the original project proposal submitted by MSU.

Globally, the cultivated potato *Solanum tuberosum* is one of the most important food crops, fourth in importance after rice, wheat, and maize. It is a highly productive crop and provides significant nutrition in developing country diets. For example, a single medium-sized potato contains about half the daily adult requirement of Vitamin C.

PTM is one of the most damaging pests in potatoes grown in the tropical and sub-tropical climates of developing countries. It causes severe damage in growing plants by mining leaves and stems, which disrupts photosynthesis and destroys growing tips; and by mining the tubers underground. In unrefrigerated conditions, it causes even greater damage in storage, due to secondary bacterial infection which renders the tubers unfit for human consumption or for use as seed. Farmers normally use large and frequent applications of insecticides, both in the field and in subsequent storage, to avoid PTM damage.

The development of potatoes with resistance to PTM, intended to result in substantial reduction in the application of harmful pesticides, was therefore awarded high priority in the ABSP project. At the time, adequate resistance had not been achieved through classical breeding, and the use of specific genes from the bacterium *Bacillus thuringiensis* (Bt) was yielding promising results in pest control with other crops in the United States. Priority was consequently awarded to transgenic approaches.

Potato is an important crop in the state of Michigan, and Michigan State University has a strong tradition and solid reputation in potato research and potato breeding. It is also worth noting that, as potato is a root crop, it has a relatively undeveloped seed sector. There is therefore little private sector breeding of potato, except for “niche markets”.

At the time the ABSP project was launched, research was already under way at MSU on the development and management of both natural and engineered resistance to Colorado Potato Beetle. MSU was therefore able to mobilise a strong team of scientists with proven capabilities in the genetics and breeding of potato, as well as entomologists working on the control of insects in potatoes. In addition, Dr John Dodds, who became the first Managing Director of ABSP, had previously been employed as Head of Research at the International Potato Centre (CIP) in Peru.

The essential objective of the research was to use transgenic potato plants expressing toxin genes from Bt as parental material in a breeding program to develop improved populations of potatoes resistant to PTM. The populations would subsequently be used to select improved advanced lines directed toward varietal development. Close cooperation between the laboratory and field programs was an important feature of the research effort.

As PTM is not indigenous to Michigan, during the first phase of research PTM specimens were imported from CIP to MSU. Dr Ramesh Saxena, an entomologist from CIP, worked as a visiting professor in Dr. Sticklen’s laboratory on collaborative research to evaluate the transgenic plants already developed against the growth, reproduction and behaviour of PTM at the laboratory and greenhouse levels.

During the first phase of ABSP, a suitable transformation and regeneration system for potato was developed and toxin genes from the Bt bacterium were inserted into cultivated potato germplasm. It was then planned in Phase II to build on previous work and to incorporate additional resistance genes and improved germplasm to develop a long-term resistance management strategy for this important pest.

Research was originally conducted using an unmodified wild Bt construct, but this was replaced following a recommendation of the Technical Advisory Group. During the second phase of the project the codon-modified Bt-cryV gene was obtained from Garst Seeds Company (formally ICI seeds and subsequently Syngenta) under a Materials Transfer Agreement (MTA). ICI Seeds, which was one of the early ABSP private partners, had initially developed the Bt-cryV gene for corn transformation. The gene was considered suitable for use in potato transformation and was initially obtained for research purposes only within the ABSP project. (See below for discussion on IPRs.) In later years the gene was renamed Bt-cry1Ia1

Research partners

Research collaboration was established from 1992 with Egyptian and Indonesian scientists and institutions: the Agricultural Genetic Engineering Institute (AGERI) in Egypt and the Central Research Institute for Food Crops (CRIFC) in Indonesia. CIP was a partner from the outset and made key contributions from the early research phase to field-testing at its station in Egypt.

In the second phase of ABSP, collaboration between MSU researchers and developing country collaborators was extended to include South Africa which was interested in the field testing of promising potato lines.

Product development

Agronomic evaluation of the Bt-transgenic potato lines was initiated in Michigan in 1994. Annual agronomic evaluations have since been conducted at this location and the trial size has varied to accommodate the number of Bt-lines being tested. These trials have shown that the agronomic performance of many of the Bt transgenic lines is similar to their non-transgenic cultivar.

Between 1993 and 1996, first greenhouse testing and then field-testing of the transgenic potato was conducted at a potato farm in Michigan. These tests were conducted on a non-Egyptian variety and, because PTM is not indigenous in Michigan, field performance was evaluated against the tobacco hornworm.

In 1995, the research team was ready to transfer their material to Egypt for testing, but this was delayed because USAID required more time to ensure compliance with United States environmental regulations involved in sending transgenic material overseas. Furthermore Egypt's biosafety guidelines were not yet implemented and operational. The MSU team therefore attempted to field-test the transgenic material in California using PTM, but this evaluation was unsuccessful due to the high temperatures which destroyed the adult moths before they had begun to lay eggs.

By 1996 the MSU team had established that the gene was effectively resistant to PTM and began transformation with the Dutch potato cultivar Spunta, which is in the public domain and therefore free of IPP. By 1997 the MSU laboratory was able to send its first- and second-generation Spunta material to Egypt for a small field test.

— ***in Egypt***

The first field test of genetically engineered potatoes in Egypt took place in January 1997 at AGERI, after the Egyptian biosafety regulations were established. The purpose of the trial was to evaluate 14 Bt-transgenic potato lines for field resistance to PTM. These first results were very promising, both with respect to foliar mining and tuber infestation.

Subsequent trials have been conducted at AGERI and, since 1999, at the CIP Potato Research Station located in the Delta potato-producing region. The field and storage trials at the CIP Research Station were successful in identifying the best performing Bt-cry1Ia1 Spunta lines (Spunta-G2 and Spunta G-3). Spunta is a popular local fresh market cultivar in Egypt. Phenotypically, they are similar to untransformed Spunta.

In total five years of field trials have now been conducted in Egypt in two locations, both in the field and in storage. The data collected during these trials indicate control of PTM in the tuber of between

99 and 100 per cent. The storage trials have demonstrated that, under ambient temperature using the traditional Nawalla storage system widespread among small farmers in Egypt, the resistance to PTM holds for approximately 2-3 months. In cold storage, which is used by most commercial potato producers, resistance appears to hold for up to a year.

MSU researchers have prepared lines for field-testing targeted specifically at the Egyptian chip processing industry. In 2002 it was planned to test a number of these lines from seed produced in the United States on commercial farms in Egypt. However, due to current provisions of Egyptian plant registration laws this was not authorised.

Multi-location trials of Bt potato have not yet been conducted in Egypt.

— ***in Indonesia***

In October 1997, MSU sent transgenic lines of the potato cultivars Atlantic and Lemhi Russet containing the cry1Ia1 gene for greenhouse testing. Glasshouse tests which were conducted in 1998 showed that the cry1Ia1 protein was very effective against PTM. The next step in the evaluation and product development process should have been contained field-testing of the Bt potato lines. However, this was postponed in 1999 for reasons discussed below (see biosafety).

— ***in South Africa***

In South Africa, the MSU-developed PTM-resistant lines of the cultivar Spunta were field-tested by the Vegetable and Ornamental Plant Institute (VOPI) in 2001/2002 at Roodeplaat, Pretoria. In the first year of trials the Spunta G2 and Spunta G3 lines were free of tuber moth damage in the field, in both foliage and tuber. In storage trials, they were highly resistant to the PTM in diffused light storage tests.

The following year (2002/2003) field tests were carried out at 2 sites: Roodeplaat and Ceres in the Western Cape Province, which is a major table and seed-potato producing region. These tests gave similar results in terms of resistance to PTM. In addition, the yield of the Spunta lines (both transgenic and non-transgenic) proved 30 per cent higher than BPI which is a major South African cultivar.

Biosafety

From the beginning, complying with biosafety regulations and procedures, whether in the United States or partner countries, has been a time-consuming, complicated activity within the ABSP project. Probably the first step taken to comply related to the USDA/ APHIS permit which was required to import specimens of PTM from CIP in Peru to MSU.

At the time the ABSP project was initiated, regulations regarding the release, management and commercialisation of GMOs, or products derived from GMOs, were already in place in the United

States and methods for risk assessment, whether for food safety or for the environment, had already been developed and implemented. This was not the case with the developing country partners.

When the transgenic potatoes were ready for field evaluation in Egypt and Indonesia, neither biosafety guidelines nor containment facilities were available. The construction of a greenhouse facility at AGERI was undertaken in 1995 in collaboration with the University of Arizona. This biocontainment facility was the first of its kind in Africa, outside South Africa, and served as a model for a similar facility built in Indonesia with joint funding by the World Bank and the Indonesian government.

At the time the potatoes were finally ready for field evaluation and the biosafety guidelines and containment in place in Egypt, a further delay occurred as USAID was unable to give clearance to move such material to another country before first reviewing the implications of the product in terms of its existing environmental regulations. An ad hoc committee was created and USAID clearance was finally obtained in 1996.

As indicated below, in all three countries included in this study, a number of complex and time-consuming biosafety issues still remain to be resolved before application can be made for commercialisation of the Bt potato.

In Egypt, a report was prepared in 2001 which provided recommendations on food safety and environmental safety assessment guidelines for the commercialization of transgenic crops. At the time of writing, it is not clear whether these were adopted by the National Biosafety Committee. It is clear, however, that food and feed safety, as well as environmental impact assessments will be required to complete the biosafety procedures required prior to commercialisation.

In addition to the lack of clarity in the policy for commercial-scale biosafety approval, an additional issue arose in Egypt during the late stages of ABSP. The Bt potatoes being developed are of the Spunta variety which is a popular variety for local consumption. With the European Union ban on imports of GMOs in place, Egypt would be required to ensure that it could effectively segregate the Bt potatoes from the non-transgenic varieties exported to Europe. This trade issue has undoubtedly had an impact on the efforts of AGERI to move the Bt potatoes closer to commercialization.

In the case of Indonesia, the contained field testing of Bt potato lines which was to have taken place following the successful greenhouse tests was postponed (1999) when the Indonesian authorities announced their intention to revise the provisions on biosafety to include food safety assessment. Transgenic lines developed by MSU (Atlantic and Spunta), which have higher levels of cry11a1 expression and improved resistance to PTM, are still awaiting contained field testing.

In South Africa, a number of time-consuming biosafety steps need to be accomplished before application could be made for commercialisation of the Bt potato. These include the collection of data required for food and feed safety; environmental impact assessment; and socio-economic impact assessment. A “road map” for fulfilling these requirements has been established with ABSP funding. The estimated cost for the food and feed safety and environmental impact studies is in the order of $900,000 over a period of four years.

Intellectual property rights

Thus far, the proprietary technology used in the development of the Bt potato is without freedom to operate beyond the research stage. The proprietary technology includes: the Bt-cry11a1 gene owned by Syngenta, the 35s promoter and the NTP-II selectable marker gene owned by Monsanto. This IPR constraint applies in all three countries included in this study: Egypt, Indonesia, South Africa.

The ABSP project at MSU licensed the cryV gene (now referred to as cryIIal) from the ICI Seeds Company on October 21, 1994. The gene was licensed for research purposes only to develop transgenic potatoes resistant to PTM. The initial licence, granted for a period of three years, was extended for an additional 3 years (until October 2000) by the Garst Seed Company on October 7, 1997. At the end of that period the Syngenta Company agreed to a further extension of the licence, first until until June 2002 and, subsequently, until 31 December 2002. The research licence has been further extended to allow for the period of negotiation needed to obtain a commercial licence from Syngenta applicable to South Africa.

In January 2003, a meeting between ABSP, a USAID representative and representatives of the Syngenta company was held in Basel, Switzerland, to discuss the commercialization of Bt potatoes in developing countries. The outcome of the meeting was that the Syngenta company was willing to grant a royalty-free commercial licence to MSU to make this technology available to developing country partners under certain terms and conditions. The company also offered to work with MSU to obtain freedom to operate (FTO) on third party intellectual properties used in the development of the Bt potato product, which include the NPT-II selectable marker and CAMV 35s promoter.

MSU is currently in the process of negotiating a non-exclusive research, development and commercial licence with the Syngenta Company for the cry1Ia1 gene used in the development of PTM-resistant Bt lines. The first target country/territory for commercialization will be South Africa.

Of the three countries, South Africa is the only one in which intellectual property protection is neither a legal nor institutional impediment. In both Egypt and Indonesia, the lack of clarity regarding IPRs is a clear constraint to the transfer of proprietary biotechnology.

Socio-economic impact assessment

An *ex ante* study which has assessed the costs and benefits of the PTM-resistant potato was conducted with respect to Egypt and South Africa (Guenther et.al. 2002). The findings suggest this technology would contribute significant benefits to consumers in terms of a more abundant supply, lower prices and higher quality. Enhancing the supply of low-priced, nutritious food would be of particular benefit to poor consumers in both countries.

In assessing the costs and benefits at the farm level, the findings suggest that in the aggregate Bt potato would benefit potato farmers in terms of reduced insecticide costs, increased yields, improved quality and reduced post-harvest losses. Nevertheless, there would be some winners and some losers. Atchley (2000) found that the impact for resource-poor farmers in South Africa could be negative even if they did adopt PTM-resistant potato because the increased production from the large commercial farms which adopt the technology could drive down prices. Since the resource-poor farmers spend relatively little to control PTM, their cost savings in terms of cash would be small.

One assumption made in the study is that potatoes from resource-poor farms compete in the same markets as those from large commercial farms and all growers receive the same average price. Although in all likelihood there is some market overlap, the isolated location and poor transport systems in many rural communities reduce the external influence on their local produce markets. In those isolated South African areas where many resource-poor farmers live, the producer benefits of PTM resistance might indeed be positive. Since accurate information on PTM damage is not available for resource poor farmers and the budget calculations used opportunity costs, the actual benefits may be understated. What is certain is that lower potato prices would benefit poor consumers living in rural communities.

The same study suggests that the competitive position of both Egypt and South Africa, would be enhanced with the GM technology, particularly with respect to potato exports. This would depend, of course, on export markets being open to transgenic crops, which is not the case at present for countries of the European Union.

Prospects for commercialization

In each of the three countries included in this study, commercialization/diffusion prospects for the Bt potato remain unclear. All field testing thus far conducted has illustrated the efficacy of the technology in the control of PTM, both in the field and post-harvest. In addition, as PTM poses a threat to both the quantity and quality of local production, and the demand for potato is increasing in all three countries, there is in principle a clear demand for the technology.

Despite the potential demand, however, constraints to commercialization exist in all three countries and in some respects, the constraints are common to all three. For example, in all three cases outstanding biosafety issues need to be addressed.

Egypt is, in principle, the most advanced of the three countries in that several years of field-testing of Bt potato have already been conducted, although these have not yet included multi-location trials. Trials have already been conducted with cultivars which are popular with local consumers. Nevertheless, food safety and environmental risk assessment are still outstanding and the specific, detailed data requirements for those assessments have not yet been determined.

In the case of Indonesia, only contained glasshouse trials have thus far been conducted.

In South Africa, a number of constraints to commercialisation remain. One is that multi-location field trials will be needed to test the effectiveness of the technology. To date, the cultivars which have been field-tested are not those most in demand by producers and consumers. Further time will therefore be required for the technology to be transferred into local, popular cultivars. An added complication is that it will be necessary for the technology to be integrated into cultivars grown by resource-poor farmers. The necessary transformation work will be conducted by VOPI.

Again, in all three countries, negotiations would need to be conducted (or completed in the case of South Africa) with Syngenta and, possibly, other companies to resolve any outstanding IPR and/or licensing issues.

Assuming the biosafety and IPR issues are resolved, it is still not clear how the Bt potato would be produced and distributed. In the case of Egypt, some interest has been shown in the production of the transgenic potato by a private company, but the company is interested principally in the export market rather than distribution for the domestic market. One company, with which discussions were held during a recent visit, may be prepared to help meet the costs of biosafety procedures which would otherwise need to be met by AGERI.

In the case of South Africa, uncertainty remains regarding who would produce the potato destined for resource-poor farmers. If the technology is developed by ARC, it is not clear which private sector partner would be prepared to go into production and distribution. During a recent visit to South Africa, it was made clear that private companies would be interested in distribution to commercial farmers, but less inclined to market to resource-poor farmers. Discussions have since taken place between VOPI and a company which already supplies to small farmers.

Indonesia has recently conducted a study funded by the Japanese International Cooperation Agency (JICA) to examine how a network system for high quality seed potato multiplication and distribution in Indonesia might be organized. This network would involve potato growers in some of the most productive potato-growing regions and is a first step towards establishing a production and distribution system for the future which could be effective in the distribution of the Bt potato.

A major obstacle to final technology diffusion in all three countries is the adverse public perception of GM technology. Egypt has not yet released a transgenic crop and is extremely adverse, in the case of the Bt potato, to taking the risk of losing its growing European export market for potato. Even if the technology were released for the domestic market, Egypt would need to have a traceability system in place to guarantee that non-transgenic export potato had not been "contaminated". While South Africa is well advanced in preparing procedures for identity preservation, this is not yet the case in Egypt.

Indonesia has already released Bt cotton, but has thus far been unable to move forward on a food crop due to the lack of approved food safety guidelines and in the face of strong opposition from environmental NGOs. And, indeed, at the time of writing, Monsanto has decided to suspend its production of Bt cotton in Indonesia.

* * *

In summary, more than 40 Bt potato lines have been field-tested in Michigan, Egypt and South Africa over the life of the ABSP project. Not only have they performed well agronomically, but they have also expressed excellent resistance to PTM both in the field and in storage. The obstacles to commercialization in Egypt and Indonesia lie with factors which are not directly related to the intrinsic properties of the technology.

Technology 2: Transgenic and non-transgenic disease and virus-resistant cucurbits

Research

The genetic engineering of cucurbits using coat protein genes for potyvirus resistance was one of the technologies included in the original proposal by MSU for the ABSP project. Potyviruses in general form the largest and most economically important group of plant viruses which infect cucurbit crops in particular: cucumbers, squashes and melons. Within this group of viruses, zucchini yellow mosaic virus (ZYMV), watermelon mosaic virus (WMV), the watermelon strain of papaya ringspot virus (PRSV-W) and cucumber mosaic virus (CMV) cause severe economic losses in cucurbit crops in developing countries. These viruses can cause crop losses ranging between 50 and 100 per cent. ZYMV in particular is a new, extremely aggressive virus first reported in Europe in 1981, which has subsequently spread rapidly throughout the world.

The overall goal of cucurbit research under ABSP was to develop high quality cucurbits with multiple virus and disease resistances. To that end, a two-pronged research approach was taken using a combination of molecular genetics and conventional breeding approaches. The former approach was led by Dr Rebecca Grumet at MSU who, at that time, had already c1oned and sequenced ZYMV and was working on a transformation system for introducing this coat protein into cucurbit crops. The latter approach was led by Cornell University which has a long tradition in the breeding of cucurbits, combining virology, plant breeding and biotechnology methods.

At the outset, MSU was to take the lead in this research. ABSP's collaboration with Cornell University began in 1993 under a collaborative project with AGERI, funded by the USAID Mission in Cairo. Cornell University has had a long history of research collaboration with Egypt, beginning in the 1970s, when Dr. Henry Munger started a collaborative melon breeding program. When the ABSP/Egypt project started in 1993, Dr Munger was included as a collaborator to continue and build upon past linkages and experience in collaborative melon breeding. When Dr. Munger retired in 1995, Dr Margaret Kyle Jahn succeeded him in leading the project.

For a number of years the major objective of MSU to develop an efficient transformation system for cucurbits was focused on the development of a novel non regeneration dependent system for cucurbits. Two possible approaches were investigated; one an electro- transformation system already developed for use with legume crops, and the other pollen-tube transformation widely used in China for several crops. Finally, neither of these approaches produced the desired results, but cucumber was eventually successfully transformed in 2002 by means of an *agrobacterium*-mediated system using cotyledons and regeneration through tissue culture.

Collaboration between MSU and AGERI led to the transfer of melon transformation techniques and the ZYMV coat protein gene to AGERI. This gene has been used successfully by scientists at AGERI to produce transgenic melons and squash.

With respect to the non-transgenic approach, the Cornell research team made significant progress during Phase 1 of ABSP, and resistance to one or more of the major virus diseases was achieved. Until 1996, all funding for the cucurbits research at Cornell was provided by USAID/Cairo and all the work focused on Egypt. However, as viruses are a serious problem all over the world, given the success achieved at Cornell, funding from the core ABSP project was made available in the second phase of the ABSP, that is from 1997.

During the life of ABSP, a wide array of breeding lines were developed at Cornell for 4 cucurbit species. These included:

- Zucchini (including the Eskandarany type), for virus and powdery mildew resistance;
- Tropical pumpkin, for multi-virus and powdery mildew resistance;
- Melons, for multi-virus and powdery mildew resistance; and
- Cucumber (including Beit Alpha and Asian varieties), for various combinations of four viruses and powdery and downy mildew resistance.

Product development

The team at Cornell has been active in establishing contacts with both public research institutions and private companies all over the world and in transferring material for evaluation or for product development. Cornell material has thus been transferred to a growing number of countries in Africa, Asia and Latin America.

In 2000 Cornell hosted a major field day at Ithaca, attended by 15 seed companies from around the world. Following that successful field day, in 2001 ABSP supported efforts to make Cornell's cucurbit material available to additional developing countries by organizing international trials of some Cornell materials. Two of the trial countries were South Africa and Indonesia, where Cornell had already established contacts with private seed companies willing to collaborate in the trials. Cornell material was also sent to the HRI in Egypt for testing.

— ***in Egypt***

For reasons which are not clear, the collaboration with AGERI and the Horticultural Research Institute for the testing of non-transgenic material from Cornell was not pursued.

However, the collaboration between AGERI and MSU on research on transgenic cucurbits continued. AGERI researchers have transformed squash plants of a local Egyptian cultivar of the Eskandarany type, using a construct with the ZYMV coat protein gene developed by MSU. Resistance has been evaluated under greenhouse and field conditions at AGERI. Preliminary field trials in 1999 and 2000 demonstrated that between 92 and 96 per cent of the transformed plants were highly resistant to ZYMV infection, with symptoms of virus infection not appearing until 8 weeks post-inoculation.

Melons have also been transformed to resist ZYMV and these plants have been tested in the greenhouse. AGERI researchers have also developed a transformation and regeneration system for Shahd El-Dokki, a local Egyptian cultivar. Two lines were tested through the R2 generation and a number of plants appeared to be free of virus symptoms at six weeks post inoculation with ZYMV.

AGERI researchers have introduced the ZYMV coat protein gene into cucumber plants using a local cultivar Beit Alpha via *Agrobacterium tumefaciens* transformation. Four lines contain the ZYMV coat protein gene via ELISA and PCR analysis and await further characterisation.

AGERI researchers have also established a regeneration system in watermelon using the Egyptian cultivars Giza 1 and Giza 2.

— *in Indonesia*

In Indonesia, East West Seed Company conducted field trials and evaluation of several of Cornell's cucumber and melon breeding progenies in 2001. The cucumber material consisted of five Beit Alpha type cucumber progenies with multiple disease resistance, resistance to four viruses and to several leafspot diseases. Melon material included 12 cantaloupe and honey dew type melon progenies bred for powdery mildew resistance and resistance to the same four viruses. The essential purpose of these trials was to obtain a general idea of the acceptability, potential and performance of the Cornell cucumber and melon germplasm.

It is to be noted that the cucumber type of the Cornell progenies was different from that preferred by Indonesian consumers. Indonesian consumers prefer a very pale green (almost white) and smooth cucumber to the Beita Alpha type. In the case of the melon trials, the Cornell virus-resistant melon germplasm generally matured later, was less vigorous and lower-yielding than Indonesian types. However, consumer acceptance would not be a problem as the Cornell material is similar to melon varieties grown in Indonesia.

East West Seed concluded that Cornell material had potential both for disease and virus resistance in a backcrossing program. It would be necessary, however, to determine which virus strains are the most prevalent in Indonesia. East-West was particularly interested in the gummy stem blight (GSB) resistance potential in the Cornell germplasm.

East West seed estimated that, in the case of cucumber, it would take 19 generations to incorporate virus resistance into a variety acceptable to Indonesian consumers. In addition, two generations would be required to carry out multi-locational testing (dry and wet season) and an additional year to produce seed. Assuming three generations per year, six years would be required to develop a virus-resistant hybrid cucumber variety, and seven to eight years to introduce the variety into the market. Similarly, an estimated 5 years would be necessary to incorporate virus resistance into a melon variety. Thus, 6 to 7 years would be required to introduce a melon variety into the market.

— ***South Africa***

Collaboration between Alpha Seed Company of South Africa and Cornell's cucurbits program began in the autumn of 1999, independent of ABSP. When ABSP began organising international trials of Cornell's cucurbit lines in 2001, Cornell recommended Alpha Seed as a collaborator. Alpha Seed subsequently agreed to field test various Cornell lines in Spring 2001.

Included in the Cornell experimental lines were: Eskandarany-type squash; melon; butternut squash; and cucumber. Trials were not organised to give any indication of yield gain potential of the Cornell sources of resistance, although they did demonstrate the resistance potential.

Zucchini, melon, butternut squash and cucumber have now all been tested in South Africa (Mather et al., 2002). It would take about five years for a multiple virus and fungus-resistant variety of zucchini and yellow squash to be released in South Africa; five years for melon with Fusarium wilt resistance; and three years for Cornell and a South African seed company to certify a butternut squash variety with PM resistance. With respect to cucumber, this depends on the time it would take for Cornell to cross its multiple virus- and fungal-resistant Beit Alpha material with the more popular English type favoured in South Africa.

Biosafety

Egypt is the only one of the three countries to have pursued research on transgenic cucurbits and particular biosafety measures (other than phyto-sanitary) are not, of course, required for the material developed by Cornell University. Although several years of field-testing have now been conducted with transgenic squash, watermelon and melon, multi-location testing has not yet been carried out and biosafety procedures for food and environmental safety – as for transgenic potato — would need to be clearly determined and carried out before application could be made for commercialisation of these new technologies.

Intellectual property rights

As with the Bt potato, a number of IPR issues would need to be resolved before any of the transgenic cucurbit products could be commercialised.

MSU shared with AGERI a construct containing the viral coat protein gene, together with a 35s promoter, NAS terminator and NPT-II selectable marker. This arrangement has been for research purposes only. The coat protein gene, which was cloned by Dr. Rebecca Grumet at MSU, is not protected and is therefore in the public domain. The coat protein approach/strategy, patented last year as a joint invention between Washington University and Monsanto, has been licensed to Monsanto Company by Washington University. The 35s promoter and NPT-II marker gene are owned by Monsanto Company, but no patent has been taken out in Egypt. If the cucurbit technology is to be commercialized in Egypt, a clear IP audit will need to be carried out and FTO negotiated.

The IPR situation is quite different with respect to the cucurbits developed by Cornell.
Over the 50 years of Cornell's breeding program, germplasm was shared informally with private sector seed companies in the United States and in developing countries. In recent years these formerly personal relationships have been formalized and recipients of Cornell material are now required to sign a Material Transfer Agreement (MTA). The MTA agreement specifies that if the company incorporates a Cornell line in a new variety, Cornell will be paid a royalty based on sales, typically 5 per cent if one parent is from Cornell and 10 per cent if two parents are from Cornell.

Socio-economic impact assessment (Mather et al 2002)

An *ex-ante* assessment of the impact of Cornell's disease-resistant cucurbits has been conducted for Indonesia and South Africa. The primary focus of the study was to assess whether or not the potential benefits from developing disease-resistant cucurbit varieties for Indonesia and South Africa would generate a positive rate of return to the entire ABSP/Cornell cucurbits investment. However, it also used analysis of the cucurbit sub-sector to investigate the potential distribution of aggregate benefits among different types of producers and consumers.

The analysis suggests that, in the case of Indonesia, the new disease-resistant varieties would increase income and generate employment for small-scale farmers as well as reduce the retail price for all cucumber consumers and higher-income melon consumers.

In the case of South Africa, however, the distribution of potential benefits would be skewed as the new varieties would increase the income of large-scale (white) growers and primarily reduce retail prices for high-income whites. While these crops would generate demand for labour for black women, black farmers would not benefit as these crops are not traditionally grown by small-scale farmers.

Prospects for commercialisation

Interviews with seed companies in Indonesia, Egypt and South Africa suggest the prospects for commercialisation of the non-transgenic cucurbits are promising. However, some 2-5 years would be required for ensuring that the virus- and disease resistance is effective in cultivars for which local demand is strong. Prospects are most promising for: cucumber in Indonesia; melon and squash in Egypt; and pumpkin or squash in South Africa. In all three cases, interest has been shown on the part of private seed companies.

Prospects for the transgenic cucurbits in Egypt are unclear for reasons which bear no relation to the efficacy of the technology. One reason is that biosafety procedures need to be carried out and it is uncertain whether, at present, Egypt has the necessary human and institutional capacities. There is also the problem of meeting the high financial costs of conducting complex and time-consuming biosafety assessments. A final issue is political, that is to say the Egyptian government appears reluctant to confront vigorous media opposition to GMOs and to go ahead with the commercialisation or final diffusion of transgenic crops.

* * *

The two transgenic biotechnologies which have been traced have performed well both in terms of agronomic performance and in disease- and pest-resistance. They still require testing in different geographic areas and production conditions through multi-location testing. However, moving closer to diffusion to farmers is constrained not so much by characteristics of the technologies, but by problems of product development, including regulatory hurdles.

Chapter IV

KEY LESSONS FROM ABSP

This chapter attempts to distil key lessons from the ABSP project, particularly as they relate to the two technologies on which this study has focused. It is not the intention here to enumerate all the notable achievements of ABSP. Instead the chapter focuses on lessons from the ABSP experience likely to be most relevant to other publicly-funded agricultural biotechnology projects. The areas of focus are: research; policy activities; product development and technology diffusion; private sector partnerships; management.

The ABSP project officially terminated at the end of June 2003. During its lifetime, changes occurred within the project in terms of direction, objectives and management. Management were confronted with funding uncertainty during the first phase of the project and, in the second phase, with an external environment which had changed from one where new biotechnologies – and, in particular, transgenic crops – were perceived by the general public as a potentially positive development, to one where consumers and NGOs alike were united in a number of countries in their opposition to GMOs. Negative attitudes towards GMOs, expressed most vigorously in Europe, also affected developing country attitudes.

The ABSP project had a number of unique, pioneering features. First and foremost, was the goal it set to make transgenic crops available to developing country partners. Secondly, it established innovative public/private partnerships and partnerships between private companies. Thirdly, it sought to link research with emerging policy issues specific to biotechnology: biosafety and IPRs.

Perhaps the most significant achievement of ABSP was the extent to which it raised awareness in developing countries, not only of scientific developments in agricultural biotechnology, but also of the need for appropriate policies and institutions to underpin the development and application of biotechnology innovations in their particular country contexts. This was achieved not only through the various policy activities conducted both in the United States and in developing countries, but also through communication and networking activities throughout the life of the project. In addition, project staff participated actively in international meetings on agricultural biotechnology and in meetings in developing countries which were not directly involved in the ABSP project. This gave the project a high profile within the international biotechnology and development communities.

Research

— *Research priorities*

It is to be recalled that the ABSP project was designed and implemented before any transgenic crop had been commercially released and at a time when agricultural biotechnology research was in its infancy in most developing countries. At the outset, ABSP research projects were initiated without extensive prior consultation with developing countries regarding their particular needs and priorities. Priority was given to research on problems identified as being of "global" relevance which, if successful, would have positive impact on developing countries as a whole.

As a consequence, in most cases, the strategy followed involved simply taking techniques available "off the shelf". The initial research projects were actually extensions of ongoing research projects conducted by leaders at US universities, rather than resulting from a process guided by strategic planning, with coordinated input from all participants in both the US and developing countries.

Given the eagerness of USAID to see products developed within a short time frame, this approach might have been understandable in the first phase of ABSP, but there was time to review and, if appropriate, adjust the approach in the second phase. Research activities could have had greater impact during the term of the project had a system been implemented based, firstly, on the identification of needs **in** and **by** partner countries and, secondly, seeking to match those needs with techniques available from advanced laboratories in the US or elsewhere.

Contrary to what might have been expected, basic research projects were initiated in collaboration with AGERI in the final two years of the program. These projects undoubtedly yielded positive output in terms of biological research, but not in terms of achieving the objectives set for ABSP in Phase II. In view of the limited resources and time available, greater returns to investment could probably have been secured by concentrating on the development of the products closest to commercialization, rather than initiating activities that could not reach field-testing within the life of ABSP. However, as suggested in the section below on management, AGERI received generous funding from the USAID Cairo Mission and was therefore not dependent on the ABSP project for funding. As a consequence, ABSP management was not in a position to exercise control over AGERI's research portfolio.

— ***Research collaboration***

ABSP provided developing country scientists a rare opportunity for collaborative research on some of the significant advances made thus far in modern biotechnology. It has enhanced research capacities and consequently had important impacts on human resources development and capacity building for modern biotechnology research in partner countries. The main research developments occurred in the production of genetically modified plants which confer pest and disease resistance (Bt potato and maize and virus-resistant/tolerant cucurbits, sweet potato and tomato). By improving micro-propagation methods for bananas, coffee, ornamental plants and pineapple, and improved cucurbit seeds produced by traditional methods, the research activities also contributed to increased agricultural productivity. In the latter stages of ABSP, projects were implemented to produce drought and salinity tolerance in wheat and tomato. Improved nutrient content in the form of high beta-carotene mustard oil is in early phases of research collaboration between a developing country (India) and the US private sector (Monsanto), with the objective of transforming local Indian mustard varieties.

ABSP has to be acknowledged as a unique program for producing new and/or adapted knowledge, techniques and tools of high quality. It also adopted and managed innovative approaches in terms of both the scientific procedures used, and the structure of the collaborative efforts to pursue research activities within international cooperation frameworks. Research collaborations involving creative partnerships between both public and private sectors in the US and in developing countries, represent one of the major accomplishments of the project.

In addition to providing training and facilitating access to new techniques for developing country scientists, the linking of research and specific policy aspects also enhanced their awareness of the complex issues involved in the management and application of agricultural biotechnology. Targeted research institutions in Egypt and Indonesia, which also benefited from investments in necessary infrastructure, have developed the skills required for independently conducting world class scientific research. In many cases, scientific research stimulated and promoted policy activities, influencing the creation of the regulatory framework necessary to support the commercialization of biotechnology products.

ABSP's connections with the private sector offered unique opportunities for developing country scientists to gain first-hand experience of the working environment and scientific research performed at US industry level. Interactions with the private sector have resulted in excellent learning experiences of mutual benefit and in-house training opportunities offered with Pioneer and Monsanto are considered extremely valuable learning experiences by the scientists concerned.

In the course of the final evaluation, difficulties in coordinating the joint efforts of United States and developing country scientists were observed for some research activities. This situation could be a consequence of the very limited number of meetings organized for the purpose of monitoring progress and for detailed, regular discussions on the scientific content of projects and experiments. Such meetings should have been considered a necessity in view of the complexity of the research activities performed within individual projects.

However, it could also be a consequence of a lack of commitment to common objectives on the part of individual developing country scientists or of the public research institutions which were ABSP partners in research collaboration.

Had capacity-building through collaborative research, together with support for the institutional development necessary to underpin the development of agricultural biotechnology remained the sole objectives of ABSP, it would have to be acknowledged as a resounding success. The scientific achievements of ABSP are undeniable, both with respect to the training of developing country scientists and the acquisition of enabling research techniques which have been successfully transferred to participating countries. These include: the use of genetic markers for a number of crops; bioreactor micropropagation methods; improved tissue culture techniques; new transformation methods for cucurbits, tomatoes, potatoes and sweet potatoes.

Policy activities

— *Biosafety*

As already emphasized, the ABSP project was initiated at a time when, worldwide, the management of biotechnology applications was in its infancy. Transgenic products had not yet been commercialized and developing countries were working through the initial stages of interpreting and complying with international agreements, writing national laws or setting up other legal arrangements to regulate the biosafety of GMOs.

Under the ABSP project many young researchers, senior scientists and administrators were able to attend biosafety courses, seminars and workshops. Others were exposed to bench training, sometimes in the private sector. By sponsoring scientists who would become leaders at their home institutions, ABSP helped to forge the necessary links between scientific capacity building and policy development.

Through its workshops and internships, ABSP was instrumental in the significant progress its partner countries have made in setting up national as well as institutional biosafety systems and in their implementation. Capacity-building activities in this area have resulted in the drafting and adoption of biosafety and/or food safety guidelines or the drafting of biosafety laws in Indonesia, Egypt and Kenya.

During its second phase, ABSP carried its biosafety activities a step further by providing short-term technical assistance to countries on request. It has also prepared a Biosafety Review Workbook designed to complement technical training for developing country scientists, Institutional Biosafety Committee (IBC) members, and members of the National Biosafety Committee. This Workbook provides supporting information for government biotechnology regulators and monitors.

From 1999 ABSP activities were extended regionally in Africa through its Southern Africa Regional Biosafety Program (SARB) and with ASARECA.

— *IPRs*

At the time the ABSP project began, developing countries were in the process of revising or setting up new regimes to regulate IPRs in conformity with the TRIPs Agreement. In the same way as with biosafety, the ABSP project has been instrumental in creating awareness in its developing country partners of the importance of IPRs in biotechnology research. It has made a major contribution to the training of scientists and senior managers in the management of intellectual property. It has also made a significant contribution to institutional developments related to IPRs in Indonesia, Morocco, Egypt and Kenya.

In the terminology of the ABSP project, IPRs became equated early on with "technology transfer". This came about for a number of reasons. Firstly, the transfer of proprietary GM research materials (for example, a patented gene) from MSU to a developing country partner was, indeed, a new issue. It therefore required contractual arrangements which at one and the same time protected the IPRs of the patent-holder and ensured its safe transfer. Secondly, most developing country partners did not have appropriate intellectual property protection in place for GMOs. Consequently, it was necessary either to draw up the appropriate legislation within an existing legal framework or, where required, create new institutions.

Another reason was that important changes had recently occurred in United States federal policies regarding IPRs. From the mid-1980s it became possible for public research institutions to apply for IPRs and to become owners of those proprietary techniques whereas in the past, IPRs would have become the property of the federal government. This measure was intended both as an incentive for the transfer of publicly-generated technology towards commercial product development and as a means of rewarding scientists for their innovations. Following the introduction of this legislation many US universities, including MSU, set up Technology Transfer Offices.

ABSP made a significant contribution in several developing countries in raising awareness regarding IPR issues, both at the level of developing country partner institutions and at national level. At the institutional level, it raised awareness of the concept of intellectual assets and the need to introduce institutional IPR policies. It was instrumental not only in supporting the development and drafting of new IP measures but also in the setting up of technology transfer offices such as those which had recently been set up in US universities, for example, the Office for Technology Transfer and Intellectual Property (OTTIP) at AGERI.

ABSP played a key role in the development and drafting of the plant variety protection (PVP) laws in Indonesia and Kenya. It also played a key role in supporting the establishment of the Intellectual Property and Technology Transfer office (Kantor Pengelola Kekayaan Intelektual dan Alih Teknologi – KIAT) linked to the Indonesian Agency for Agricultural Research and Development in Indonesia, and the Technology Management and Commercialization Office linked to the ARC in Egypt. These offices are successfully identifying and licensing technologies generated within the public research system.

ABSP involvement in these various IPR activities also undoubtedly provided assurances to the private sector companies whose proprietary technology was acquired and transferred to developing countries and thus influenced them in agreeing to enter into these international technology transfer projects.

— *The limitations of policy perspectives*

The linking of collaborative research to biosafety and IPRs was one of the innovative features of the ABSP project. Biosafety and IPR policy issues were addressed from two different angles: (1) issues associated directly with specific technologies being developed through collaborative research and therefore at research project level and, (2) from the perspective of capacity-building in developing countries and therefore at institutional or national level.

In terms of issues related to specific technologies, time-consuming, capacity-intensive and costly biosafety procedures remain to be resolved for all the transgenic products which have been developed within the program and, more specifically, for the two technologies on which this study has focused. No provision was made in the ABSP budget for contributing to the costs of complying with the necessary regulatory procedures for the risk assessment complex of the "near market" technologies, even though the ABSP Annual Impact Report dated July 2000 acknowledged that "………depending on the stringency of the commercialization procedures, it will be difficult for a public-funded effort to meet the regulatory costs".

Similarly, IPR issues associated with the biotechnologies developed under ABSP have not yet been resolved. For example, freedom to operate (FTO) beyond research is not assured in most of the collaborative research projects and, particularly, with respect to the two technologies closest to the market; the Bt potatoes and transgenic cucurbits. This is the case with the Syngenta gene for potato transformation and it is not clear whether countries are free to use common promoters such as Monsanto's 35S.

The more recent collaborative research projects (for example, maize transformation with Pioneer; stress-tolerant wheat at AGERI) are ensuring the resolution of FTO issues in the early stages of the research. However, all MTAs of projects closest to commercialization were originally designed and signed to cover research only, leaving product development and commercial applications for subsequent negotiation. As one of ABSPs major goals was indeed to move transgenic products towards commercialization, this seems to have been a short-sighted approach.

On the other hand, achievements with respect to biosafety and IPR policies were notable in terms of capacity-building and in facilitating institutional innovation in those areas in developing countries. That having been said, biosafety undoubtedly became an issue for ABSP which would require more time, effort and both human and financial resources than could have been envisaged at the outset of the project. Neither USAID nor ABSP could have foreseen the strength of opposition which developed on the part of NGOs and, in Europe on the part of consumers, to the introduction of GM foods.

This opposition has had a number of consequences. Many developing country governments are reticent to introduce GMOs and have consequently taken an extremely cautious approach *(precautionary principle)* in developing and, more important, implementing biosafety guidelines or legislation. This has resulted in the adoption of cumbersome, complex national biosafety systems which are proving both difficult and impractical to implement, partly because countries do not necessarily have the technical capacities required and partly due to their high cost.

The situation with respect to IPRs is perhaps less sensitive than biosafety, but countries are still in the process of revising their national legal and institutional systems for the protection of intellectual property and so problems of interpretation, application and implementation remain.

Developing countries in general, and the countries included in this study in particular, have formulated pro-biotechnology policies and invested in biotechnology research. And, in the course of the ABSP project, public research institutions in these countries have been involved in collaborative research on GMOs. In principle, it is in the countries' own interests to ensure that, to the extent possible, the results of that research come to fruition in the form of new genetic technologies.

This is not necessarily proving to be the case, as trade policy has now further complicated the situation. Developing country policy-makers are thus confronted not only with internal opposition to GMOs in general, and to imported GMOs in particular, but also the possibility that trade barriers could be put in place by countries of the European Union against agricultural imports "contaminated" by GMOs. This no doubt partially explains why so little progress is being made towards the acceptance and implementation of the new regulatory frameworks.

The overall outcomes of ABSP's policy activities are mixed. While it should have been possible to be more far-sighted regarding "internal" IPR and FTO issues, ABSP management could not have foreseen the directions in which biotechnology-related policies would evolve in developing countries. It could nevertheless have been more attuned to the evolution of broader policy issues in partner countries which would impinge on the development and commercialisation of biotechnology products, particularly transgenic products.

Perhaps the important lesson to be learnt from this experience is that while it is important to aim at a balance between the amount of resources and effort directed to project versus broader policy levels, this may be extremely difficult to achieve.

Beyond research: product development and technology diffusion

Commercialization was implicit in the objectives of the ABSP project from the outset but became more explicit following the October 1998 Report of the Technical Advisory Group. As stated in Chapter I the principal objective of the second phase of the project was "to improve the capacity and policy environment for the use, management and commercialization of agricultural biotechnology in developing countries and transition economies". In order to achieve that objective the TAG report proposed that emphasis should be shifted away from research to the delivery of research products and that a commercialization specialist be included in the management team.

As interpreted in the first phase of the project, technology transfer was intimately linked to IPRs and biosafety. The term technology transfer was thus narrowly defined and referred essentially to the new issues and requirements which arose in research collaboration with private sector and developing country partners and, consequently, to the transfer of research skills, techniques and materials. Similarly, field-testing was regarded more as a step which had to be taken to comply with biosafety procedures than as an essential step in moving closer to product development.

Despite the delays brought about by the need to conform to new biosafety regulations or to build new biosafety capacities, first within USAID itself and subsequently in partner countries, a number of products generated by the research were tested, first in the United States and, subsequently, in developing countries. At least confined testing, initially with material from MSU but later with local cultivars, was conducted in each of the three countries included in this study. And, in the case of both the Bt potatoes and cucurbits (both transgenic and non-transgenic), field-testing has been conducted over a number of years and has illustrated the effectiveness of the technologies.

Moving forward to product development through field-testing provided a unique opportunity in developing country partners for "hands-on" experience in developing capacity for risk assessment and management. It should also have provided an early opportunity for developing country partners to establish and consolidate links with local public agricultural institutions (for example, those which provided test sites and/or conducted agronomic and field evaluations), public or private seed companies, local farmers or farmers' groups, NGOs, with a view to future product development, production and distribution. Only in the case of the non-transgenic cucurbits developed by Cornell have product development links been made. These have been successful, not only in Egypt, Indonesia and South Africa, but in a growing number of other countries.

Paving the way towards commercialisation should have implied a more comprehensive approach to technology transfer, encompassing technology transfer **beyond** research and **beyond** field-testing, to the development and production of a biotechnology product and the final delivery (or diffusion) of that product in the farmer's field or to the final consumer. This would have required additional, complementary skills, particlarly in marketing and/or socio-economics and sound knowledge of local markets. It may also have required identifying and enlisting additional partners – including private sector partners — in the project.

It is clear that commercial partners will not be found to undertake the production and/or diffusion of ABSP's "near-market biotechnologies", without realistic, positive assessment of the market prospects of the product. Furthermore, field interviews with private companies lead to the conclusion that companies will require a "finished product", that is, a technology product unencumbered by the financial, technical and time constraints of biosafety assessments and procedures. IPRs will need to be resolved on a case-by-case basis, which is a lesser constraint.

Clearly it was not the mission of ABSP *per se* to commercialize products generated by the program. ABSP could nevertheless have played a more effective role in encouraging partner countries to develop the linkages, partnerships (both public and private) and expertise required to move the technologies generated by its collaborative research from field-testing to product development to commercialization and diffusion.

Private sector partnerships

In the original project proposal, it was stated that "In the case of the development of genetically engineered crops resistant to local pests in LDCs, various innovative linkages will be sought to allow the private sector to profit from new developments while making the technology available to developing countries at a fair price." The recruitment of a commercialization specialist was also included in the proposal to "work jointly with all parties concerned (including the private sector) to develop a commercialization project for genetically engineered crops". As already indicated, this post was never filled.

Private sector partnerships were entered into during the life of the project for different reasons. In the first instance, collaboration between DNA Plant Technology, a plant biotechnology company in Oakland, California, and Agribiotecnologia de Costa Rica (ACR) in Costa Rica, a micropropagation company, focused on investigating the potential of embryo regeneration using DNAP's proprietary bioreactor technology to increase the production of pineapple, coffee, palms and banana. Private companies (Monsanto and Garst Seeds) were also the source of proprietary genes and contractual arrangements were concluded for their use in research. In-house training for developing country scientists in companies involved in research collaboration under the ABSP project (Pioneer and Monsanto) was a third form of partnership.

No concerted strategy was developed, however, for approaching private companies either in the United States or in developing countries to determine their interest or otherwise in the development, production and distribution of the transgenic technologies being developed by the ABSP project research. And no concerted approach was developed for negotiations with private companies beyond research.

In contrast to the situation with respect to the two transgenic technologies analysed in this study, the cucurbit team at Cornell has been successful in collaborating with private seed companies in each of the three countries included, at least for the testing of its material. To date only one seed company has entered into a licensing agreement for the use of Cornell lines, but it is anticipated this will be followed by other revenue-generating agreements.

Had greater effort been concentrated on the release of Cornell's lines in Egypt, Indonesia or South Africa, and licensing arrangements already established, this may have constituted a solid network for the subsequent commercialisation of transgenic products.

That not being the case, private sector collaboration as partners in the ABSP project has been confined essentially to the use of proprietary technology in research. The ABSP/private sector partnerships were innovative in that they have contributed critical elements of the technologies developed through collaborative research. However, except in the case of collaboration on transgenic maize between Pioneer in the United States and AGERI, the private sector partners demonstrated little interest in maintaining a stake in the further development of these technologies in developing countries.

Management

Given its broad thematic and geographic coverage, the heterogeneity of its partners, personnel changes in ABSP and its partners, shifts in emphasis between the first and second phases, severe budget cuts in the first phase of the project, changes in USAID policy, and dramatic changes in the external perception of transgenic technologies during the life of ABSP, the management of this complex international program presented some daunting challenges.

The fact that local or regional USAID Missions were encouraged to "buy into" the ABSP project had both positive and negative outcomes. On the positive side, the contribution of the USAID Cairo Mission to AGERI of around $7 million during the term of ABSP, enabled AGERI to undertake research and other activities on a scale which would certainly not have been contemplated from ABSP core funding. Conversely, this generous funding created a situation where it was virtually impossible for ABSP management to exercise any authority over AGERI, whether with respect to the directions and output of research or to product development and commercialization.

In retrospect, the expectations for ABSP voiced in the original proposal – product development within 3-5 years — were unrealistic. This should have been realized early in the life of the project, the more so when the budget was severely cut. However, the vision set was neither readjusted nor more sharply focused as it became apparent that making significant progress towards commercialisation during the second phase of the project was, at the least, problematic. On the contrary, by the end of the project the objectives (both geographic and scientific) became more diffuse rather than more focused.

When ABSP began in 1991, activities consisted exclusively of research projects. In 1993 the first biosafety workshop and internships took place, followed by an internship in IPR. As the project developed and external funding was provided for collaborative research, management sought to maintain a balance by investing proportionately more core funds and management staff time into policy-related activities. In Phase II, a "new generation" of policy support activities began and the geographic focus was extended to the Eastern and Southern Africa regions.

Over time, changes occurred in the structure and composition of ABSP's management team and, after the first joint Managing Director resigned, subsequent Directors were no longer faculty staff. Excellent working relations were established and maintained between the International Agricultural Institute, the host institution at MSU, and ABSP management. These good working relations were helpful in enabling ABSP to survive the drastic budget cut in its second year, and to weather subsequent budget cuts and delays. The MSU Office of Intellectual Property (OIP), founded the year after ABSP began, provided timely IPR expertise which ABSP needed to negotiate contracts between private companies and developing country partners which complied with Federal regulations but at the same time met company requirements.

Several changes occurred in the structure and composition of the management team at MSU – particularly with respect to its Director(s) — during the life of the program. However, particularly towards the end of the program following the resignation of Dr. Catherine Ives, considerable effort was made to ensure a smooth transition to the new direction of Dr. Johan Brink. Other members of the small core staff remained throughout the life of the project. On more than one occasion during the briefing for the Final Evaluation and during subsequent visits to MSU, staff members have described the enriching learning experience it was for them, as part of ABSP, to interact so closely with individual scientists from developing countries and, on field visits to partner countries, to understand better the institutional and cultural environment of partner countries. Clearly, each individual staff member has felt closely involved and highly committed to the project.

It is not clear how the decision to abolish the TAG and replace it with an External Board of Directors was made. In fact, the TAG met on only a few occasions and so no timely, systematic evaluation of scientific results and progress was made. This may have had a negative impact on research output as research projects continued with little evaluation or scrutiny and with no clear time frames set for product development.

Neither the TAG, the External Board, nor the Internal Board appears to have met with sufficient regularity or frequency to have provided adequate direction, guidance and support to ABSP management. No provision was made for « go no-go » decisions with respect to different program activities and no provision was made for the inclusion of new skills or competence as the focus shifted – in principle – away from research towards product development and commercialisation.

At no time during the life of ABSP were all participants in the program brought together to meet, exchange ideas, review overall progress and identify common problems or constraints. This kind of gathering may have helped inculcate a greater sense of partnership and commitment to the ABSP network than was found during field visits.

Despite its many and sometimes ground-breaking achievements, at the end of the ABSP project, that is after almost 12 years and investment in the order of $13 million, the delivery to farmers of new biotechnology products generated through its collaborative research – particularly transgenics – remains uncertain.

Chapter V

NARROWING THE GAP BETWEEN BIOTECHNOLOGY RESEARCH AND TECHNOLOGY DIFFUSION

In the foregoing chapters, the broad lines of the ABSP project have been presented. The situation with respect to two of the near-market biotechnologies developed through the project (Bt potatoes and cucurbits) has been outlined and traced in three different developing country partners; Egypt, Indonesia and South Africa. Key lessons from the ABSP experience have also been outlined.

The experience of other publicly-funded initiatives for transgenic crops

It is instructive to compare the experience of the ABSP project with other publicly-funded biotechnology research initiatives for the development of transgenic crops currently under way. A recent IFPRI study (Cohen, Zambrano et. al. 2004) has examined in detail GM crops emerging from 76 public research institution pipelines in 16 countries with developing and transitional economies in Africa, Asia, Latin America and Eastern Europe.

For each country, data and information was collected with respect to: general information on the country and lead research institution concerned; description of the crops, transgenes and desired phenotypic trait; source of genetic resources (public/private, local/foreign); the regulatory stage reached (see paragraph below); type of collaboration developed (if any) and plans for dissemination of the research outputs to farmers.

The survey has covered 209 events[2] for 46 different crops, 55 per cent of which fall within the CGIAR mandate. The remaining 45 per cent include cotton, vegetables and fruit. Events were analysed according to a well-defined set of regulatory stages: experimental; confined field trials; "scale-up"; commercial release. Of the 200 events which could be classified, 127 are grouped as experimental; 44 in confined trials; 22 (mostly in China) in scale-up testing; and 7 commercial releases.

Most genetic material used in research among the 15 countries has been provided by local, public sources (85 per cent local and 3 per cent foreign) and only 5 per cent from private sources. The types of research partnerships involved are indicated in Table 4 below. For 39 per cent of the events recorded in the survey, some form of partnership was indicated, but in 61 per cent of the cases the research was being conducted by a single, public research institution.

Public-private sector collaboration was found in only 8 per cent of all events, with the international private sector involved in a majority of cases and local seed companies playing only a minor role.

[2] An event is a specific gene insertion in a particular crop which results in a desired expressed trait in the crop. For example, the insertion of Bt into various cotton varieties is considered to be one event.

Table 4. Types of research partnerships

Institutional arrangement	Asia	Latin America	Africa	Bulgaria	Total
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

Source: Cohen, Zambrano et. al., 2004

In response to the question regarding preliminary plans for the dissemination of research outputs, it was found that there are no plans for moving towards product development and technology distribution and no links have yet been made with public or private partners which might facilitate and/or execute that process.

Another study conducted recently for the CGIAR Science Council has used a number of case studies to determine the status of living modified organisms (LMOs, the definition used in the Cartagena Biosafety Protocol) under development by the CGIAR Centres and their partners. Several centres have initiated research programs using gene technology, including the use of Bt genes to address insect resistance in rice, maize, pigeon pea, chickpea, sorghum and cowpea. Other Centre efforts are directed towards developing LMOs resistant to bacterial, fungal and viral diseases in rice, pigeon pea and groundnuts respectively.

LMOs developed by these research programs are currently at various stages of laboratory and field testing by the Centers and their partners. The study states that these potential products have primarily been developed for their promise as "international public goods", to address constraints and commodities that are not likely to be a priority for private companies (for example, drought tolerance in African maize, disease resistance in cassava).

It is not clear how the Centres intend to mobilise the human and financial resources necessary to move the present list of experimental LMOs into potential product development.

New approaches to narrowing the gap between research and technology diffusion

The foregoing analysis of the ABSP project from the point of view of a national system for biotechnology research, product development and technology diffusion highlights the links which were either not taken into consideration when the project was designed and implemented, or which were not consolidated during the life of the project. Thus, the ABSP experience provides a valuable learning opportunity for the design of similar projects in the future.

Review of other publicly-funded agricultural biotechnology projects involving transgenic crops suggests that many are either already facing or can be expected in the near future to confront the same kinds of constraints as those of the technologies developed under ABSP reported in this study. In a few cases, there are outstanding intellectual property issues to be resolved. In all cases, there are outstanding biosafety issues to be resolved. And, in a majority of cases, no early attempt has been made to establish the links with (potential) private or public partners which will be essential for product development and distribution of the emerging new technologies.

This penultimate section draws on the collective lessons from ABSP and other experiences to date to argue in favour of new approaches to the elaboration of similar publicly-funded projects intended to develop and deliver new agricultural biotechnology products for the benefit of developing countries. The discussion includes insights from well-documented success stories of the development and commercialisation of agricultural biotechnology products. It is organised around the following issues: developing country policies and regulations; the changing roles and responsibilities of public research institutions in developing countries; the changing role of the scientific community in developing countries; the scope for public/private sector collaboration; project approach, design and management.

— *Developing country policies and regulations*

Government policies and national regulatory frameworks in developing countries are crucial components in supporting, facilitating or impeding the development and diffusion of agricultural biotechnology, particularly when publicly- or donor-funded and developed within their own public research institutions. One of the most important aspects of such policies is the formulation of a national biotechnology policy or strategy so that promising, priority areas for public research can be identified and product development and distribution systems strengthened.

Biotechnology policies and programs should be integrated within a sectoral context, within the framework of the problems confronting agriculture and agricultural research and with a clear sense of the specific problem areas to which biotechnology could best contribute. Furthermore, unless due attention is paid to the array of policies and institutions needed for sustainable agricultural development, biotechnology in itself will contribute little to agricultural improvement. Incentives for private companies, particularly local companies, will need to be considered in those policies.

Of the three countries included in the study, South Africa has already developed, and is implementing, a national strategy. Indonesia is in the process of revising earlier policies and attempting to develop a national strategy. Egypt has not yet developed a national policy or strategy for biotechnology.

Governments also have a responsibility not only to draw up clear, workable biosafety guidelines or laws but, more important, to ensure they are implemented and they have a similar responsibility for the formulation and adherence to clear rules of the game for IPRS. It is also important to ensure policy coherence among different ministries, to avoid conflicting rules and regulations, for example, between public health, environment and agriculture ministries.

Finally, governments have an important role in providing, through public institutions, technical support facilities and services for field-testing, seeds testing and multiplication, quality control, etc.

Clearly there is a continuing need for capacity- and institution-building, particularly with respect to the elaboration and implementation of regulatory frameworks for biosafety and IPRs. Perhaps more important, there is a strong need for additional case studies of the benefits and costs of specific biotechnologies – and particularly transgenic crops – so that countries can make objective, science-based decisions regarding the introduction and diffusion of new biotechnologies in their particular country context.

The scope for intervention in the evolving policy and regulatory environment in developing countries is, at best, limited. It must therefore be acknowledged that political support, or at least the support of relevant high-level decision-makers, can be crucial for the success or failure of donor-funded biotechnology projects.

— ***The changing roles and responsibilities of public research institutions in developing countries***

ABSP and other experiences of publicly-funded research provide sobering lessons for public research institutions, including universities, in developing countries which, in the past, have often been insulated from accountability. Many of these institutions remain heavily dependent on donor funding and, in the current overall climate of scarce public funding and growing pressure from their governments to produce tangible results, are faced with new challenges. These include, for example, the need to be better attuned to the needs and views of farmers and of the private sector and to be able to demonstrate that their research is appropriate and relevant to their country's needs. This implies the necessity, if product development is envisaged, to enlist potential private partners at the outset, to seek marketing/commercial/economic advice where relevant or to include this expertise in project teams. Institutions are also under pressure to increase their share of income-generating activities by providing services or performing commissioned research, possibly for producer groups or for the private sector, as a means of becoming more financially sustainable and less dependent on external funding.

Particularly for those institutions conducting research on transgenic crops, it is necessary that they enhance their capacity to incorporate regulatory compliance not only in research planning but, where appropriate, in moving towards product development. Provision for these items, until now largely neglected, needs to be taken into account in budget estimates for research. Experience also suggests there is a need for the research institutions to determine where research inputs and techniques might be accessed downstream to ensure they are not duplicating effort or "reinventing the wheel" and are thus making the most efficient use of available resources.

— ***Changing role of the scientific community in developing countries***

Developing country scientists in public institutions, particularly those involved in advanced biotechnology research, need to be aware of the implications of the changing environment in which they are conducting their research. Within their own institution, they have a responsibility to be familiar with biosafety and IPR requirements. New institutional IPR policies can also mean they will be able to profit from their own innovations. Scientists have an important role to play in interacting and communicating with the non-scientific community, including policy-makers, and in enhancing their awareness of the needs of farmers and the views of the private sector. They may also need, in order to ensure the future of their research, to communicate the message that biotechnology is not necessarily synonymous with GMOs and to point to well-documented positive socio-economic impacts.

— ***The scope for public/private sector collaboration***

It is not difficult to make a case for public/private sector collaboration in the development of biotechnology in developing country agriculture. Firstly, public funds for research in developing countries are scarce and, in most countries, as yet there is little private investment in research. Moreover, donor funding has more often diminished than increased and continued support for the IARCs is also uncertain.

These investment trends have coincided with growing consolidation in recent years among the leading companies which has given rise to a situation where only a few major multinational companies now control a large share of the world's markets for the products of biotechnology and the life sciences. It is not surprising, in these conditions, that a growing share of the knowledge embedded in the new techniques is proprietary technology, that is protected by IPRs.

In marked contrast to the earlier Green Revolution technologies which were essentially in the public domain, access to the proprietary technology owned by private companies has assumed growing importance for countries wishing to enhance their capacities in biotechnology. In the light of all these changes, there is increased pressure for countries to exploit complementarities between the public and private sectors, whether local or foreign companies.

While it is easy to make the case for public-private sector collaboration, this is a research area in which very little effort has so far been concentrated and so there are few well-documented successful experiences from which to obtain guidance. In developing countries there is little experience of public and private sector collaboration and therefore little time to build mutual trust and confidence.

A recent analysis of public/private partnerships in the CGIAR has suggested that, while the motivations and perceptions of private firms and public institutions differ and while it is difficult to dispel mistrust between the two, there is nevertheless a common "interest space" which can be identified (Spielman and von Grebmer, 2004). This space, which represents the objectives shared by both partners, can be created through incentives to facilitate partnership.

One interesting successful example of public/private collaboration in technology development and diffusion is provided with the example of a non-transgenic biotechnology product: tissue culture banana in Kenya (Wambugu and Kiome 2001). This project, in which ISAAA played a key role, provides a useful illustration of the links which were made with a diversity of public and private partners from the design phase of the project and throughout the process of research, product development and diffusion of the new biotechnology. Table 5 below lists the entities involved and indicates the roles they played in the process. It is important to note that:

- banana farmers who were to be the recipients and users of the technology were consulted at the outset
- the tissue culture research responded to a clearly-identified need
- an independent *ex-ante* study was conducted on the potential socio-economic impact of the tissue culture technology on farmers
- the roles and responsibilities of the different public and private entities were clearly defined at the outset
- credit facilities for banana farmers were arranged to cover initial purchases of the disease-free planting material.

The single well-documented example of the successful commercialization of a transgenic crop in developing countries is that of Bt cotton, a non-food crop, now grown profitably by small-scale farmers in several developing countries (Ismaël et. al, 2000). Taking South Africa as an example, in conformity with South African requirements, the Monsanto company was required to demonstrate the benefits of Bt cotton for small farmers. Farmer organisations played a key role first in volunteering to test the seed and, subsequently, through demonstrating the effectiveness of the technology to other farmers. As in the above case, credit facilities were made available for initial purchases of seed.

In the case of Bt cotton, the Monsanto Company of course bore the expenses involved in fulfilling the various biosafety and other regulatory procedures required for commercialisation in South Africa, any adaptive research which may have been required to adjust the transgenic technology to South African agronomic and production conditions, and any other steps necessary in the product development process. As has been shown in Egypt in the case of one of ABSP's near-market technologies, Bt potato, even though one company may be willing to make a contribution towards the costs, private companies in developing countries are generally not prepared to meet the substantial costs of fufilling the range of biosafety procedures required in order to bring a product

Table 5. Tissue culture banana in Kenya. Summary of main institutions involved and their responsibilities

Objective	Institutions	Main Output	Requirements
TC Production	GTL, KARI, DuRoi Laboratories (S. Africa)	Selection of varieties, tc production, quality control and assurance, training in nursery management	Enhanced public-private collaboration, stringent quality control
Strategic/ Adaptive Research	KARI, ATPS, ISAAA, farmer groups	On-station trials, varietal comparisons, spacing, agronomy, tc versus sucker comparisons, intercropping, training, demonstrations and technology diffusion	Appropriate infrastructure and policy framework
Distribution	KARI, ISAAA, CBOs, farmer groups	Distribution mechanism channels – schools, churches, on-farm trials, markets, village leaders and farmers	Well designed marketing, plan, entrepreneurial skills and willingness to participate
Links with farmers	KARI, STPS, ISAAA	Needs assessment through PRA, varietal choices, orchard management, access to tc plantlets, on-farm trials, training, large and small-scale farm demonstrations and financing	Participatory approach geared towards meeting farmer expectations and aspirations
Marketing	KARI, ATPS, ISAAA, ZEF (Germany) and farmer groups	Socio-economics: pricing, quality control, distribution and training	Market structure establishment, post-harvest handling/ packaging standards
Expansion	Micro-entrepreneurs, NGOs	Manure application, micro-irrigation, Banana Growers' Association, private investments (e.g., banana-related business and export markets)	Political and economic stability, entrepreneurial skills for identification of business opportunities
Technical backstopping	ITSC (S. Africa), John Innes Centre (UK) and DuRoi Laboratories (S. Africa)	Designing appropriate filed management packages, commercialisation, strategy, virus disease diagnostics and training	Public-private collaboration, networking and experience sharing

NB: Funding was mainly from the Rockefeller Foundation and the IDRC
Key: CBOs = Community-based organizations, NGOs = Non-governmental organizations, PRA = Participatory rural appraisals, ATPS = African Technology Policy Studies

developed through the public research system to commercialisation. And, clearly, the investment required is beyond the financial means and technical competence of AGERI. The crucial product development phase thus emerges as a major impediment to public/private sector collaboration in the commercialisation of the products of publicly-funded biotechnology research.

To become involved in product development and commercialization, private companies require, first and foremost, assurance of clear short- or longer-term market potential. And, indeed, where private sector activity is limited and markets undeveloped, it may be necessary for publicly-funded incentives to "kick start" the creation of a new technology market. Governments may also need to devise fiscal and/or other incentives for local biotechnology start-up companies or for public/private joint ventures for biotechnology with local of foreign firms.

As illustrated in the success stories referred to above, farmers and farmer cooperatives, producer groups and NGOs may all have roles to play in forging the links between product development and technology diffusion. And, indeed, farmers will be the ultimate arbiters of the success or failure of a new biotechnology. It may be necessary to create new links between different public and private interests or new combinations of market and non-market mechanisms, at this crucial final phase. Funding and/or technical support may be needed during the period necessary to "bridge the gap" until the new technology has proven its scientific, economic and social viability. Where extension services are still public sector activities, they too can play an important role as intermediaries not only with farmers but also with the private sector, for example, through ensuring the presence of local seed and other companies when new technologies are being demonstrated or field-tested.

The lessons from publicly-funded biotechnology initiatives to date suggest that most of the research under way has been proposed exclusively by scientists, from the perspective of what science might have to offer in solving a particular problem affecting plant production. Certainly it has not been undertaken from the perspective of actual **demand** in an economic sense, or of a clearly-defined **need** in a social sense. The prospects for involving private companies depend very much on market prospects and, given the negative short- to medium- demand outlook for some of the outputs of this research, the prospects of enlisting private sector collaboration are extremely limited.

— *Project approach, design and management*

ABSP and other experiences highlight the complexity of linking the biotechnology research approaches which have to date predominated within the publicly-funded national and international research communities to the "market". In most developing countries, there is a continuing need for the training of scientists in biotechnology research and methods and for capacity-building in the regulatory systems and institutions which underpin the development and introduction of biotechnology. Such training and capacity-building are realistic, attainable objectives. The attainment of more ambitious objectives such as moving from the lab to the farmer and, in development community parlance "targeting poor farmers", is much more problematic, particularly with respect to transgenic technologies.

Where it is intended that biotechnology research should eventually lead to the production of a tangible biotechnology product and to the delivery of that biotechnology product in the farmer's field, the lessons of ABSP and other publicly-funded projects highlight the need for both (1) assessment of potential demand for the intended product in specific local markets, together with socio-economic impact assessment and (2) in-depth knowledge of the national system for biotechnology research, product development and technology diffusion. This kind of analysis would, inter alia, assess the strengths and weaknesses of the seeds, agricultural inputs and agricultural services sectors and provide insights into the kinds of obstacles – apart from regulatory difficulties – likely to be encountered. It would also clarify the roles played respectively by the public and private sectors in the production and final distribution of agricultural technologies. It would then be possible to make informed judgments as to whether potential exists for private sector production and distribution (market channels), whether non-market channels could be envisaged, or whether transitional arrangements would need to be devised.

If it is considered that successful research effort has short-term market potential (that is, could be diffused through commercial channels), effort could be made to involve private sector partners either early in the research effort, further downstream at the product development phase, or subsequently in the production and diffusion of the new technology. If there is no obvious potential market demand, transitional diffusion mechanisms engaging both public and private partners (public extension systems, farmer or producer groups, NGOs) might be facilitated by "technology brokers" such as the International Service for the Acquisition of Agri-biotech Applications (ISAAA) and the African Agricultural Technology Foundation (AATF) or by "product champions" (Markham, 2002) who will become advocates for pursuing the technology through the innovation process.

The successful experiences to date highlight the importance of plotting the appropriate strategic links from research to the farmer's field from the outset. These links will need to encompass policies, public institutions and private companies, assets/disciplines/skills, and people.

In defining the scope of a project, there is an obvious need for broad consultation with all potential partners, public and private, and relevant expertise. It is then possible to identify who will provide the range of complementary expertise/assets necessary, to define their roles, and to decide how responsibilities and benefits will be shared among all the partners. It is also then possible to decide how resources might best be allocated among the different partners involved, and how they might be distributed during the different phases in the innovation process: research, product development and technology diffusion.

Only after extensive consultation and preparation is it possible to define clear, attainable objectives, including the appropriate point of intervention in the different phases as well as the type of research to be conducted: basic, applied or adaptive. It is then also possible to set realistic time-frames with benchmarks for research and product development.

Even after lengthy consultation and preparation, it may be necessary to make difficult choices and to accept inevitable trade-offs in setting objectives. Similarly it must be acknowledged that, as was evident in the ABSP project, the enabling environment for the introduction of new biotechnologies may evolve, either globally or within partner countries, in ways that are impossible to foresee. For that reason, provision should be made for go, no-go decisions, so that unpromising or unsuccessful avenues of research or what emerge as incompatible relationships or conflictual situations may be terminated.

— *Management*

The ABSP experience emphasizes the difficulties of managing complex, ambitious projects involving a multiplicity of individual partners, partner institutions and countries and highlights the need for truly committed, sensitive, competent leadership. It also raises questions regarding an appropriate management structure for a project of that magnitude. Clearly appropriate management structures are an important element in the success or otherwise of such projects. Here, the challenge is to ensure effective management of the overall project and its various elements, and at the same time devise a management structure as simple and transparent as possible, where roles and responsibilities are clearly defined, authority to take decisions is clearly allocated, and where top-level management is provided with both guidance and support.

The ABSP experience also points to the need for continuity and stability in management, particularly for long-term projects. When there are changes in top management, it is important to retain a core of management entity members so that relations with developing country partners can be maintained, the learning process can be documented and the project "memory" kept intact.

It is unlikely that the wide range of competences necessary – for example, marketing, socio-economics — will be available within small management units. In that event, it should be made possible either to hire relevant expert advice when necessary and/or to out-source.

Considerable effort also needs to be devoted to communication and information-sharing among all partners involved. This is important in order to inculcate a sense of involvement in and commitment to the project and to build trust and confidence among a diversity of public and private partners of different cultural and professional backgrounds. In the current anti-GMO climate, there is also a pressing need for public information and education.

Strategic options and issues for donors

The ABSP project and other experiences point to an urgent need to devise more comprehensive approaches to project elaboration and implementation if publicly-funded agricultural biotechnology research initiatives, particularly those involving research on transgenic technologies, are to have any tangible outcomes beyond capacity-building.

Much of the output of successful collaborative biotechnology research, particularly on transgenic crops, is unlikely to move beyond laboratory testing in developing countries unless a number of conditions are met. First and foremost is the condition of public acceptance of GMOs. Secondly, political will as well as technical and institutional capacity and financial resources will need to be brought to bear in fulfilling biosafety and IP requirements. Thirdly, new bridging mechanisms and/or incentives will be needed for the product development phase of the innovation process. Without transitional mechanisms to facilitate market development, it is unlikely that private partners will become involved in production and/or distribution of the new transgenic technologies. At the same time it is unlikely that existing public sector mechanisms, with even fewer financial and human resources at their disposal than in the past, could alone assume product development, production and distribution to farmers.

It therefore becomes pressing to develop effective strategies for ensuring that successful research output is indeed transferred towards product development and distribution to farmers or consumers. If the publicly-funded biotechnology research under way is indeed considered to be relevant, whether for solving specific problems in agricultural production, for fulfilling an identified social need, or meeting a potential market demand, then is it clear that funding support needs to be extended beyond research to subsequent phases of the biotechnology innovation process.

At this particular point in time, a large share of the research on GM crops conducted in public research institutions in developing countries is funded by donor agencies, whether through multilateral or bilateral funding, through support to the IARCs or to specific national programs or projects in developing countries. This state of affairs raises the important issue of returns to investment. The combined experience of ABSP and other publicly-funded biotechnology projects involving research on transgenic crops raise the following key alternative sets of strategic options and issues for donor investment:

1. Continued focus on the funding of research on transgenic crops

Donor agencies contribute a large share of funding for the research on transgenic crops conducted in the public research systems in developing countries. Bridging the gap between this research and the farmer's field appears in many instances to be compromised, at least in the short term. The reasons are twofold: firstly, the systems in place for linking publicly-funded research to product development and the farmer are weak or undeveloped; secondly, opposition to GMOs remains strong.

In addition, the time frames originally envisaged for moving from the lab to the farmer need to be revised and extended, to at least between 10 and 15 years.

Returns to a strategy of continued funding of research on GM technology may be considerable in terms of scientific capacity-building, but unless more attention is paid at the outset to identifying the research needs and priorities of developing countries, there is a risk of irrelevant research output.

2. Reallocation of funding to achieve better balance between research and subsequent phases of the innovation process

Funding could be distributed more evenly between research outputs and development, with more effort directed towards product development. This might include the funding of a range of product development activities beyond small-scale field trials and/or fufilling necessary biosafety requirements, leading to a finished biotechnology product.

Funding might also be directed towards supporting the creation of new market (private sector) mechanisms for product development and technology diffusion, for example, through incentives for local companies. Alternatively, it might be directed towards supporting the creation of new public/private sector (market and non-market) channels for product development and diffusion, involving public institutions, farmers, NGOs and local companies, possibly through technology "intermediaries" or "product champions".

Funding in the product development area is crucial for the transgenic technologies currently being developed in public research systems in developing countries. Such a strategy would be unlikely to yield short-term returns to investment but should yield considerable benefit in the medium-term. And, indeed, without additional investment in the product development phase, the future of "public good" technologies appears bleak.

3. Funding of non-GMO biotechnology research

A strategy of funding biotechnology research not involving GM technology would have the advantage of relatively early returns to investment in terms of product development and, possibly, better prospects of linking research output to the market. It would, of course, also have returns with respect to scientific capacity-building.

At the same time it should serve the purpose of building confidence in the agronomic, environmental and socio-economic benefits of biotechnology products. This would, in principle, consolidate the links necessary for the introduction of transgenic technologies in the short-term future.

In this case, however, countries would be under less pressure to establish and implement sound biosafety policies and institutions.

ANNEX 1

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