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Contents

The present document shares ISAAA's strategy and approaches over the first eight years of its existence, and details and discusses the strategic responses the institution has made programmatically and strategically to the changing environment in which ISAAA has operated.

Challenge

ISAAA seeks to ensure future food security, bring about a more sustainable agriculture, and contribute to poverty alleviation through a more equitable adoption of new agricultural biotechnologies.

Response

As a result of the significant changes in international agriculture that emerged during the 1980's, in particular the advent of biotechnology and proprietary science, the following responses were taken:

- Established a nonprofit broker service to facilitate agri-biotechnology transfer to developing countries;
- Developed a pragmatic program based on actual transfers and partnerships;
- Built on the comparative advantages of the private sector (in the North) and the public sector (in the South), and encourage South-South collaboration;
- Instilled trust and confidence between the various key players in agri-biotechnology;
- In Africa, strengthen programmatic activities initially in one country (Kenya) and then regionalize activities;
- In Southeast Asia, develop activities predominantly through regional collaboration;
- In Latin America, initiate activities in Mexico and Brazil, and in the future develop an appropriate strategy to assist the region, particularly IP management services.

Mission

Contribute to poverty alleviation by improving crop productivity, increasing income generation, and enhancing environmental security for resource-poor farmers.

With the advent of the first products in agriculture stemming from the life sciences, the potential to improve the human situation is historically unprecedented. Globalization, despite its many problems, now enables the mobilization of worldwide science and technology for the betterment of humankind. However, the promise is ours only if we manage to deploy improved products to the poor and wealthy alike.

Strategy

Provide honest broker services to transfer and deliver appropriate biotech applications through the building of partnerships between institutions in the South and the private sector in the North and, where possible, to strengthen South-South collaboration.

The strategy stakes out concrete, tangible end points to the transfer and delivery of appropriate biotechnology applications by building partnerships that capitalize on the comparative advantages of the public and private sectors to optimally sustain product delivery.

Program and Services

ISAAA has been set up to implement projects in Africa, Southeast Asia, and Latin America with the singular aim of delivering improved products to poor farmers (as opposed to research or the generation of knowledge). The specific services ISAAA offers to achieve these objectives are as follows:

- **Assist** developing countries to identify biotechnology priorities and needs and to assess potential socio-economic impacts.

- **Monitor** in industrialized countries the availability of proprietary biotechnology applications and evaluate their appropriateness for transfer.

- **Provide** honest broker services by developing project proposals and implementation plans, matching the needs of specific countries/institutions with those who can meet those needs.

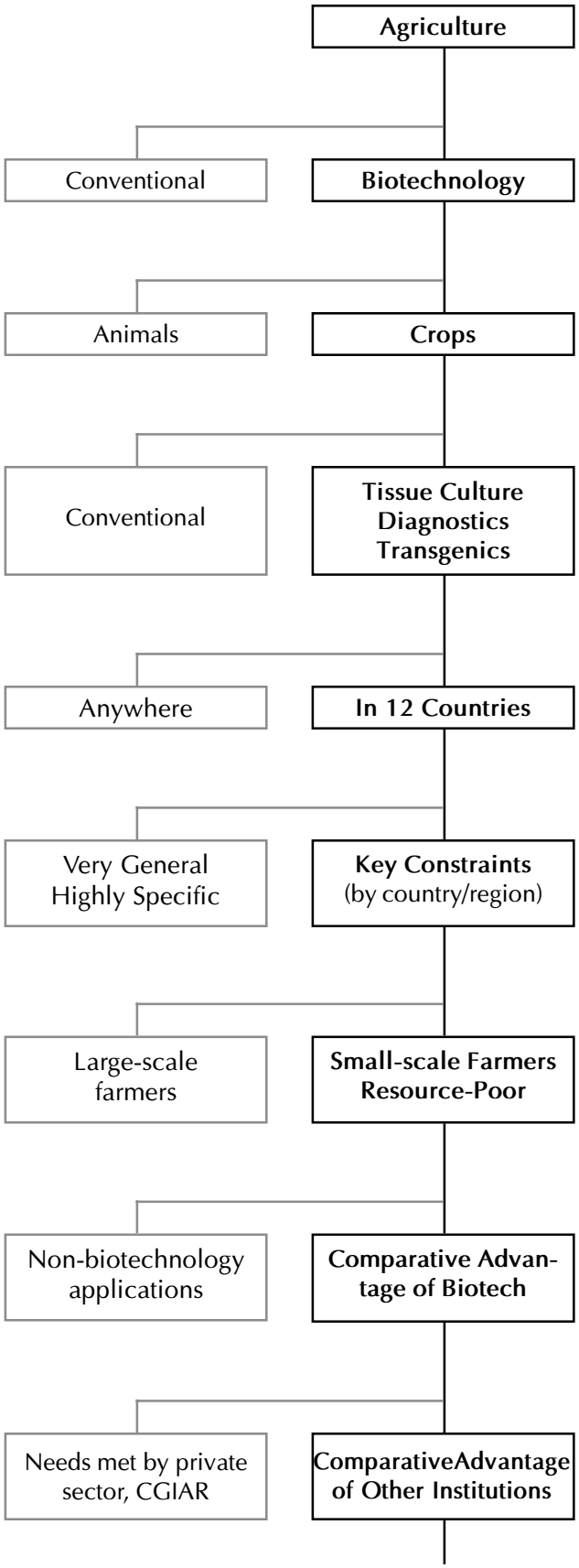
- **Mobilize** funds from donor agencies to implement projects.

- **Counsel** developing countries on a range of subjects associated with the deployment of biotechnology, including biosafety, food safety, intellectual property rights, plant breeder's rights, managing the deployment of resistant genes, and assessing socio-economic impacts.

Project Selection Criteria

The criteria that ISAAA applies throughout its program can be narrowed down and illustrated through a dichotomous key (Figure 1 below), which applies systematic criteria at each step.

Figure 1. Project Selection and Development Criteria



ISAAA deals with agriculture (as opposed, for example, to broad environmental or trade issues)

The focus is on the contribution of biotechnology, leaving aside conventional applications

Crops particularly food crops that confer environmental benefits or income generation (important to subsistence farmers)
Vegetable and fruit (which can best absorb the higher value biotech applications)

ISAAA's role is to broker projects and provide services that meet needs and priorities

ISAAA directs its efforts to a selected list of countries in Africa, Southeast Asia, and Latin America that have:

- political will
- assigned high priority to biotechnology
- certain level of capacity upon which to build projects

Programs are demand-driven
Based on needs assessment and priorities as determined together with NARS, governments, NGOs, and end users

The identified need and priority must address:

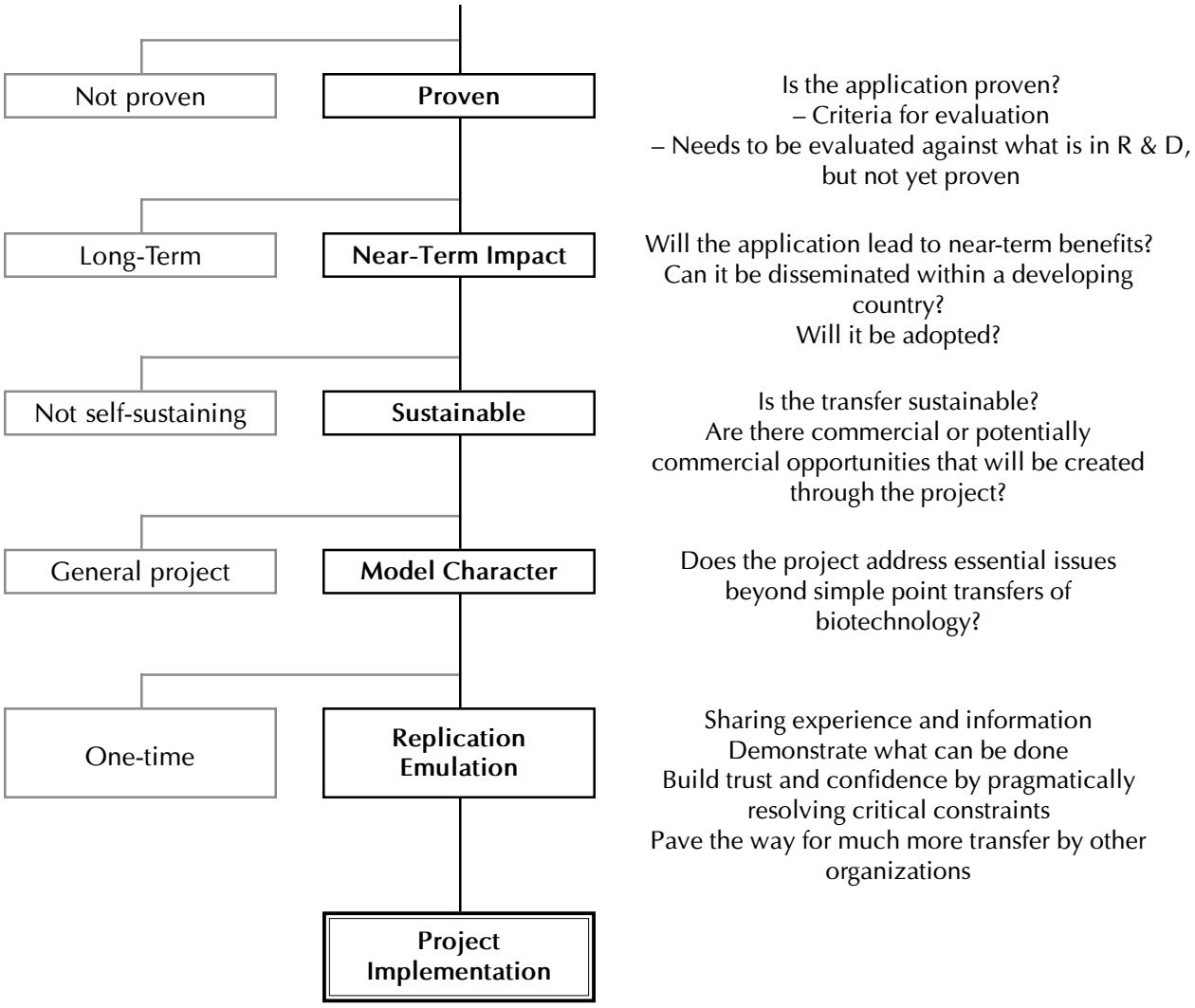
- Poverty alleviation
- Productivity enhancement
- Income generation
- Environmental security

Does biotechnology have something to offer?
Is the specific biotech application appropriate?
Can it be absorbed by relevant institutions and incorporated into traditional production systems?

Are institutions like the CGIAR adequately addressing the needs? Is the constraint considered in the strategy of corporations? In the uncharted area of biotechnology transfer, ISAAA develops full-scale projects. Over time, our role has encompassed more catalytic functions.

continued ...

Figure 1 continued. Project Selection and Development Criteria



1. Rationale for ISAAA's creation

To solve the increasingly serious poverty, hunger, and environmental problems faced by our world, the last half-century has witnessed a plethora of deliberations, pledges, and projects involving national, regional, and global institutions. The Bretton Woods institutions, the United Nations Development Program (UNDP), the UN's Environment Program (UNEP), and the Consultative Group on International Agricultural Research (CGIAR) are some examples. Tremendous ingenuity and resources have been mobilized, and many of the initiatives and institutions have been extremely resourceful and effective. Overall, however, an unprecedented number of people live in abject poverty, and our global environment continues to suffer further degradation.

The complexity of these problems has made it clear that although international regimes and institutions are important, there is no substitute for flexible, practical efforts to improve the lives of the world's poor. Master plans implemented from the top down have tended to become master messes. We now know that successful development work requires a comprehensive, integrated approach that fully considers the local contexts of the problems it seeks to solve. With that in mind, our very small but innovative organization, ISAAA, has already left its mark. Through its mission to transfer and deliver agri-biotechnology applications to developing countries, ISAAA is working to ensure that the world's subsistence farmers benefit from the agri-biotech revolution. Over the last eight years, ISAAA has made substantive contributions to improving food security, environmental protection, and small-scale farmers' incomes through unique, sustainable agri-biotech initiatives in Africa, Latin America, and Southeast Asia.

As the world economy continues to become ever more privatized, the private sector increasingly dominates agricultural biotechnology with products that are primarily geared towards agriculture in industrialized countries. As a result, the developing world once again risks being economically sidelined. Our projects and other studies have shown, however, that agri-biotech is well suited for resource-poor farmers and that it can make its greatest impact on small-scale agriculture. The benefits of agri-biotech—such as increased yields, lower input costs, reduced pesticide use, and more nutritious food—can dramatically improve the lives of subsistence farmers. Developing countries realize that they cannot afford to sit back and wait for these benefits to trickle-down to them, and so they are actively pursuing collaborations with their counterparts in the North. Yet precisely how to integrate these new technological developments into the resource-scarce research systems of the South has been a difficult question.

For years, the policy statements of developing countries have called for revamped agricultural approaches that would revitalize their economies, partly by adapting new technologies from the North to the needs of the South. Recommendations have also frequently been made to augment developing countries' capacity to create their own technologies and to develop regulations that would ensure the safe, efficient use of

agricultural advances such as biotechnology. Indeed, there has been no shortage of statements, plans, and proclamations. There have been international appeals for more of everything, which have often ended in almost nothing (consider, for example, the appeals contained in Agenda 21 of the 1992 Rio Summit for billions of dollars of additional funds annually for agriculture and agricultural biotechnology alone).

Translating these recommendations into practice is an ongoing challenge. Policies often lag far behind rhetoric, and where policies exist, implementation is rarely effective. Furthermore, there have been no efficient, trusted institutional structures to facilitate information and technology exchange between developing countries and the owners of new, private-sector technologies. Traditional institutions, such as the CGIAR, were able to transfer non-proprietary Green Revolution technologies with great success, but their impact has lessened dramatically in a global business environment increasingly dominated by proprietary science. Because of their difficulty in adapting to this changed and changing environment, confidence in the ability of institutions such as the CGIAR to foster technology exchange has eroded.

Yet the advent of agri-biotechnology offers an unprecedented opportunity to alleviate hunger and poverty. Globalization, despite its many problems, can mobilize science and technology worldwide for the betterment of humankind. However, the promise of a more prosperous and more equitable world is ours only if we are committed to deploying improved agricultural products to the poor and wealthy alike. Nearly 60% of the global population is poor and 80% of these poor depend on agriculture in one way or another for their survival. Many of them are subsistence farmers without any access to modern agricultural innovations. If we do not act to include these farmers in the agri-biotech revolution, then they will not benefit from applications that could dramatically improve their lives. ISAAA was created to ensure that agri-biotech delivers its promises to these farmers.

2. ISAAA's Establishment and History

2.1 The Inception (1990-1992)

In 1989, the World Bank sponsored a conference in Canberra, Australia, to study the implications of biotechnology on agriculture. The Bank had commissioned Drs. Clive James (then Deputy Director General at CIMMYT) and Gabrielle Persley (then on sabbatical at ISNAR) to undertake a study of the potential future role of the private sector in agriculture in the developing world. Their study concluded that a new institutional mechanism was required to forge public-private partnerships that would allow the private sector to share its proprietary science with small-scale and resource-poor farmers.

A number of donors[1] subsequently funded a feasibility study during late

[1] The Hitachi Foundation, the MacArthur, McKnight, Mott, Rockefeller, and Wallace Foundations, Monsanto, the Rockefeller Brothers Fund, the Stockholm Environment Institute, and USAID.

1990/early 1991 (under the auspices of the now defunct Resources Development Foundation), which considered more deeply the need for such a service and what would be its optimal organizational structure and role. The analysis included a prioritized list of potential projects. Dr. James led the study, with inputs from a host of people, including a Steering Committee that eventually became the founding Board of Directors[2].

ISAAA was incorporated in the USA as a non-profit organization in July 1991. Much preparatory work was done during that year by Clive James (who by then had hired the author of this *ISAAA Briefs* as a consultant) to formally launch ISAAA in March 1992. This was done in conjunction with the opening of the *Ameri*Center, hosted by Cornell University in Ithaca, New York, USA. Subsequently, the *Euro*Center, *Afri*Center, *SEAsia*Center, and Liaison Center for the *Asia*Center were established. The original plan had called for three centers in the North (North America, Europe, and Japan), each with two senior directors; and three centers in the South (Africa, Latin America, and Southeast Asia), each with one network coordinator. Table 1 (under Section 2.3) shows a series of diagrams to illustrate the evolution of ISAAA's institutional structure.

While the institution was being established, a number of projects were developed and implemented in Latin America, most notably the development of virus-resistant potatoes in Mexico with coat-protein technology donated by Monsanto (see *ISAAA Briefs* No. 7) and the development of diagnostics in maize (see *ISAAA Briefs* No. 9).

ISAAA was led from 1992 to early 1994 by Dr. David Altman, by Prof. William Lesser during the remainder of 1994, and by the author of this *ISAAA Briefs* from 1995 to late 2000.

2.2 The Three-Year External Review of ISAAA (1992-1994)

At the end of three years of operations, the Board commissioned an external review led by Sam Dryden. That Review (ISAAA, 1995) concluded that ISAAA had met or exceeded its goals and objectives and successfully implemented pioneering, demand-driven projects in an uncharted area of technology transfer. The Review endorsed the selection of target countries and a carefully selected portfolio of model projects aimed at delivering benefits to small-scale farmers. It further endorsed policy activities in biosafety and IP (Intellectual Property) that were judged to be valuable elements of project support.

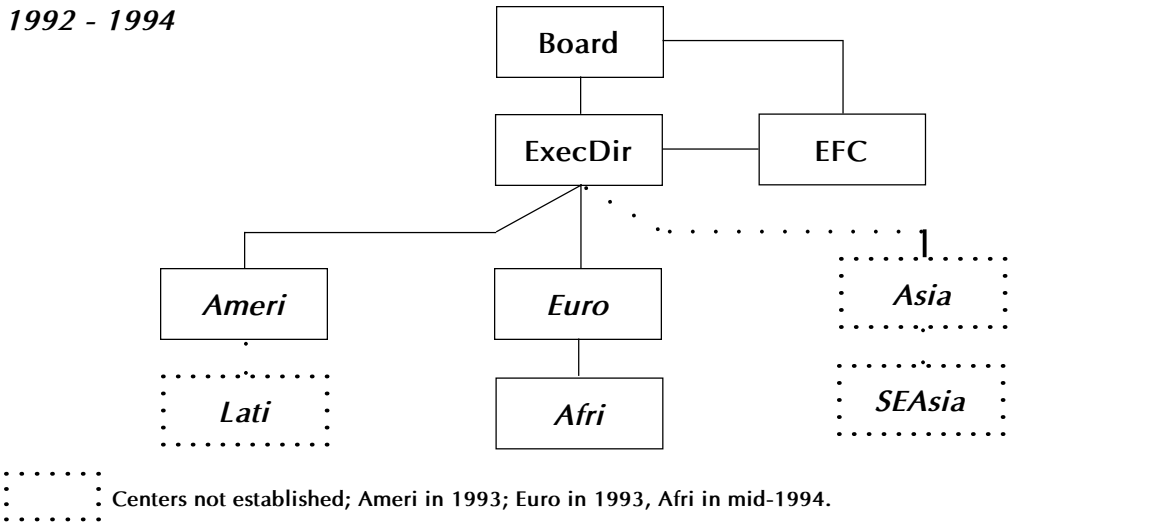
The Review made a series of recommendations, which were wholly implemented during 1995 and 1996. The most notable of these are:

- Reallocation of resources from North to South by reducing the staffing in the North and increasing staffing in the South;

- Stronger initial involvement of the end users as stakeholders;

[2] Gordon Goodman (Chairman), Norman Borlaug, Richard Flavell, Robert Fraley, Robert Goodman, Luis Herrera-Estrella, Emil Javier, Thomas Odhiambo, Vernon Ruttan, Francesco Salamini, M.S. Swaminathan, and Jasper Van Zanten.

Figure 2. The Evolution of the Organigramm of ISAAA



EFC	:	Executive and Finance Committee	Admin. Dir.	:	Director of Administration
EFPC	:	Executive, Finance and Program Committee	Prog. Dir.	:	Director of Programs
IP	:	Global IP/TT Initiative			

- Expanding the target countries to include Vietnam, among others;
- Assigning highest priority for the establishment of the *SEAsia*Center;
- Enhancement of the PVX/PVY (Potato Virus X and Y) Mexico/Monsanto Potato Model Project with resistance to PLRV;
- Establishment of a Strong Fellowship Program.

2.3 ISAAA from 1995-Present: The Evolving Institutional Structure

Initially, much emphasis was placed on developing and building a strong African program. This was followed by the establishment of the *SEAsia*Center and its associated programs, and by new initiatives that facilitate biotechnology transfer—particularly project support in IP management.

Institutionally, the Northern centers were re-structured during 1995. Senior staffing was reduced in the North and investments increased in ISAAA's Southern centers (see Figure 2). Additionally, directors of the Southern Centers reported directly to the Executive Director, rather than (as before) through a corresponding regional director in the North.

As of 1999, the Executive Director called for a new institutional structure and proposed the elimination of the position of Executive Director all together. This change, it was argued, would make ISAAA an organization more strongly anchored in the South, allow more program authority and leadership in the Southern Centers, and make ISAAA more efficient. The proposed institutional framework would also further ensure that developing countries were more active participants from start to finish in identifying, developing, and deploying technology and policy solutions.

At the Board meeting in January 2000, the ISAAA Board fully endorsed the Executive Director's proposed strategy. Accordingly, the last 6 months have been spent on the re-structuring of ISAAA.

3. ISAAA's Strategy and Programs

3.1 Overview

ISAAA exists to provide resource-poor farmers in developing countries with access to promising new agricultural technologies that will reduce poverty by increasing food production and income generation. Our rationale is based on an imaginative, new vision of technology transfer, one that treats North and South—and public and private—as equal partners in pragmatic projects that offer mutual gains. By creating relationships of trust and confidence, leadership is delegated to developing countries as technologies from the North are mobilized to catalyze economic growth that primarily targets small-scale farmers.

Through intensive information sharing and sensitization sessions at many levels within major multinational companies (from bench scientists to board rooms), we helped create an awareness about the developing world's agri-biotech needs. By calling attention to "orphan crops"—

which corporations have ignored because they are unprofitable in industrialized countries—we have promoted their potential to relieve hunger, improve nutrition, help protect the environment, and grow the economies of developing countries. These actions have given us our most valuable asset: our reputation as an honest, trustworthy broker that facilitates the transfer of appropriate biotechnology applications and products from private multinationals to nations in need. The new partnerships created have produced benefits that extend beyond simple technology transfer. Investments in training, regulations, and research capacity enhance these countries' ability to develop other technologies. It is this dynamic synergism that accounts for our success in generating sustainable agricultural projects with long-term impacts.

The philosophy of ISAAA has been—and will remain—committed to fostering a few well-done projects that respond to the needs and priorities of developing countries and that lead to the adoption of superior biotechnology applications at the farm level. This is essential to meeting the needs of resource-poor farmers and to the creation of a better environment along the following avenues:

- opening new and sustainable biotech transfer channels,
- encouraging policy change at the national, regional, and international levels, and
- building upon comparative advantages to create new opportunities for public and private sector collaboration.

With the commercialization of agricultural biotech products, particularly transgenics, now in full swing, ISAAA does not seek to strengthen the powerful market forces that are almost exclusively directed at large-scale farmers and which, in themselves, bring new shifts in equity. Instead, ISAAA exists to channel these market forces towards resource-poor farmers. This fosters equitable economic growth and ensures equitable access to these innovative applications within developing countries. Focusing on crops outside the immediate target range of corporations also holds great promise. Meanwhile, ISAAA's experience to date reveals that there is an abundance of technology and appropriate applications, but insufficient capacity and frequently weak government policies hamper the delivery of improved products. With its integral approach to biotechnology transfer, which seeks to strengthen institutional capacity, ISAAA makes a concrete contribution to improving the lives of the poor.

Indeed, in the process of conceptualizing, formulating, and preparing all projects, ISAAA facilitated and brokered technology transfers that span across two distinct areas: technology *transfer* and technology *delivery* to farmers. Ensuring that both transfers take place—first from the private sector to national institutions, and subsequently to the end user—is the only way to optimize the impact of these advanced technologies. The challenges endemic to the second transfer (the delivery of products) led the External Review to recommend that more of ISAAA's resources be reallocated to the South (see Section 2.2 above). The same

approach was taken in relationship to the more recent establishment of the *SEAsia*Center.

As workable models were put in place, new opportunities were generated. With time, ISAAA will undoubtedly change its emphasis, but our current conviction is that radically transforming small-scale agriculture means genuinely empowering the poor to selectively utilize modern technologies to complement their rich indigenous knowledge and ecological diversity. Responsive to the priorities of developing countries and uniquely situated to identify new technological advances, we hope that our novel institutional form can function as a model for others to follow, emulate, and improve upon. Indeed, as more links and relationships of trust are created between the public and the private sector, ISAAA is poised to make an even greater impact in the future, undoubtedly with a new strategy, as our projects mature and deliver larger quantities of improved products to resource-poor farmers.

It should be noted that ISAAA's international program currently focuses on about 12 developing countries: Indonesia, Malaysia, the Philippines, Thailand, and Vietnam, in Southeast Asia; Kenya and its neighboring countries, Egypt and Zimbabwe, in Africa; and Argentina, Brazil, Costa Rica, and Mexico, in Latin America. These countries, most of which already host regional collaborative projects, were chosen because they possess some capability in agricultural biotechnology. Furthermore, they all have the political will to pursue and adopt biotechnology applications. Within each region, ISAAA works with several other countries that either participate directly in the regional projects or stand to benefit from their spillover effects.

3.2 Project strategy

ISAAA is guided by the following project strategy:

- **A focus on near-term applications that have been tested in industrial countries** and that have the highest probability for successful transfer and dissemination. We seek technologies that are broadly applicable, attractive to end-users, and that can be effectively disseminated.

- **A concentration on applications that will make horticulture, forestry, and food and cash crops more productive** while simultaneously benefiting the environment. We emphasize crops grown by poor farmers that can increase their incomes. Biotechnology is especially valuable for vegetables and fruits because these are high-value crops that benefit from the use of the new technology's value-added products. We also offer alternatives to toxic pesticides (e.g., genetic solutions) for crop protection. Our forestry activities are geared towards species in high commercial demand—including several tree species threatened with extinction. We seek to satisfy markets and preserve biodiversity through appropriate biotechnology applications.

- **A specialization in three types of application: tissue culture, diagnostics, and transgenic plants.** Tissue culture is a low-cost, relatively simple, yet powerful technology that complements traditional crop improvement programs. It is useful for the mass propagation of biodiverse genetic material and for identifying and developing disease-free planting material. Diagnostic technologies can be used to identify disease problems, improve control strategies, and ensure disease-free planting material. Transgenic plants, particularly those with genes that confer resistance to pests and diseases, can increase and stabilize crop yields, creating substantial gains in food supplies and in the income-earning potential of resource-poor farmers. Transgenic plants also foster sustainable agriculture by reducing the need for toxic pesticides. We continue to explore opportunities to deploy biological control systems that use transgenic crops.

In practice, one of the key elements of our strategy is the selection of projects. In this process, a dichotomous key is applied (see Executive Summary). Its logical sequence determines what projects are selected and, to a large extent, the project development process. To date, it has led to the following sharply focused projects:

Latin America

- **Maize:** Development and use of diagnostics in Brazil (CNPMS/EMBRAPA) and in the public and private sectors of Latin America. Pioneer Hi-Bred International Inc. donated the technology, and EMBRAPA and Pioneer offered financial support (see *ISAAA Briefs* No. 9 for details).
- **Potato:** PVX/PVY and PLRV resistance in Mexico (CINVESTAV). Monsanto donated technology and training, and the Rockefeller Foundation provided funding (see *ISAAA Briefs* No. 7 for details).
- **Cassava:** Use of a selectable marker (mannose-6-phosphate isomerase) by CIAT, Colombia. Novartis Seeds provided the technology and training, which was funded through the ISAAA Biotechnology Fellowship Program. This led in 1996 to one of the first use agreements between a company and a center of the CGIAR.

Africa

- **Banana:** Tissue culture propagation transferred to Kenya (KARI) from the DuRoi Laboratories and ITSC in South Africa. IDRC (Canada) and the Rockefeller Foundation funded the project (see *ISAAA Briefs* No. 10 for details).
- **Maize:** Diagnostics for Maize Streak Virus and the determination of its genetic basis in Kenya (through KARI) and other programs in sub-Saharan Africa. Technology and training comes from the John Innes Centre (UK) and Novartis Seeds. The Rockefeller Foundation is providing funding (see *ISAAA Briefs* No. 16 for details).
- **Multipurpose trees:** Tissue culture for the propagation in

Kenya (through FHMC) of *Grevillea robusta*, *Eucalyptus* species, and *Acacia melanoxylon* (a replacement for ebony). Technology and training comes from Mondi Forests, South Africa. The Gatsby Charitable Foundation, UK, is providing funding.

- **Sweet potato:** Virus resistance (SPFMV) in Kenya (KARI and the surrounding region). Monsanto donated the technology, and USAID and the Kenyan national program offered financial support (see *ISAAA Briefs* No. 13 for details).

South East Asia

- **Papaya:** Resistance to PRSV in Indonesia, Malaysia, Thailand, the Philippines, and Vietnam. Monsanto and the University of Hawaii are collaborating on this project, and funding is being obtained from several sources (see *ISAAA Briefs* No. 11 and *ISAAA Biennial Report 1997-1999: New Partnerships for Prosperity* for details).
- **Papaya:** Delayed ripening in Indonesia, Malaysia, Thailand, Philippines and Vietnam. This collaborative project of Zeneca and the University of Nottingham is being funded from several sources (see *ISAAA Briefs* No. 11 for details).
- **Sweet potato:** Insect resistance in Vietnam. Technology and training are being provided by Novartis Seeds through the ISAAA Biotechnology Fellowship Program. The Friedrich Miescher Institute in Basel and Kenya's national program are also collaborating (see *ISAAA Biennial Report 1997-1999: New Partnerships for Prosperity* for details).
- **Black Rot Diagnostic in Crucifers** (completed; WSU [Washington State University]/ AVRDC [Asian Vegetable Research and Development Center]).
- **Virus Diagnostics in Tomato** (completed; see Fellowship report, *ISAAA Briefs* No. 15 and *ISAAA Biennial Report 1997-1999: New Partnerships for Prosperity;* Indonesia/Novartis).
- **Biosafety of Insect resistant maize** in the Philippines (completed; see Fellowship report, *ISAAA Briefs* No. 15; Philippines/ Cargill Seeds).

3.3 Project implementation

In order to implement well-conceived and focused demonstration projects, we built the following key tools into project management and oversight. These have allowed us to account for critical measures during the formulation and implementation phase:

- Project Formulation: Projects are formulated as clearly defined business plans. End-users are involved from the beginning, including entities that may appear peripheral at first. Much responsibility at this stage is delegated to our collaborating institutions and individuals. In many cases, we also draw on experts in the particular technology or crop biotechnology application to ensure scientific rigor and the application of existing know-how, specifically as it relates to the product development process.

The latter is often provided by companies who have more experience in developing products that meet market standards.

- Work Plans: The project proposals lead to regularly updated work plans that assign responsibilities, establish milestones, and set relevant deadlines. This allows all collaborating people and institutions to view individual contributions within the overall strategy, while simultaneously enabling ISAAA to better exercise a certain measure of control when circumstances warrant. In some cases, this may include control over disbursing funds.

- Overall Project Oversight: The Executive, Finance, and Program Committee of ISAAA, which is composed of Board officers and senior ISAAA staff (formerly the Executive Director only), holds in-depth discussions at regular intervals.

- Specific Project Oversight Group: ISAAA set up small groups of senior and influential individuals in host countries to oversee certain complex projects. The groups include major stakeholders and local entrepreneurs who meet frequently to provide oversight and guidance. This approach provides quality control and builds institutional structures to support small enterprises. These, in turn, can undertake new initiatives in other countries, thus expanding the benefits of the project and ensuring the sustainability of biotech transfer.

- Project Reviews: Carried out at regular intervals and contracted by ISAAA, reviews are conducted by individuals who are closely involved in and familiar with the technologies, but generally not otherwise associated with the projects.

3.4 Ensuring impact

Projects are aimed to make impacts at five complementary levels:

1. Impact at the farm level, predominantly directed at the environment and at resource-poor and small-scale farmers (e.g., tissue culture bananas in Kenya and Eastern and Central Africa).

2. Impact by opening biotechnology transfer channels. Reaching out to small-scale and resource-poor farmers paves the way for the introduction and adoption of new technologies in the future. In addition, other institutions can follow more easily once a foothold has been established (e.g., multipurpose trees, mastering conventional technology, regional strategic nurseries).

3. Encourage policy changes through carefully selected projects with beneficial products that will lead countries to adopt technologies in the near term for small-scale farmers (e.g., biosafety, IP).

4. Create new opportunities leading to further donations of technology, joint

ventures, and the commercialization of biotechnology (e.g., delayed ripening in papaya in Southeast Asia).

5. Human capacity building through hands-on training. We have provided over 100 fellows and 350 workshop participants from developing countries with practical training from private corporations, government agencies, and universities. These training efforts have dramatically strengthened the institutional and human capacity of our client countries to safely and efficiently adapt, develop, and deploy agri-biotechnology applications. Our fellows constitute an informal but powerful network of trusted individuals, many of whom are becoming important leaders in biotechnology in their respective countries. Similarly, new business opportunities have been created as local private agri-biotech entrepreneurs move forward. Private sector companies have also benefited tremendously from the chance to have their materials and products evaluated in Africa, Asia, and Latin America. They have built valuable institutional links that not only facilitate technology transfer but also help to create new markets through increased incomes.

3.5 Project and program support services

3.5.1 Biosafety and Food Safety

As new genetically modified crops reach farmers' fields, biosafety has become an important worldwide concern. Since its inception, ISAAA has worked to ensure that for all projects involving genetically engineered plants, all products must be tested and introduced safely. Any test must comply with all existing biosafety regulations. To-date, however, relatively few developing countries have put appropriate biosafety policies and procedures in place. Accordingly, ISAAA also provides for capacity building in certain countries lacking regulations. Several of these projects have catalyzed national efforts to form biosafety committees and formulate safe, effective policies and procedures.

Early on, ISAAA significantly invested in building the capacity for regulatory oversight in developing countries. We organized six major biosafety workshops from 1992 to 1998. Held in Costa Rica, Argentina, Indonesia, Kenya (two), and Malaysia, the workshops involved regulation specialists in approximately 25 countries of Africa, Asia, and Latin America. A recently completed project funded by the Rockefeller Foundation helped develop and implement biosafety regulatory mechanisms in Brazil, Indonesia, Malaysia, and Thailand. ISAAA has worked closely with several other organizations concerned with biosafety, has provided funds for hands-on internships, and has collaborated with such entities as the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), the Stockholm Environment Institute (SEI), the International Service for National Agricultural Research (ISNAR), and the United Nations Environment Program (UNEP).

Today, the focus is more specific within projects. Current activities include the facilitation of field trials in the

Philippines with appropriate training fellowships, a biosafety workshop specifically focused on papaya biosafety aspects, food safety internships, and more.

3.5.2 Intellectual Property/ Technology Transfer (IP/TT) Initiative

Resolving intellectual property and proprietary science issues has always been ISAAA's underlying rationale. Beginning with the brokering of commercial-type licensing agreements in mid-1995, and with the creation of ISAAA's Global IP/TT Management Initiative in 1999, ISAAA has now formalized and strengthened its activities. This has meant not only establishing a formal structure for our various IP/TT activities, but also expanding contacts with professionals and developing new relationships with other agricultural research institutions, such as the CGIAR.

R. David Kryder, an experienced specialist with practical, in-depth knowledge of the field and a pragmatic mindset, leads the IP/TT Initiative. His varied activities in the first year of operation have placed ISAAA conspicuously on the IP/TT map. Managing IP is a complicated process, one that is unfamiliar to many of our collaborators but essential to their successful use of agri-biotech. Through our workshops and fellowships, we offer training in identifying, analyzing, and establishing patent protections. They learn that it is necessary to search out the potential patent holders of all of the technologies they work with (a process that requires freedom-to-operate reviews; see Kryder *et al.*, 2000). Furthermore, since patents are national—not international—laws, it is also necessary to pursue possible patent holders in multiple nations. Such searches require resources that our client countries lack, which puts ISAAA in a unique position to offer the needed assistance. The demand for our IP/TT services—and the opportunities this presents to ISAAA—cannot be overstated.

The Global IP/TT Initiative recognizes that ISAAA's biotechnology transfer activities almost invariably require the resolution of intellectual property and ownership issues (even when a public sector entity simply wishes to donate technology to developing countries). The primary focus, therefore, is on serving ISAAA's biotechnology transfer projects, although increasingly other institutions have requested assistance. We now offer tailor-made internship programs, a web-based Virtual Workshop on IP and licensing issues, IP management services, and perform preliminary freedom-to-operate reviews.

3.5.3 The ISAAA Private Sector Biotechnology Fellowship Program

Because human capital is the most important factor for sustainable and successful projects, ISAAA established a Fellowship fund to invest in leaders who will carry its work forward. These fellowships are awarded exclusively to advance biotechnology transfer projects brokered by ISAAA or to provide for hands-on training of policy-makers (e.g., in biosafety, intellectual property management, etc.) Over 100 fellows have already received specific training awards (with another 300 people having participated in ISAAA workshops). They

have been the catalysts for executing some of the technology transfer projects and for broadening their impact in the developing world. These fellowships—as varied as the countries, people, and institutions involved—have contributed to building biotechnology capacity and to making national programs sustainable. They have accomplished much in a short time (see ISAAA 1996 *[Fellowships that Shape the Future]* and *ISAAA Briefs* No. 15 for more details).

3.5.4 Global Information Sharing and Food Biotechnology Policy/Public Acceptance

ISAAA has long emphasized the importance of sharing current and up-to-date information about project experiences, the global status of transgenic crops, biotechnology assessment studies, socio-economic impacts, intellectual property issues, and biosafety. Major titles are listed in the reference section of this *ISAAA Briefs* and are available at www.isaaa.org and www.cabweb.org.

More recently, ISAAA launched an information sharing initiative by organizing a "Traveling Workshop" in which six senior policy-makers from Southeast Asia visited Europe and North American regulators, policymakers, corporations, and environmental pressure groups (see *ISAAA Briefs* No. 18 for details). The participants gained a deep understanding of different regulatory approaches and of their effect on public perception and acceptance. They found this opportunity most timely, useful, and stimulating, as exemplified by the comment of one participant: *"What I learned from this honest, robust, and very balanced dialogue exceeded my expectations."* Initiating a transparent, science-based, and urgently needed debate about food biotechnology that for once included the needs and concerns of developing countries, our Traveling Workshop took an important step forward in creating a more equitable discussion about the benefits and risks of agricultural biotechnology.

Sound decision-making requires credible sources of information, and too often developing countries have been left out of the agri-biotech information loop. These groundbreaking dialogues sought to build trust where suspicion had previously choked its possibility. And as a result of their experiences, the participants offered a series of recommendations to ISAAA, one of which was the urgent establishment of a *Global Knowledge Center on Crop Biotechnology*. ISAAA will soon formally launch this Initiative, which will be implemented and managed by Dr. Randy Hautea, Director of ISAAA's *SEAsia*Center.

We hope that the *ISAAA Briefs* in general and the information that will be disseminated through the *Global Knowledge Center* will continue the conversation begun by the Traveling Workshop, and that a fairer debate about agri-biotech will lead to a fairer distribution of its benefits. For this reason—and also in light of the fact that too little information is a form of misinformation—we distribute the *ISAAA Briefs* free of charge to any order from developing countries and actively encourage them to copy the publications for the widest possible circulation.

There are three major questions one may ask in respect to the changing environment in which ISAAA operates:

1. Has ISAAA correctly anticipated the essential needs it tried to address over the past eight years?

2. Is ISAAA's strategy and approach today still relevant?

3. Is there a reason for ISAAA's continued existence and if so, in what way should ISAAA adapt its strategy to respond to future challenges and opportunities where it may make a contribution?

4.1 Past challenges and responses—Comparative advantage of ISAAA today—Lessons learned

Looking at the generic issues ISAAA has addressed over the span of its existence, there is no doubt that ISAAA addresses some of the most difficult and puzzling issues confronting the international agricultural development community today, namely:

- coping with the proprietary nature of agricultural biotechnology so that the resource-poor have access to these major innovations

- forging public-private partnerships to optimize research and development investments by the private and public sectors, and similarly to enable sound policy and strategy development as regards to agricultural biotechnology (in developing countries, at corporations, with donor agencies, and with institutions assisting developing countries)

- ensuring that developing countries have the opportunity to test for themselves the benefits and constraints of agricultural biotechnology and proprietary technologies, thus enabling them to develop policies and national strategies in congruence with local and national needs, priorities, and preferences.

In addition, five characteristics of ISAAA's program, strategy, and institutional structure should be highlighted. They distinguish ISAAA from other organizations and indicate its relative strengths and comparative advantages.

4.1.1 Pioneer role of ISAAA in successful biotechnology transfer projects

The first substantial planting of transgenic crops took place in 1996 with a total of 6 million hectares. This increased to well over 40 million hectares in 2000. Given that the specific benefits of biotechnology to farmers and to the environment are increasingly clear (see, for example, *ISAAA Briefs* No. 14), our client countries are accordingly more anxious to participate in biotechnology transfer programs and test for themselves the relevance of the technology in their

agricultural and socio-economic settings. Not surprisingly, our services are more in demand today than ever before.

In addition, institutions such as the World Bank and the CGIAR recognize ISAAA's pioneering strategy in the ongoing facilitation of proprietary biotechnology transfer and brokerage of public-private partnerships. Assigning high priority to these efforts and ISAAA's strategy, which seeks out complementary partnerships and win-win situations, these institutions recognize our efforts as an appropriate working model. In fact, the private sector's development of an ever-expanding number of biotechnology applications and commercial transgenic crops indicates a significantly increased need for ISAAA's services today than was present at its founding. There are now more opportunities to forge equitable partnerships between national programs and the private sector, as well as with institutions such as the CGIAR. Thanks to our years of rich experience, ISAAA is now uniquely situated to continue to broker new, creative partnerships that share superior biotechnology applications with client countries for the benefit of resource-poor farmers and the environment.

4.1.2 Comparative advantage and interface between public-private sector

As an honest broker of technology with a track record of successful use agreements, ISAAA is exceptionally placed to provide intellectual property management and brokering services. Increasingly, national programs are developing their own strategies, and so they are seeking qualified nationals with hands-on training in IP management activities or experience working with the private sector. Furthermore, as developing countries increasingly adopt the view that national programs "own" the "proprietary" genetic material that they have adapted for internal use, these countries also acknowledge that enhancing this material with proprietary biotechnology applications requires building public-private partnerships. National programs simply do not have all of the technology (most of which is proprietary) to move ahead efficiently on their own. Thus public-private partnerships will become more common and more complicated, which will require renewed emphasis on IP issues to broker equitable deals or joint ventures.

ISAAA also has a proven record of successfully brokered agreements between companies and centers of the CGIAR. Broadening the use of technology from the restricted domain of research to field-level distribution achieves the joint benefits of visible commercialization and the alleviation of hunger. Effective collaboration between IARCs and the private sector also requires ISAAA's distinctive range of services so that new approaches can be developed, since the all too frequent Material Transfer Agreements do not allow the Centers to use the technology in finished products and pass them on to national programs. ISAAA's status as an honest broker allows it to effectively assist with direct transfers of technology from the private sector to national programs. Cosponsored by public- and private-sector institutions, ISAAA enjoys a comparative advantage as it offers services efficiently, pragmatically, and to maximum effect.

4.1.3 No financial interests in the technology

Given the numerous interest groups in the field, perhaps ISAAA's most important characteristic is its status as a financially neutral and honest broker. This tr`ansparency instills trust and confidence, and due to the complexities of such agreements, these attributes are essential to success. Developing countries that receive donated technologies will likely have financial interests in the technology, yet royalty-free licenses generally exclude export, even for the products derived from biotechnology (e.g., rice grains for consumption). These countries may wish, therefore, to move from royalty-free licensing to other more complex agreements that are negotiated and implemented with greater difficulty. In this context, corporations may be reluctant to proceed with agreements and projects without an independent organization stepping in to assume the time-consuming role of quality control and troubleshooting. ISAAA fills this structural gap.

In addition, national or international companies might be interested in secondary products (e.g., the starch of cassava), further adding to the complexity of transfer agreements. In such instances, joint ventures are the most practical way to proceed. The diverse skill set exemplified by ISAAA's Global IP/TT Initiative enables the negotiation and maintenance of such transfers to occur with greater facility. Because ISAAA does not have a financial stake in these operations, it can provide credible advice and services to both its client countries and corporations.

4.1.4 No ownership of products being transferred

Unlike other organizations, ISAAA does not generate, own, or use the technologies it transfers. This high degree of independence makes ISAAA's operations credible as it interfaces with the various institutions that serve developing countries. ISAAA's independence has already been critical in relation to two CGIAR centers that wanted to access a technology for commercial "use"—as opposed to only material transfer. The importance of ISAAA's independence is also evident in cases where the CGIAR centers wish both to use the technology themselves and to share it with national programs. Although the centers may be limited to sourcing technologies from the collaborating corporations, ISAAA's mission and tactics can help balance the interests of national programs with the strategic interests of corporations.

4.1.5 Complementary activities/role to the Consultative Group on International Agricultural Research (CGIAR)

The complementarity between the CGIAR and ISAAA is detailed in Table 1. It shows, among other things, how the services of ISAAA serve the CGIAR (e.g., agreements brokered between corporations and the CGIAR by ISAAA), and how the CGIAR's work facilitates that of ISAAA (e.g., through capacity building and the mobilization of resources).

It should be noted, however, that ISAAA primarily serves the NARS as it helps build biotech ventures using private-sector technologies and nationally owned germplasm. Such undertakings benefit the private sector by developing projects that complement their business plans.

Table 1. The CGIAR and ISAAA Compared

CGIAR Consultative Group on International Agricultural Research	ISAAA International Service for the Acquisition of Agri-biotech Applications
Mandate Created to generate, adapt, and transfer agricultural technologies in a wide area	***Mandate*** Specifically created to facilitate proprietary biotechnology transfer
Serves "megaenvironments" Generates intermediate germplasm material for distribution to national programs and conducts system-wide research	***Responding to national needs and priorities*** Biotech transfer to incorporate new genes to enhance finished products; tailor-made projects that respond to specific national needs.
Exclusive focus on public good products The CGIAR, must, by its charter, deal with public goods available to all and cannot exclude a specific developing or industrial country from enjoying the benefits of its work	***Flexible to deal with public and private goods*** Set-up to deal with public and proprietary goods. As policies in developing countries evolve towards stronger private involvement, ISAAA is well placed to strengthen that process
Intermediate germplasm Incorporating genes through the CGIAR is a different route than directly with NARS; the CGIAR's approach will continue to play an important role for developing countries, particularly the smaller ones and those with weaker NARS	***Finished varieties*** The larger NARS want to apply biotech themselves; ISAAA has carefully selected the more advanced countries as the primary target; for a second phase, countries prepared to play a regional leadership are targeted
User of biotech As a user of biotech products that they generate, the CGIAR must tread a fine line between providing biosafety advice and advancing regulatory frameworks in biosafety and intellectual property rights	***Broker of biotech*** ISAAA can credibly provide for advice in biosafety and intellectual property rights; it has no conflict of interest as it is not a user of the technology, and can provide credible broker services to developing countries
Specific crops The CGIAR deals with most of the staples, including rice, wheat, corn, beans, etc., but it does not deal with many crops that can also benefit from biotech and that increase the incomes of subsistence farmers or reduce pesticide use	***All options open*** ISAAA can tailor-made projects to respond to national needs and those of the small-scale farmer that most increase revenues or reduce the need for pesticides (e.g., cotton); also options to develop areas where there are business interests (e.g., starch in sweet potatoes)
Training in enabling technologies Offers both generic and specific training in breeding and related agricultural technologies, including biotechnology and breeding-related biotechnology applications	***Hands-on training in product development and private "approaches" and "philosophies"*** Offers training opportunities focused around the transfer and development of a specific product within a corporate environment
Private sector interface Works on the strengthening links with private companies that are not members of the CGIAR	***Private sector interface*** Works with private companies that are donors of technology and members of ISAAA

NARS: National Agricultural Research Systems

Source: Compiled by Anatole F. Kratigger (1998)

4.2 ISAAA's current effectiveness

As to the second question posed above, i.e. whether ISAAA's current strategy and approach today is still relevant, it can unequivocally be stated that despite the enormous changes in the environment in which we operate, ISAAA's mission today is even more relevant and urgent. The world's population continues its exponential growth, most of which is taking place in developing countries, where the twin specters of hunger and poverty already afflict millions and where 15,000 children die each and every day from malnutrition and related causes. Our efforts to transfer noncommercial agri-biotech applications from the private sector directly to national agricultural research centers in the South remain critical. These technologies can play a key role in alleviating poverty in developing countries by sustainably increasing crop yields and protecting the environment.

Similarly, ISAAA's strategy is of the highest relevance today because changes in the commercial side of agri-biotech and its research environment make our "full-service" approach optimal. We build capacity in such areas as product development, regulatory oversight, and biotechnology policy, all of which are essential elements in any developing country's strategy to adopt biotechnology applications, whether developed by its own public sector or transferred through the indigenous or multinational private sector.

Furthermore, training in IP management and research on the socio-economic impact of agri-biotech receive our focused attention. Our integrated broker and transfer services are unique in their attempt to facilitate technology transfer from the beginning of a project to its end, from product research to its distribution to farmers. The rapid changes in the field of agri-biotech, however, have also made it increasingly challenging for ISAAA to raise the necessary funds to ensure programmatic and institutional sustainability.

It is evident that ISAAA is not the only organization addressing these challenges. Indeed, a range of institutions are contributing by addressing these needs from somewhat different perspectives. The author of this *ISAAA Briefs*, having led this effort for many years, is not in a position to judge ISAAA's relative effectiveness with complete objectivity, but ISAAA undoubtedly has contributed significantly in this area.

4.3 Future challenges and strategic responses

4.3.1 General challenges

The future operations of ISAAA, as well as of agri-biotechnology transfer in general, are greatly influenced by changes in the international development environment. Key elements of the factors that influence agri-biotechnology transfer and adoption in developing countries are:

- The downturn in commercial agriculture has spurred the consolidation of life science companies, with some even returning to their roots in seeds, biotech, and/or chemicals.

Currently, research investment is diminishing for products valued by developing countries. Monsanto, for example, has halted their entire rice program and many other crop research programs that certainly would have benefited developing countries.

- Notwithstanding industry consolidation, the number of intellectual property rights claims (i.e., patents included in a single agri-biotech product) increase daily, making it more difficult to obtain freedom to operate-even when technologies are donated.

- Genomics is becoming more costly, although it holds more promise to deliver value added products than current traditional biotechnology applications. Unfortunately, these research efforts are geared almost exclusively towards the generation of products of relevance to the food, processing, energy, and environmental industries of the North. Developing countries and their resource-poor farmers are least likely to greatly benefit from these advances.

- The opposition to GMOs in Europe, and somewhat in the USA, increases the reticence of bilateral and multilateral institutions to support biotechnology projects involving genetically modified organisms. Caution now prevails regarding projects involving GMOs.

- Similarly, certain developing countries hesitate to deploy GMOs, even for national use, due to a perceived risk of the loss of lucrative export markets.

- Funding by bilateral agencies for international agricultural research and development is declining.

- The efforts required to broker a biotech transfer deal pale in comparison to ensuring the proper functioning of all institutional interactions at the downstream end. (Accordingly, ISAAA now focus more on the downstream aspect of projects, especially during the conceptualization phase, thus increasing both the complexity and size of such undertakings).

- The increasing complexity of our program, and the resulting new responsibilities placed on ISAAA's senior staff, led the Executive Director to modify our institutional structure (see section 2.3).

Public acceptance, intellectual property complexities and management, and the inefficiency of seed distribution systems to small-scale farmers are the most pertinent challenges today.

4.3.2 Public acceptance and the complexity of intellectual property management

Agri-biotechnology is currently caught in a maelstrom of controversy, most of it flowing from emotions and

unexamined opinions than from rational dialogue and critique. In practice, however, there is a great deal of stated opposition to the use of biotechnology in the food supply chain within developed countries. Increasingly, many developing countries, fearful of being used as "technology proving laboratories," have reversed their initial broad acceptance of agri-biotechnology as the dawn of a new day of food security.

Sometimes, the forces opposed to agri-biotechnology (more specifically the anti-GM groups) have pointed to the consolidation of biotech components in the portfolios of a few wealthy entities (multi-national corporations, well-endowed universities, etc.) as "proof" that agri-biotech is part of a plot to manage the world's food supply. These anti-GM voices point to expanded statutory protection to verify their outdated viewpoints, which are more often anti-multinational corporation rather than anti-technological progress. Yet their very actions against the technology, which allows them to draw public attention and create public fears, leads paradoxically towards increased industry consolidation-the very outcome that they fundamentally oppose.

4.3.3 Inefficient seed distribution systems and intellectual property laws

Most agricultural products, because they are living organisms, have the ability to reproduce themselves. With the inclusion of GM components in many recently released improved agricultural products, the potential exists for such organisms to pass along their biotech components, whether the components are IP-protected or not, from generation to generation.

This has prompted the rise of new seed marketing schemes that are calling into question the historical patterns of seed distribution. Nowhere is this shift more evident than among the more advanced developing countries. These countries, generally weak or entirely lacking in biotech research and biosafety capacity, and often possessing a history of technology "piracy," are seen by the owners of biotech components as unacceptable recipients of the latest agri-biotech improved products. They fear that these very expensive components will become public property.

At the same time, developing countries are the ones that could potentially benefit the most from the technological advancements that are protected by IP. This conflict has promoted the development of "locking" technologies such as the so called "terminator gene". This locking gene had great potential to minimize the risk of environmental harm by GM crops while permitting the owners of IP protected components to extract a return on their investments.

Until more predictable IP laws are in place in developing countries, it appears that many of the benefits of advanced biotech agricultural products will be denied to resource-poor farmers. New systems of improved seed and agricultural product distribution will be required that allow farmers in developing countries to

benefit while not denying a proper return on investments by the private sector. Because statutory protection laws are on a country-by-country basis and not internationally applicable, owners of IP must consider many permutations and combinations of such laws to obtain worldwide protection for their discoveries.

For ISAAA, these changes in the environment have tremendous implications in terms of our future strategy. These are regularly discussed by ISAAA's Board, which has made the policy decisions that have allowed ISAAA to respond to the challenges it faces. ISAAA's new institutional structure also goes a long way towards ensuring that its characteristic flexibility and tailor-made development strategy will continue into the future.

5. Conclusions: Turning stumbling blocks into stepping stones

We can all look back with a sense of accomplishment at what ISAAA has done. By putting a human face on the numberless poor—and arguably also on some nameless corporate executives—we have helped to create new partnerships that are directing some of the energies unleashed by globalization to the people who most need them. We can certainly say of our efforts that they have contributed—albeit still too little—to making the world a more human place. ISAAA should continue to act with open-minded caution and daring prudence, transforming whatever stone lies in its way into a stepping stone to greater achievements.

Thanks to its light and agile institutional form, ISAAA responds quickly and flexibly to the fast-changing field of biotechnology. ISAAA's open structure also enhances its receptivity, permitting the practice of a reflexive leadership that emphasizes dialogue, comprehensive project planning, and teamwork. In these ways, ISAAA taps the creativity, innovation, and leadership of all its partners. In the final analysis, the success of ISAAA's remarkable and inspiring journey will depend upon the efforts of these partners. ISAAA's existence should not be measured by its size as an institution or even by its long-term existence, but by the perpetuation of the values that animate it and that are embodied in the improved seeds that will flourish in small-scale farmer's fields.

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