ISNAR's Strategy and Experience in Social Research on Agricultural Biotechnology

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ABSTRACT

Mobilizing modern biotechnology to serve agricultural research in developing countries implies new investments, changes in the way research is managed, and growing responsibilities for agricultural policymakers, research managers, and scientists.

At the agricultural policy level, comprehensive strategies are needed to ensure that biotechnology serves national agricultural objectives and targets communities most in need. Government officials assuming these responsibilities play a crucial role in setting policies, research agendas, and developing regulatory capacity for agricultural biotechnology. Their task is made difficult because public budgets for agricultural research are severely constrained; human capacity is limited and extensive international debate on the merits and safety of biotechnology complicate timely decision-making.

At the institutional level, new institutional structures will be needed to successfully integrate biotechnology in agricultural research organizations and programs. Changes in the structure of research organizations may be required, for example, to absorb the high initial capital costs. Considering the dominant role played by the private sector, new linkage mechanisms are required that comply with intellectual property rights and international and national IP regulations. Introducing genetically modified organisms in the laboratory or in the field will require establishing national and institutional systems for biosafety review and risk assessment.

As a growing number of CGIAR research centers consider the development and release of genetically modified products, it is crucial to enhance our understanding of the political and institutional factors that influence their adoption and diffusion.

Over the past decade, ISNAR has responded to the challenges described above, by implementing an integrated, and expanding program of research, training and advisory services on major policy and management aspects of agricultural biotechnology. The paper will describe the methodologies applied and findings to date, and emphasize in what way the policy and management processes for agricultural innovation processes are changing as a result of the introduction of modern biotechnology.

I. Introduction

The advent of biotechnology[1], in particular genetic engineering, and related debate has been a blessing for researchers studying the social, policy and economic aspects of agricultural technologies. The debate has resulted in renewed attention for the broad issues associated with the costs, benefits and risks of introducing new technologies in agriculture. Equity and safety issues associated with biotechnology and genetically modified organisms (GMOs) are being debated virtually all around the world, in forums ranging from grassroots "citizens' panels" to public debates in developed and developing countries, to major UN gatherings such as the World Food Summit and the recent World Summit on Sustainable Development. Since the mid-1980s, a range of donor agencies invest additional funds in agricultural biotechnology capacity development in developing countries, to narrow the technology gap between advanced and developing nations and / or to enhance the necessary skills for the judicious introduction and safe management of biotechnology.

Mobilizing modern biotechnology to serve agricultural research in developing countries implies new investments, changes in the way research is managed, and growing responsibilities for agricultural policymakers, research managers, and scientists. At the agricultural policy level, comprehensive strategies are needed to ensure that biotechnology serves national agricultural objectives and targets communities most in need. Government officials assuming these responsibilities play a crucial role in setting policies, research agendas, and developing regulatory capacity for agricultural biotechnology. Their task is made difficult because public budgets for agricultural research are severely constrained; human capacity is limited and extensive debate on the merits and safety of biotechnology complicate timely decision-making. At the institutional level, new institutional structures will be needed to successfully integrate biotechnology in agricultural research organizations and programs. Changes in the structure of research organizations may be required, for example, to absorb the high initial capital costs. Considering the dominant role played by the private sector, new linkage mechanisms are required that comply with intellectual property rights and international and national IP regulations. Introducing genetically modified organisms in the laboratory or in the field will require establishing national and institutional systems for biosafety review and risk assessment.

The present paper summarizes findings from ISNAR's work on agricultural biotechnology, and the methodologies applied, emphasizing in what way the policy and management of agricultural innovation processes are changing as a result of the introduction of modern biotechnology. The paper includes an initial assessment of the success and failure factors that have affected our work, and lessons learned along the way. Finally, we would like to call attention to the need for more structured inter-center collaboration on the subject. As a growing number of CGIAR research centers consider the development and release of genetically modified products, it is crucial to enhance our understanding of the political and institutional factors that influence their adoption and diffusion. At the same time, centers are building up valuable, hands-on experience in important management aspects of agricultural biotechnology, which would be of benefit to national partners.

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[1] Biotechnology: "Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (Convention on Biological Diversity). 2. "Interpreted in a narrow sense, ... a range of different molecular technologies such as gene manipulation and gene transfer, DNA typing and cloning of plants and animals" (FAO's statement on biotechnology).
Source: FAO Glossary of Biotechnology for Food and Agriculture, 2002.
URL: http://www.fao.org/biotech/index_glossary.asp?lang=en

II. Biotechnology in developing-country agriculture: Policy implications

Governments considering whether or not to invest in agricultural biotechnology need to determine where the most pressing needs and priorities lie and if biotechnology can meet those needs and fit those priorities. Ideally, national capacity development in agricultural biotechnology is guided by a comprehensive strategy that spells out priority areas for biotechnology R&D, expected products and impact, the implementing agencies and required funding levels and sources. In doing so, a number of issues require special attention: (1) making sure that national capacity is available to assess the available information on new developments in biotechnology, the performance of biotechnology products in other countries, and the potential application of new developments to national priorities; (2) ascertaining the cost of research and development (R&D) and the infrastructure required; (3) ensuring that regulations are in place for assessing the risks whether new products may pose to human health and the environment; (4) managing intellectual property rights and public-private partnerships; and (5) creating or enhancing the delivery systems that will get new products to farmers and consumers.

A number of recent reports point to the vital role the public sector has in advancing biotechnology for development[2], particularly with a view to having national policies and strategies in place to ensure access to new technology, manage the risks properly, and ensure the equitable distribution of benefits. Most recently, the UN Economic Commission for Africa confirmed this view[3], and called for African governments to:

- Promote African-focused biotechnology research in which emphasis is laid on "orphan crops", particularly cassava, millet sorghum, sweet potato and yams but also other cereals such as maize, rice and wheat;
- Develop African-owned biotechnology policies whereby all the relevant stakeholders, including civil society, private sector farmer organizations, are involved in the formulation of national plans;
- Establish national regulatory institutions for risk assessment and management since most African countries have inadequate human resource capacity to perform these functions;
- Increase investment in modern biotechnology research. The current levels in most African countries are very low (hardly 2% of the total agricultural research funds);
- Promote public/private sector partnership in modern biotechnology research; and
- Strengthen the linkages between modern crop biotechnology and its use in practical plant breeding.

Much of this upbeat language can be explained by the initial positive results from the introduction of genetically modified (GM) maize and cotton in countries such as Egypt and South Africa. However, the actual uptake of GM products in the developing world is very slow, for a major part caused by the absence of an enabling policy environment as outlined by UN ECA resulting in a very cautious approach to the introduction and regulatory decision-making for biotechnology products. As of 2001, the total area planted to GM crops world-wide was 52.6 million hectares (130 million acres), or 1.3 percent of total global cropland

[2] For example, the UNDP Human Development Report 2001 on "Making New Technologies Work for Human Development".
[3] UN ECA. 2002. Harnessing Technologies for Sustainable Development. Addis Ababa: UN Economic Commission for Africa.

area, and 99 percent of the total GM crop acreage was confined to only four countries: the United States (68%), Argentina (22%), Canada (6%), and China (3%)[4].

III. ISNAR's response: Research strategy and experience to date

ISNAR responded to the challenges outlined above by establishing a program for policy research, advisory services and outreach / training on strategic aspects of agricultural biotechnology. It did so in close collaboration with the "founding" donor agency (Government of The Netherlands), by formulating a 5-year work plan and recruiting a team for what is now called ISNAR's Biotechnology Service (IBS). Launched in 1993, the overall goal of IBS is to support innovation in agricultural research by responding to policy and management needs for biotechnology. Specifically, the project:

- Supports policy and strategy development that enhances capacity in agricultural biotechnology
- Assists in developing leadership skills among policymakers and research managers for integrating biotechnology in agricultural research programs
- Harnesses the internationally available expertise to respond to identified technical, policy, and management needs

It is important to note that the IBS project was set up as a "service" (not a research project), by ISNAR, The Netherlands' Special Programme on Biotechnology and Development, and initially guided by a Steering Committee. The approach adopted for the IBS project evolved as follows:

- Emphasis was first on information collection and dissemination (e.g., through ISNAR research reports), and attendance at national and regional conferences, workshops, and seminars.
- A series of IBS regional policy seminars (1994-1996) served to (1) Examine national policies and priorities for agricultural biotechnology research; (2) Analyze case studies to determine current and future needs in research management and planning for agricultural biotechnology; (3) Determine needs among participating countries for follow-up actions.
- The policy seminars and analysis of their results formed the basis for a 5-year follow-up proposal (1998-2002). Major activity areas were determined based on priorities emerging from the policy seminars, with increased emphasis on economic analysis, biosafety capacity building, and the management of intellectual property rights. The "research component" for these subjects increased, carried out by IBS staff and collaborating experts (see below).
- Completed and ongoing IBS research together with invited contributions from expert organizations constitute the backbone for a 2-week training program on "Managing Biotechnology in a Time of Transition", which is aimed at enhancing the management and leadership skills of research managers responsible for implementing agricultural biotechnology research.

Over the past decade, ISNAR's program on biotechnology evolved in parallel with changing priorities and information needs expressed by national partner institutes. As a result, the "research component" of our work increased, which forms the main subject of this paper. Current priority areas are: (1) Defining biotechnology research agendas; (2) Assessing impact

[4] Data from the International Service for the Acquisition of Agri-biotech Applications (ISAAA).

and benefits; (3) Managing risks; and, (4) Managing intellectual property. Activities in these areas are reviewed in the following sections.

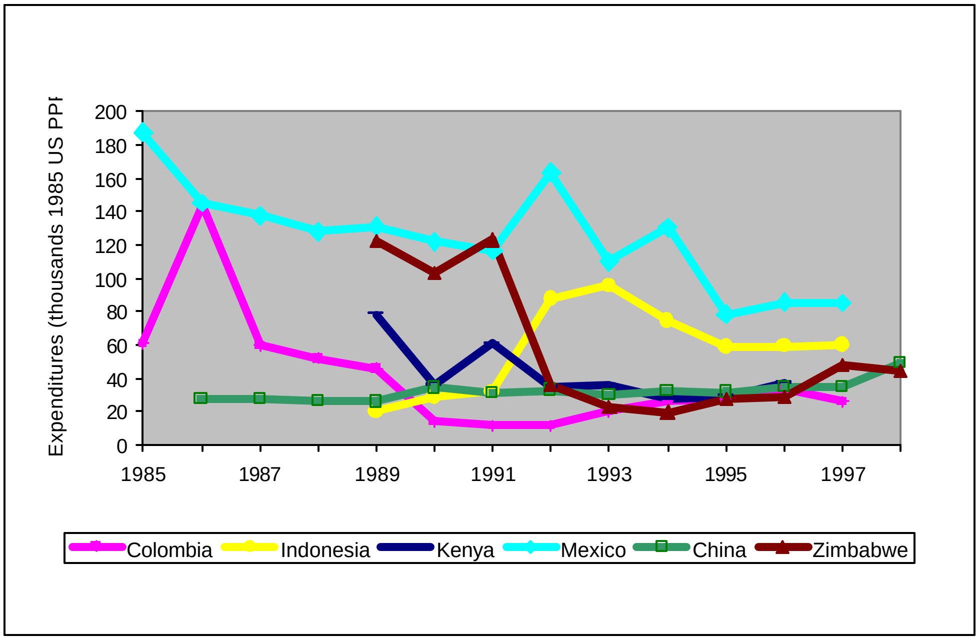
Defining research agendas

A fundamental first step in defining a national or institutional strategy for agricultural biotechnology is to assess the current capacity available to introduce and apply the technologies involved. The level of financial and human resources available for agricultural biotechnology research are two indicators to approach the available R&D capacity. However, very little comprehensive and consistent data on resources for agricultural biotechnology in developing countries that allows comparisons between countries. To address the lack of data and analysis, IBS conducted six surveys between 1998 and 2000 in selected national agricultural research systems — Colombia, China, Mexico, Kenya, Indonesia, and Zimbabwe — to provide an overview of their agricultural plant biotechnology research capacity. Surveys were designed to gather information on public and private sector research capacity by examining institutional development, and previous and current human resources and investment patterns of a representative number of institutions and organizations. Data was collected for the period 1985-1998 in Colombia, China and Mexico. Data was collected for a slightly different period in Kenya (1989-1996), Zimbabwe (1989-1998) and Indonesia (1989-1997). A detailed analysis of data collected can be found in Falck-Zepeda *et al.* (2002)[5].

Agricultural biotechnology in the six countries surveyed has received a great deal of attention from their governments, which is evident in the establishment of special mechanisms to promote biotechnology capacity development, such as dedicated biotechnology research centers and the creation of post-graduate programs, and the formulation of guiding policies and regulatory frameworks (for biosafety and intellectual property rights). However, survey results also indicate that advanced biotechnology techniques are being used in only a few public-sector research organizations. Most organizations are still in the first stages of developing biotechnology research capacity, and only started or intensified their biotechnology research activities in the early 1990s. Although expenditures on agricultural biotechnology research grew annually in all six countries, the proportion of biotechnology expenditures to total agricultural research expenditures was small and less than half that of developed countries. The number of researchers grew much faster than expenditures, which led to a significant decline in the operating expenditures per researcher (see Figure 1 below). This is an indication of a trend towards un-sustainability or low performance, exacerbated by the fact that funding and execution of biotechnology research in the six countries depends highly on the public sector, with only limited participation of the private sector. Moreover, donor contributions constituted the largest source of funding for agricultural biotechnology research in African countries included in the survey. If these countries cannot generate a capacity for sustainable financing, the current high degree of donor dependency raises concerns about the ability of these countries to expand — or merely maintain — their agricultural biotechnology efforts.

[5] Falck Zepeda, J., C. Falconi, J.I. Cohen and J. Komen. 2002. Agricultural Biotechnology in Developing Countries: Investments and Human Resources from Six Selected National Agricultural Research Systems. Paper prepared for the 6th International Conference on Agricultural Biotechnologies: New Avenues for Production, Consumption and Technology Transfer. Ravello (Italy), 11 – 14 July 2002.

Figure 1. Agricultural Plant Biotechnology Expenditures per Researcher



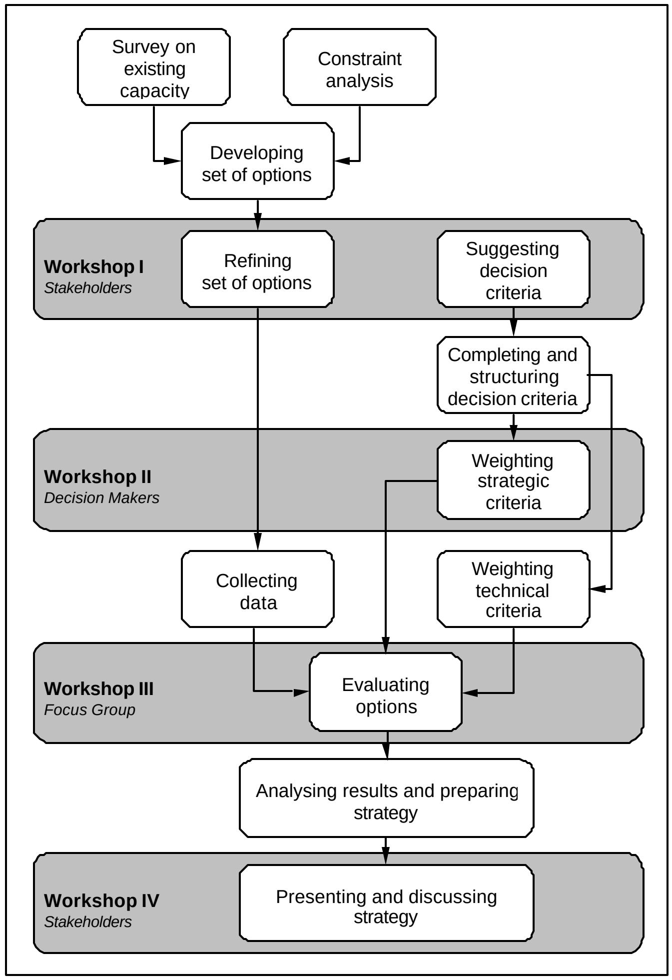
Given the situation sketched above, the importance of carefully determining a limited set of priority areas for agricultural biotechnology research cannot be underestimated. In collaboration with the Swiss Federal Institute of Technology (ETH), Department of Agricultural Economics, ISNAR developed and evaluated a priority-setting approach for biotechnology research. The tool applied in this activity is the Analytic Hierarchy Process (AHP), a versatile group decision-making tool that can incorporate subjective judgments. The basic steps for priority setting in agricultural biotechnology are not different from those for research in general. However, a number of issues require special attention due to particular characteristics of this emerging technology. Among these are (1) uncertainty created by lack of experience and availability of data on the performance of biotechnology, (2) the difficulty of estimating research and development costs in this area, (3) qualitative factors related to human health and environmental effects of biotechnology products, and (4) other factors complicating the measurement of technology performance, for example, the fact that biotechnology research often generates intermediate products for use by related research programs rather than products to be used by farmers or other such end users.

The successful application of the AHP approach in Chile's National Biotechnology Program in 1996 led to a research project, titled "Enhancing the Analytic Hierarchy Process as a Decision Support Tool for Biotechnology Programs", which aimed to elaborate on the decision support tool and to disseminate it to public research managers in other developing countries. For this purpose two more case studies were planned and executed. One focused on defining the biotechnology research program in The Philippines and one identified and evaluated alternative investment options for building biotechnology capacity in Uganda [6]. In these countries, teams were formed of local scientists and policy makers, who helped

[6] A CD-ROM containing all resulting AHP project reports and peer-reviewed publications was produced by ISNAR and ETH, and is available upon request.

determine the main investment options and decision criteria for selection. Final priorities were derived through a series of workshops , involving a wide range of stakeholder groups, as presented in Figure 2.

Figure 2. Process Used in the AHP Priority-Setting Exercise

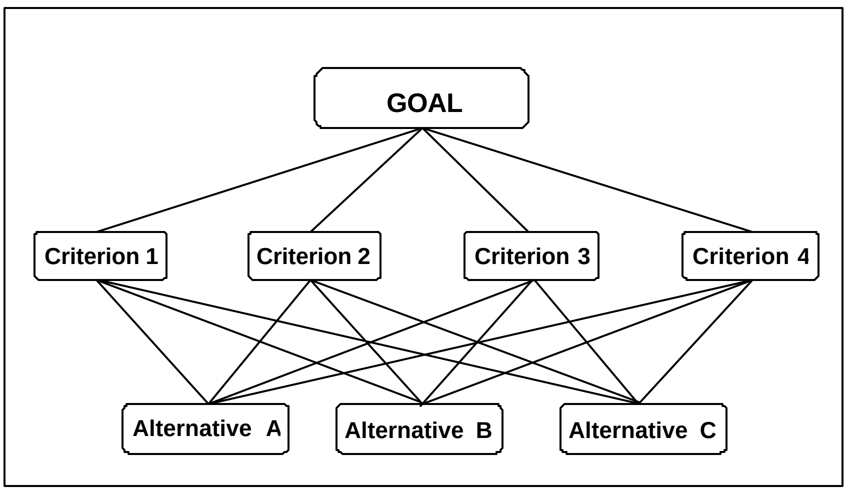


In the case of Uganda, for example, the objective of the exercise was to come up with a strategy on how best the country should strengthen its research capacities in agricultural biotechnology. This was achieved by identifying and developing a set of five investment options, evaluating them against relevant decision criteria, and selecting the most promising option. In Uganda, the option on “Promoting Animal Health” emerged as the top priority, on the basis of which a strategy for strengthening biotechnology research capacity has been designed. The strategy document outlines the implementation of the primary option, including the financial implications, discusses its strengths as well as the challenges involved in implementing it, and suggests a monitoring and evaluation system.

In general, it was found that AHP helps to structure and analyze decision problems by breaking down the complex problem into a hierarchical order and by employing pair-wise comparisons of its elements to determine choices among the set of alternatives. AHP is based on three principles corresponding to the steps described below: decomposition of a complex unstructured problem; comparative judgments about its components; and synthesis of priorities derived from a set of individual judgments.

Step one consists of breaking down the decision problem into a hierarchical structure. Figure 3 below presents a basic hierarchy that is made up of three levels. The top level is the general goal of the exercise as agreed upon by the participants, *e.g*. selecting the investment alternative that contributes most to the sustainable agricultural development of the country. The second level consists of decision criteria that are conceived relevant for the achievement of the goal. Ultimately, the criteria correspond to the national development objectives but usually have to be further detailed in order to give them operational meaning. The bottom level encompasses the alternatives. Whereas the importance of the decision criteria is determined with respect to the goal of the exercise, the priorities of the research alternatives are established with respect to each criterion of the adjacent level. To introduce more precision in the evaluation process, criteria can be split up in sub-criteria, inserting an additional level to the hierarchy, but exponentially increasing the complexity of the decision-making process.

Figure 3 . The Basic Structure of a Hierarchy



Breaking down a complex decision problem into its essential component and structure them hierarchically helps research managers to focus on smaller parts of the decision, which are easier to handle. The structuring process also improves the understanding of the problem since each component (goal, criteria, and alternatives) has to be carefully defined in order to clarify its meaning.

Step two consists of evaluating the research alternatives and weighting the criteria. The alternatives are compared in pairs to assess their relative preference with respect to each of the criteria at the next higher level. Similarly, the criteria are compared in pairs to define their importance with respect to the goal. Finally, step three consists of pulling together the partial results of the evaluation to get the final priorities of the alternatives. The synthesis consists of multiplying the relative priorities of each alternative with the corresponding criteria weight and summing up the results to obtain the final composite priorities with respect to the goal stated at the top level of the hierarchy.

Assessing impact and benefits

Early on in the life of IBS, the importance was recognized to feed strategy de velopment and priority setting for agricultural biotechnology with sound economic data. However, primarily due to rapid turnover of staff, this component took quite a while to get underway. The economic impact of biotechnology on rural development in developing countries has been the subject of several studies, conferences and discussions, however, there is a scarcity of conclusive data. This is partly because of the novelty of biotechnology products. In addition, there has been little interest in analyzing the socioeconomic impact of other, longer established biotechnology innovations, such as micropropagation.

In order to address these limitations, IBS organized an expert consultation in June 2001, titled “Biotechnology and Rural Livelihood: Enhancing the Benefits”. The meeting was held in order to examine a rural livelihoods framework, and potential case studies to quantify and qualify the actual or potential impact of agricultural biotechnology on the livelihoods of poor rural farmers in developing countries. As presented during the consultation, preliminary evidence from studies regarding the economic impact of genetically modified, insect-resistant cotton (Bt cotton) in developing countries (China, Mexico, South Africa), indicates that the adoption of Bt cotton leads to higher yields, and a marked decrease in pesticide use, bearing substantial environmental and human-health benefits.

For example, Huang *et al*. (2001)[7] estimate the impact of Bt cotton in China. China approved Bt cotton for cultivation since 1998. Two competing varieties of Bt cotton were approved for cultivation in different provinces, one developed by the Chinese Academy of Agricultural Sciences, a second variety produced and introduced into China by a joint venture between Monsanto and a Chinese partner. Estimations from these researchers indicate that Bt cotton in general has a significant advantage over conventional cotton. In the surveys conducted in 1999 and 2000, the authors reported that, on average, growers using Bt cotton reduced pesticide use from 55 to 16 kg of formulated product per hectare. In addition, Bt cotton adopters reduced the number of insecticide sprays per crop from 20 to 7. In addition to a 70% pesticide reduction, the authors also noted the almost complete elimination of highly toxic organochlorines and organophoshates insecticides. Preliminary evidence in this study suggests that the use of Bt cotton resulted in a significant positive effect on farmers’ health. The authors noted that 30% of farmers who used conventional cotton varieties reported health problems associated with spraying compared with only 9% who used Bt cotton. The authors concluded that the evidence is quite clear that Bt cotton reduces pesticide use and is likely to be beneficial to health and the environment.

The papers examined at the consultation highlight the importance for researchers to examine all the linkages affected by the introduction of a technology in a community. For example, the China study showcases potential public health and environmental implications that may escape traditional socio-economic studies. What is more important is the need to examine the impact of the technology on the community as a whole. Communities in developing countries are bound to use additional measurements of wealth and security apart from monetary considerations. In addition, communities may use informal and formal institutions as well as intangible interrelationships between different members in a community to deal with innovation. Based on the findings of the consultation, IBS developed a proposal, adopting a

[7] Huang, J., R. Hu, C. Pray, F. Qiao and S. Rozelle. 2001. Biotechnology as an Alternative to Chemical Pesticides: A Case Study of Bt Cotton in China. Paper presented at the expert consultation “Biotechnology and Rural Livelihood: Enhancing the Benefits”. ISNAR, The Hague, June 25-28, 2002.

broader, "sustainable livelihoods" approach to study the impact of agricultural biotechnology. The purpose of the study would be to improve the understanding and analysis of the impact of biotechnology on rural livelihood, and build capacity for such research among partner institutes in developing countries. Pilot research activities are planned in Colombia and Uganda, in collaboration with national researchers and sister centers such as CIAT, IFPRI and IPGRI.

Managing risks: Biosafety

Establishing and maintaining a functional, effective biosafety system presents various challenges. It requires adequate and dependable funding. It entails education and coordination across various government ministries, universities and research institutes, private sector interests, individual scientists, and the public. Significant investments may be needed in training and human resource development, information and communications systems, facilities, and feedback mechanisms.

"Biosafety" is associated with the use of genetically modified organisms (GMOs) and, more generally, with the introduction of non-indigenous species into natural or managed ecosystems. Biosafety regulation — the policies and procedures adopted to ensure the environmentally safe application of modern biotechnology — has been extensively discussed at various national and international forums. Much of the discussion has focused on developing guidelines, appropriate legal frameworks, and, at the international level, on developing a legally binding International Biosafety Protocol.

Currently, biosafety reviews generally focus on a limited number of environmental issues associated with the release of transgenic crops. Two of these concern the possibility that crops or their relatives may invade new territory, displace existing plant communities, or reduce species biodiversity. They may have added importance in regions that are centers of origin or diversity for the crop. *Weediness* — the potential for a crop to become established and to persist and spread into new habitats as a result of newly introduced genes — is an issue when there is scientific evidence that acquisition of the new genes is sufficient to convert a domesticated species into a successful weed. *Gene flow* — in which new genes are spread by normal outcrossing to wild or weedy relatives of the engineered crop — becomes an issue if the new trait(s) confers a fitness advantage and becomes stably introgressed into the recipient genome. *Toxicity* is an issue associated with human health concerns over allergenicity and the safety of biotechnology foods and potential negative effects on non-target organisms, especially beneficial species. *Pest and pathogen effects* include a range of possible consequences such as the generation of novel viruses by molecular exchange within a transgenic plant, or emergence of target pest populations resistant to an engineered control mechanism, such as the expression of B.t. toxins.

Current IBS research analyzes the management and functioning, and possible enhancement, of national biosafety systems. This part of our program is implemented as a joint activity with a biosafety specialist based at Virginia Tech. Case-study research has been completed in Egypt and Argentina, and was recently started in Kenya. Studies completed to date[8] have

[8] Burachick, M.S. and P.L. Traynor. 2002. Analysis of a National Biosafety System: Regulatory Policies and Procedures in Argentina. ISNAR Country Report 63. The Hague: International Service for National Agricultural Research; Madkour, M., A.S. El Nawawy and P.L. Traynor. 2000. Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt. ISNAR Country Report 62. The Hague: International Service for National Agricultural Research.

yielded a rich set of recommendations to improve the management and functioning of the national biosafety system, which will not be detailed in this paper.

In Egypt and Argentina, the Ministry of Agriculture is the lead government entity overseeing agricultural biotechnology and biosafety. It is within this ministry that environmental safety evaluations are conducted, and decision made regarding field tests or commercial releases; the Ministry of Environment has a lesser role, if any. Both countries have constituted advisory committees that conduct technical reviews and risk assessments, and make recommendations for decisions regarding release applications. Food safety evaluations are primarily conducted through the Ministry of Health.

In both countries, collaboration and coordination between the different ministries involved in the biosafety system was found to be a major area for improvement. A case in point would be harmonization between existing regulations for seed registration and biosafety regulations. In addition to biosafety review and approval, GMO crops intended for commercial use also are subject to existing regulations for seed registration, and may involve sanitary and phytosanitary regulations governing import, as well. There is potential for the respective authorities to overlap, which could lead to discord between the agencies involved, delays in review procedures, and confusion on the part of the proponent. In both Egypt and Argentina, regulatory officials have worked to coordinate their respective requirements, with varying degrees of success.

The main challenge being faced in both countries is to build the necessary human capacity to conduct science-based risk assessments and biosafety studies. In the two countries studied, limited technical capacity in biotechnology creates the potential for conflicts of interest, when biosafety committee members also appear in the role of applicant seeking committee approvals. This situation has the potential to erode public confidence in the biosafety system. Typically, membership on a biosafety committee is an unpaid position added to a person's regular duties.

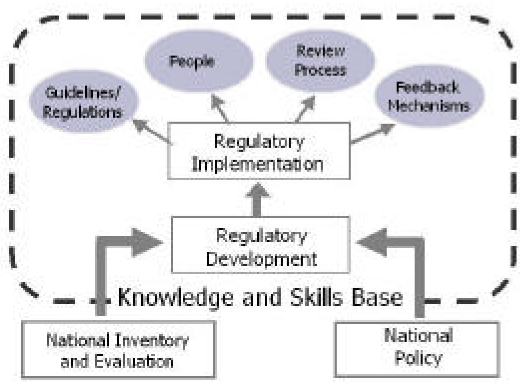
In an effort to build upon the experiences gained through these prior country studies, ISNAR organized an international expert consultation in July 2001 for the purpose of developing a Conceptual Framework to systematically address regulatory implementation and capacity building needs within developing countries. More specifically, the framework was intended to a) expand upon the conceptual basis previously described; b) address the integration of biosafety with other regulatory systems; c) incorporate newly identified components, concepts and lessons derived from other national, regional and international experiences analyzed during the consultation; and d) elaborate policy issues and options that directly bear on the design and efficacy of the biosafety system.

The conceptual framework[9] addresses five elements identified by the consultation participants as fundamental to the development and implementation of a national biosafety system (see Figure 4 below). The first two, national policies, strategies and research agendas regarding biotechnology and biosafety, and a national inventory and evaluation, provide the foundation for subsequent regulatory implementation. The next element, requisite knowledge, skills and capacity base, is the resource environment within which the final two elements occur: development of regulations and implementation of regulations.

[9] McLean, Morven ; Robert Frederick, Patricia Traynor, Joel Cohen and John Komen. 2002. A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity and Regulation. ISNAR Briefing Paper 47.

The framework aims to clarify critical decision points in the development of a national biosafety system; examine choices among policy options; and delineate some of the scientific and social dimensions of these options. It seeks to complement ongoing regional and global projects that facilitate the development of national biosafety guidelines and frameworks. It is also intended to serve as a tool to assist donors and other providers of assistance to target capacity building investments.

Figure 4. The Basic Elements of a National Biosafety System



Managing intellectual property and proprietary science

A final challenge discussed in this paper involves the fact that some form of intellectual property rights protects most biotechnology processes and products, many of which are owned by private-sector companies. Public, national, and international agricultural research organizations working in and with developing countries also develop and use protected materials. The legal and management implications of using proprietary biotechnologies and disseminating products resulting from them are complex. National agricultural research organizations (NAROs) of developing countries, international agricultural research centers (IARCs) and advanced research institutes are collectively affected by changes in proprietary rights as related to agricultural research. These changes are particularly relevant to these partners in research because of two related developments: First is the increasing importance of biotechnology in public agricultural research organizations. Second is the growing position of the private sector in international agricultural research. Profound changes are taking place in the agricultural research environment, including company mergers and industry consolidation, increasing private investments in agricultural biotechnology, market concentration and, consequently, an increased emphasis on acquisition and protection of intellectual property. Publicly funded research organizations need a proactive response to these changes.

In recent years, IBS in collaboration with a legal specialist based in Costa Rica, has conducted surveys to determine the extent to which proprietary research inputs are used at seven international agricultural research centers and in national agricultural research organizations in Latin America and Southeast Asia [10]. The surveys show that proprietary technologies and materials that are protected through intellectual property rights have made important contributions to the research programs of the institutes involved. The increasing use of proprietary materials also means greater reliance on licenses, material transfer agreements, and other legal agreements. Both national and international public research institutes therefore require suitable institutional and legal frameworks and human capacities for managing intellectual property. They are exploring and establishing new institutional structures, such as "research liaison offices" or "technology transfer offices", appointing IP officers and developing IP statutes. With such legal expertise, research organizations can protect inventions when necessary and use them to negotiate access to and use of proprietary technologies owned by others. The adoption of more proactive strategies for the management of IP requires significant time and investment. These investments are needed to learn by doing, and test institutional arrangements for their effectiveness, responsiveness and abilities to address complex legal conditions and agreements expected in the future.

The majority of CGIAR centers recently started developing in-house IP management capacity. The CGIAR Central Advisory Service (CAS) on Intellectual Property, which is based at ISNAR, supports their efforts. CAS assists the CGIAR centers by providing and facilitating expert advice, and enhancing knowledge exchange on intellectual property issues. CAS' specific objectives are to:

- Consult with centers regarding R&D activities with implications for managing proprietary technology, followed by preparation of expert reports;
- Serve as a liaison for CGIAR centers with expert organizations and legal expertise regarding proprietary technology and the management of intellectual property rights (IPR);
- Establish mechanisms for documentation, communication and exchange of experience among the CGIAR centers, and the global agricultural research community.

The challenge currently facing ISNAR and IBS is to establish a similar support service for national agricultural research organizations, building on the expertise and tools developed by CAS and individual CGIAR centers.

IV. Conclusions and recommendations

When properly targeted and managed, new technologies can help raise incomes for resource-poor farmers as well as contribute to improved food security. In a rapidly moving field such as biotechnology, national R&D efforts coupled with increased research-management capacity is essential, in order to prudently monitor new trends, develop (or import) and apply the new techniques and products. In close collaboration with national agricultural research organizations in partner countries, expert organizations worldwide, and a range of CGIAR centers, IBS contributes to achieving overall development goals through the appropriate targeting and careful management of agricultural biotechnology.

Based on our experiences over the past decade, a number of "lessons learned" are proposed below. While some of them may sound obvious, they are nonetheless important as we find

[10] Cohen, J.I., C. Falconi, J. Komen and M. Blakeney. 1998. Proprietary biotechnology inputs and international agricultural research. ISNAR Briefing Paper 39. The Hague: International Service for National Agricultural Research; Salazar, S., C. Falconi, J. Komen and J.I. Cohen. 2000. The use of proprietary biotechnology research inputs at selected Latin American NAROs. ISNAR Briefing Paper 44. The Hague: International Service for National Agricultural Research.

too few long-term, multi-disciplinary research efforts in the CGIAR system, while collaboration between centers around major challenges is limited too.

The following five lessons are suggested for discussion at the conference:

1. The importance of building multi-disciplinary project teams to carry out a clearly defined, multi-year program of work cannot be repeated too often. With regard to IBS, this started with a 2-person team in 1993 (1 plant breeder / geneticist, 1 political scientist) that has grown to 3.5 positions currently (1 plant breeder / geneticist, 1 political scientist, 1 agricultural economist, 0.5 biosafety specialist), complemented by a network of collaborating experts.

2. The project's orientation towards tangible outputs and outreach activities, organized around topics that are of immediate relevance to national partners, leads to a high visibility as confirmed by the large number of requests to IBS for information, advice, reports, attendance at meetings, and the like. This approach, coupled to a high degree of project team independence, contributed greatly to the steady expansion of IBS's funding basis, and the "spinning off" of new services such as CAS. In 2002, advanced plans and a funding proposal were developed for launching a special service for advisory services and capacity-building support on biosafety.

3. Those activities that were developed and implemented in close collaboration with expert organizations in partner countries, advanced research institutes, and CGIAR centers have been most successful. This type of collaborative arrangements ensures relevance to the countries involved, and adequate technical content and backstopping, which would normally not be achieved by a relatively small project team based at ISNAR. It is a prominent feature of IBS's work on biosafety, and its training activities. Although the costs associated with the development and implementation of combined efforts are higher than going alone, these investments pay off in terms of increased impact.

4. An active program for seminars and courses has been key to achieving short-term impact. Each event included an evaluation of IBS materials; involved invited experts from CGIAR centers and other advanced institutes, and resulted in plans for follow-up actions at the country level (regional seminars) or the individual level (management course). Important outcomes from courses and seminars include:

    - Application of new research management tools (e.g., the analytic hierarchy process - AHP);
    - Definition of institutional and national priorities for agricultural biotechnology;
    - Formulation of institutional and national guidelines for biosafety and/or IPR;
    - New bilateral and regional partnerships.

5. In short, the main strengths of the project are as follows:

    - ISNAR, interested donor agencies and NARS representatives worked jointly to establish IBS and determine the project's program of work, leading to the adoption of a long-term perspective and stable financial basis.
    - At the outset, ISNAR appointed a team, not a single individual, to carry out the project. ISNAR made an effort to maintain team stability and autonomy, also in times of staffing turnover and organizational changes. The project manager was

given a high degree of autonomy in directly approaching donor agencies to complement support to IBS.

- The project emphasizes the generation of tangible outputs of relevant to partners and clients. Research results are used in training / outreach activities, which in turn feed research activities.

The main challenge / weakness faced at this point is that the wide range of activities carried out so far, urgently calls for analysis so that more specific guidance can be provided to national partner organizations struggling with the many issues posed by modern biotechnology. The fact that this has not been accomplished yet lies in the fact that, as a project running on "earmarked" funding only, most activities have a limited timeframe and financial basis. To start addressing the challenge, long-term collaboration will have to be sought with research groups in developed and developing countries, as well as with fellow social researchers in CGIAR centers.