FAO-APAARI Expert Consultation on the Status of Biotechnology in Agriculture in Asia and the Pacific

21-23 March 2002

PROCEEDINGS

FAO Regional Office for Asia and the Pacific

and

Asia-Pacific Association of Agricultural Research Institutions

Bangkok, Thailand
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Bangkok, Thailand
Preface

The FAO-APAARI Expert Consultation on the Status of Biotechnology in Agriculture in Asia and the Pacific was organized to assess the positive effects and areas of concern; with focus on types of policy advocacy, information, training and capacity building to ensure biosafety standards; identify experts and institutions, and reconfirm the needs for and requirements/arrangements for the establishment of biotechnology network. The initiative is considered as most opportune in view of several issues that have generated global debates pertaining to biotechnology.

The progress in biotechnology research and promotion of biotechnologies for the ultimate benefit in the developing countries is faced with certain impediments such as lack of clear priorities and how best to integrate research efforts with broader objectives set for agricultural research coupled with the much hyped issues of biosafety and bioethics. Support to public and private sector initiatives in biotechnology is crucial at this juncture for the sustainable advances in crop, animal and aquatic productivity and for strengthening our food, health and livelihood security system. All this would be possible, if the right institutions are in place, right human resource is available, enabling environment exists, inter-institutional, inter-regional and inter-national linkages exist and access to knowledge, both new and traditional is possible.

The Expert Consultation addressed these problems and issues encountered for promotion of biotechnological applications in improving agricultural production and provided some useful recommendations that are relevant for the Asia-Pacific region. In this endeavour, it benefited greatly from the diverse stakeholders who participated and contributed to its success particularly from the rich experience of Prof. Asis Datta, Prof. S. Bhumiratna and Prof. Jikun Huang as resource persons and about 50 participants from the regional NARS, IARCs, CGIAR, Private sector, and NGOs.

I wish to thank the FAO authorities specially, Dr R.B. Singh, ADG and Regional Representative, FAO-RAP, for providing an opportunity to APAARI to organize this meeting. We are grateful to the resource persons and the participants for their valuable presentations, keen interest and inputs during the course of deliberations. The help and cooperation extended by Dr Malcolm Hazelman, nodal officer from FAO-RAP is gratefully acknowledged. I thank Dr (Ms) Mary Taylor for her ready acceptance to serve as the rapporteur and able handling of the responsibility. Last but not the least, I wish to place on record the excellent teamwork of APAARI secretariat – Mr P.K. Saha, T.O, FAO; Dr A.K. Bawa; Ms Urairat; Ms Sophia; and Ms Rujee Raktham that made the Expert Consultation very successful.

(R.S. PARODA)

Executive Secretary, APAARI
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List of Acronyms

ACIAR  Australian Centre for International Agricultural Research
ADB  Asian Development Bank
AIT  Asian Institute of Technology
APAARI  Asia Pacific Association of Agricultural Research Institutions
APSA  The Asia and Pacific Seed Association
ARD  Agricultural Research for Development
AREEO  Agricultural Research Education and Extension Organization
ASEAN  Association of Southeast Asian Nations
AVRDC  Asian Vegetable Research and Development Centre
BARC  Bangladesh Agricultural Research Council
CAAS  Chinese Academy of Agricultural Sciences
CARP  Sri Lankan Council for Agricultural Research Policy
CGIAR  Consultative Group on International Agricultural Research
CIMMYT  International Maize and Wheat Improvement Centre
DBT  Department of Biotechnology
DOA  Department of Agriculture (Thailand)
DST  Department of Science and Technology
FAO  Food and Agriculture Organization of the United Nations
FAO-RAP  FAO Regional Office for Asia and the Pacific
GFAR  Global Forum on Agricultural Research
GMO  Genetically Modified Organisms
HRD  Human Resource Development
IARC  International Agricultural Research Centre
ICAR  Indian Council of Agricultural Research
ICGEB  International Centre for Genetic Engineering and Biotechnology
ICRISAT  International Crops Research Institute for the Semi-Arid Tropics
ICT  Information and Communication Technology
ILRI  International Livestock Research Institute
IPM  Integrated Pest Management
IPR  Intellectual Property Rights
ISNAR  International Service for National Agricultural Research
ITPGR  International Treaty on Plant Genetic Resources
LIPI  Indonesian Institute of Sciences
MARDI  Malaysian Agricultural Research and Development Institute
NARC  Nepal Agricultural Research Council
NARI  National Agricultural Research Institute (Papua New Guinea)
NARS  National Agricultural Research Systems
NCGB  National Centre for Genetic Engineering and Biotechnology
NGO  Non-Governmental Organization
NRM  Natural Resource Management
PARC  Pakistan Agricultural Research Council
PCARRD  Philippine Council for Agriculture, Forestry and Natural Resources Research and Development
PGR  Plant Genetic Resources
PIC  Pacific Island Countries
PVP  Plant Variety Protection
R&D  Research and Development
RDA  Rural Development Administration (South Korea)
SPC  Secretariat of Pacific Community
TRIPS  Trade Related Intellectual Property Rights
UNU  United Nations University
FAO-APAARI Expert Consultation on the Status of Biotechnology in Agriculture in Asia and the Pacific

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BACKGROUND

The Food and Agriculture Organization of the United Nations through a Letter of Agreement (Appendix-I) with the Asia-Pacific Association of Agricultural Research Institutions (APAARI) proposed to undertake studies to assess the needs and capacity of countries in Asia pertaining to biotechnology covering the following aspects:

- assess the positive effects including the areas of potential concern.
- types of policy advice, information and technical assistance required.
- training and capacity-building support requirements including how and where to meet such needs.
- assessment of technology options available and relevant for meeting the needs.
- identify useful regulatory environments to ensure biosafety and harmonization with international standards.
- identify important institutions and individuals involved in biotechnology including their specialties and strengths.
- reconfirmation of the need for and requirements/arrangements for the establishment of a regional biotechnology network.
- organize a regional Expert Consultation.

As a follow-up of this Agreement, FAO-APAARI jointly organized an Expert Consultation on the Status of Biotechnology in Agriculture in Asia and the Pacific at FAO Regional Office for Asia and the Pacific (FAO-RAP), Bangkok from 21–23 March 2002 as per the programme (Annexure-I) and there were about 50 participants (Annexure-II) representing regional NARS, IARCs, CG Institutions, NGOs, and Private Sector. The expertise of three leading biotechnologists in the region was availed to prepare the discussion papers on the sub-regions i.e. West and South Asia, the ASEAN region and China.

The deliberations were conducted in six technical sessions and a round table discussion cum plenary session. A brief report of the proceedings is presented.

INAUGURAL SESSION

Chairperson : R.N. Sapkota

Dr Malcolm Hazelman, Senior Extension, Education and Communication Officer of the FAO-RAP and Nodal Officer for the Expert Consultation, welcomed the participants on behalf of the organizers.

Dr R.S. Paroda, Executive Secretary, APAARI, presented the objectives of the Expert Consultation and also extended a warm welcome to the participants. In his brief address, Dr Paroda highlighted the important role of biotechnology to improve agricultural production and productivity and the need to make it more sustainable, environmentally safe and cost effective to realize the overall goal of achieving food and nutritional security and poverty alleviation. Given the growth of the population and consequent increase in demand for the food, faster application of biotechnological tools to develop most of the varieties/species with desirable traits of productivity and quality, was indispensable. He urged the participants to develop a consensus to facilitate smoother
adoption of biotechnologies. He expressed concern with regard to the slow pace in adoption of technologies compared to the time taken for their generation. In view of the new options and exciting opportunities offered by biotechnology, he stressed on the need to move forward to harness their benefits. Recognizing the lack of capacity of several NARS in the region, he called upon the participants to suggest suitable mechanism of cooperation to overcome the problems that cannot be addressed at the institutional level, individually.

The Chairperson Dr R.N. Sapkota, who is also the Chairperson for APAARI, stressed on the importance of biotechnology in agriculture and advocated the need to adopt an aggressive approach to ensure enhanced application of biotechnologies in agriculture and to try to dispel the doubts, fears and apprehensions through scientific dialogue and public awareness programmes. It was mentioned that some element of risk was always in-built in any new technology but then this alone should not become the deciding factor to reject or accept it. He encouraged countries to ensure that proper testing and regulatory and policy mechanisms are in place to take care of biosafety and bio-ethical concerns.

The inaugural address was delivered by Dr R.B. Singh, Assistant Director General and Regional Representative of FAO Regional Office for Asia and the Pacific. Dr Singh mentioned the increasing incidence of hunger, poverty, population growth, food and nutritional insecurity, environmental degradation, and falling investments in agriculture as some of the major challenges confronting developments in agriculture. The meeting was informed that the share of Asia in the increased global demand for cereals by 2030 was estimated to rise by 48 per cent. In this scenario, increase in the biological yields, improving nutrient content of soils, agricultural intensification and sustainable management of natural resources were identified as the major challenges. Dr Singh elaborated on the profound issues, perils in form of ethics of use of human genetic information, transgenic crops and livestock, food and environmental safety and IPRs. He opined that right to adequate food, informed choice and right to democratic participation with regard to the use of GMOs was essential. Among the bio-safety concerns, human health, bio-terrorism, resistance build up, limiting farmers’ choices to crop management, loss of biodiversity and harmonization of bio-safety standards and protocols were deemed to be of high importance. The transparency of sanitary and phyto-sanitary measures needs to be ensured and the “one size fits all” approach be discarded. To address the environmental issues, he suggested having regulations at the national, institutional, and international levels together with clear guidelines for field tests and commercial release. The role of partnerships and scientific alliances whether public-private, local-national international, inter governmental, with NGOs, farmers associations, educational institutions, developed and the developing nations; were deemed to be of paramount importance in the fast changing R&D environment wherein the best results were expected to emerge by working together.

Dr (Ms) Mary Taylor, representing the Pacific Community, was elected as the Rapporteur for the Expert Consultation.

Mr P.K. Saha, Technical Officer FAO-RAP and Liaison Officer, APAARI proposed the vote of thanks.

Session 1: Regional Status of Agricultural Biotechnology
Chairperson : R.B. Singh
Co-Chairman : Abbas Keshavarz

In this session, two papers namely on the “Status of Biotechnology Applications in Agriculture and Allied Sectors in the West and South Asia” by Prof. Asis Datta, and “Agricultural Biotechnology Development, Policy and Impacts in China” by Prof. Jikun Huang, Centre for Chinese Agricultural Policy, Chinese Academy of Sciences, were presented.
Status of Biotechnology Applications in Agriculture and Allied Sectors in the West and South Asia

Prof. Asis Datta

The presentation by Prof. Asis Datta from India focused on the sub-regional status of biotechnology in NARS in general and India in particular, covering institutes, biotechnology in public and private institutions, issues and concerns, trends in development of biotechnology, linkages, biosafety issues, IPRs and policy initiatives related to biotechnology. He mentioned that the fundamental challenge the world is facing currently is how to ensure that the people who are living in poverty have access to adequate food to maintain a healthy life. The situation appeared grave for over 800 million poor and food insecure people and therefore, remains the most desirable objective of sustainable development.

Even though the Green Revolution had successfully averted a world food crisis during the late 1960s and early 1970s, it was anticipated that advanced biotechnology and genetic engineering could play a major role in food production for the future. Value addition to the conventional methods of agricultural development through the use of modern biotechnology acts as a driving force for the growth of the biotechnology industry, and investment is expected to increase in future. Therefore, it was emphasized that the agro-industry should realize the potential long-term benefits of biotechnology and shape their business plans and activities accordingly. The potential of biotechnology was recognized as it offered technically viable solutions to the most urgent problems in the agricultural and environmental sectors. However, the social, legal and economic problems arising from injudicious and uncontrolled use and application of biotechnology needed to be addressed. Biotechnology applications to increase food self-sufficiency in densely populated countries in South and West Asia was inevitable.

The example of the new ‘Golden Rice’ which offers an exciting opportunity to complement Vitamin A supplementation programmes, particularly in rural areas was cited. Biotechnology – one of the many tools of agricultural research and development was foreseen to contribute to economic development by helping to promote sustainable development centred on small farmers in the developing countries. Agricultural biotechnology, especially genetic engineering, was expected to play an important role in improving agricultural productivity, food, fibre, etc. The presentation highlighted that the concerns relating to biosafety as well as about intellectual property rights (IPRs) cannot be ignored. Effective regulatory mechanisms and safeguards were needed so that the impact of agricultural biotechnology is both productive and benign. There is a moral imperative to make GM crops readily available to developing countries that want them, to help combat world hunger and poverty.

Prof. Datta mentioned that farmers should have access to the improved agricultural technologies through a participatory approach. The percolation of benefits of information and communication networks to the rural areas, especially for small farmers was an imperative. The potential of genetic engineering and biotechnology was considered necessary to increase agricultural production and productivity, enhance the environment, and improve food safety and quality. When poor small farmers have access to land, agricultural extension services, marketing opportunities, working equipments and credit, then high yield variety seeds adapted to the biotope and resistant to pests can be developed with the use of genetics and biotechnology to bring more food to the small farmers. Finally, it was mentioned that for sustainable agricultural development and sustainable food security, better governance and new technologies such as genetic engineering and biotechnology in the coming days would be an imperative.

Agricultural Biotechnology Development, Policy and Impacts in China

Prof. Jikun Huang (presented by Prof. (Ms) Qinfang Wang)

In the second presentation made by Prof. (Ms) Qinfang Wang from CAAS, China on behalf of Prof. Huang, it was stated that for China agricultural biotechnology is a strategically significant tool to improve its national food security, a means to raise agricultural productivity, and create a competitive position in international agricultural markets. The objective also addressed the perception that policy makers have of the risk associated with the dependence of national food security on imported technologies. Despite the growing debate worldwide
on GM crops, China has decisively developed agricultural biotechnology since the mid-1980s and has emerged as the first country to commercialize a GM crop and was also the fourth country in terms of GM crop area in 2000. The meeting was informed that China has about 20 genetically modified plants that are in the pipeline for commercialization.

Prof. Wang informed that the institutional framework for supporting agricultural biotechnology research programme in China is complex both at national and local levels. The review of the current institutional arrangements also shows that the coordination among institutions and consolidation of agricultural biotechnology programmes will be essential for China to create a stronger and more effective biotechnology research programme in the future.

An elaborate account of China’s efforts in promoting biotechnology was presented that covered increased research emphasis over time, efforts made to improve research capacity, increase the stock of knowledge and technology, and promote commercialization of the biotechnology that was significantly needed by farmers (i.e. Bt cotton). Research capacity in terms of both quantity and quality had improved significantly. On the other hand, further improvement in human capacity was felt necessary to establish an internationally competitive biotechnology research programme and to achieve the overall goal of promoting agricultural biotechnology in China.

An encouraging feature of China’s advances in biotechnology was attributed to the growth of government investments in agricultural biotechnology research. In contrast to stagnating expenditures on agricultural research in general, investments in agricultural biotechnology have increased significantly since the early 1980s. The number of researchers increased rapidly over the past 15 years and so did the investments, measured as expenditure per scientist, which has more than doubled.

An examination of the research focuses of agricultural biotechnology research reveals that the food security objective and the current farmers’ demands for specific traits and crops have been incorporated into priority setting. Moreover, the current priority setting of investments in agricultural biotechnology research has led to investment in favour of the commodities in which China does not have much comparative advantage in the international market such as grain, cotton and oil crops, which implies that China is targeting its GMO products at the domestic market.

The review on the impact studies have shown that small farmers obtained increased incomes from adopting Bt cotton. Farmers who grew most popular Bt varieties reduced their costs of production by 20 to 23 percent over new non-Bt varieties while prices of cotton were about the same for Bt and non-Bt varieties. In addition it may allow some farm families that did not have enough food to increase their food purchases and food consumption. More importantly, the use of Bt cotton has substantially reduced pollution by pesticides in the regions where it was adopted. Farmers’ and farm labourers’ exposure to pesticides has been reduced. Biodiversity of insects also appears to have been enhanced by the adoption of Bt cotton.

It was mentioned that China too is faced with issues of consumer safety and acceptance, many competing factors are putting pressures on policy makers to decide whether or not to continue to commercialize transgenic crops. The demand of producers (for productivity-enhancing technology) and consumers (for cost savings), the current size and rate of increase of research investments, and past success in developing technologies suggest that products from China’s plant biotechnology industry will one day become widespread within China. China also could become an exporter of biotechnology research methods and commodities as opportunities for contract research, the sales of genes, markers and other tools, and exporting GM varieties are expanding in both industrialized and developing countries. Globally, China has several advantages; it has many well-trained scientists, a low cost research environment, and large collections of germplasm.

Although there are still uncertainties about how durable is the current Bt cotton resistance to bollworm and about environmental impacts of Bt cotton, when compared to the known environmental and health problems caused by pesticides, it would seem that Bt cotton is a desirable alternative, particularly in countries like India
which have major bollworm problems. In conclusion, China’s case suggests that more developing countries should seriously consider allowing the cultivation of GMOs such as Bt cotton because it offers an effective way of controlling a serious pest of cotton, reducing pesticide use, and improving the health of farmers and farm workers. In addition, less developed countries should be open to such other biotechnologies that pass their environmental and safety standards and allow farmers to choose the technologies that best fit their farming systems. Finally, Prof. Wang mentioned that China was pursuing one of the largest agricultural biotechnology programmes while addressing both, the positive and the negative ecological effects and proposing new regulations on safety issues.

**ASEAN Agro-Biotechnology: Overview and Recommendation on Regional Collaboration**

**Dr S. Bhumiratna, NCGB, Bangkok, Thailand**

The paper presented an overview of biotechnology application in agriculture in the ASEAN region, assessing the positive effects and the areas of concern, the biotechnological options available and relevant to meet the basic needs, and the status of existing regulatory environments. It also proposed possible mechanisms/arrangements for the establishment of a regional biotechnology network and recommended collaborative activities to strengthen agricultural biotechnology as a tool for regional development.

The salient features of the ASEAN region mentioned were high population of about 500 million, a total area of 4.5 million square kilometers, a combined gross domestic product of US$ 737 billion, and total trade of US$ 720 billion. Agriculture is a critical factor for the rebuilding of economies and for employment of people from the depressed industrial sector. Thailand, for example, is implementing the “sufficiency” concept where agricultural activity plays a critical role in the process.

To avoid returning to the commodity-based agricultural economies and to enhance yields and create value from the commodities, the region is trying to ride the fourth wave of the Genomic revolution in the hope of utilizing biotechnology to add value and create product differentiation, as well as building knowledge-based competitiveness implying thereby that biotechnology has been identified as a key component to accelerate agricultural development. Biotechnological programme needed to be fully integrated into research and continued commitment to basic research was considered necessary to fulfill benefits offered by the emerging technologies.

In terms of trade, it was mentioned that ASEAN is in the process of setting up necessary infrastructure to regulate and control the research, commercialization and trade of GMO products. Although only a few ASEAN countries have clearly approved the use of GM food crops as human and animal feed, ASEAN as a whole has imported products such as GM-soy, GM-maize and processed food-products. For these and several other reasons, the technology raises more troubling issues than any other technology revolution in ASEAN history. Some of the important issues and concerns, which are being considered at the ASEAN regional level, relate to biosafety, public awareness, and access for small farmers and IPR.

It is expected that more genetically engineered crops and other food products will come into the market over the next few years. Obviously, the movement of GMOs for research and trade between countries would be a matter of concern for ASEAN. There is therefore an urgent need for ASEAN to take a regional approach to develop standard procedures for regulating these products. Of the 10 members in ASEAN, at least 4 countries, Indonesia, Malaysia, Philippines and Thailand, have successfully conducted field trials of GMOs of crop varieties. Indonesia is the only country, which has approved the environmental release of Bt cotton.

The ASEAN region was classified into two groups based on their GMO policies. The first group included those countries, which had not yet developed any policy related to GMOs yet. Existing legislation in ASEAN countries/region generally follows the sanitary and phytosanitary instruments and Acts enacted in these areas, to regulate importation of GMOs. Examples of these are the Plant Quarantine Act, Animal Control Act and Fisheries Act. Other legislation includes the Food Act and Hazardous Substance Act.

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1 The paper was presented in another session but for the sake of readers' convenience, has been included with other status papers.
Recent studies by AFIC Market Research between 1998-1999 which include Thailand, Philippines, Malaysia and Indonesia showed that the public in general, was not very aware of food biotechnology. The survey showed that, most countries of ASEAN do not have any structured or organized public education programmes relating to GMOs. In this regard, the Malaysian National Biotechnology Directorate is stepping up efforts to implement their public awareness programmes. The programmes include school and public forum lectures, preparation and distribution of pamphlets and promotion of understanding through mass media. Most countries have information such as frequently asked questions (FAQs) on their websites. Information related to issues such as labeling of GM products, which was "demanded" on the basis of the public's "right to be informed" is also being addressed. It appears that countries have three choices in terms of labeling: mandatory, voluntary or no labeling.

Given that agriculture in ASEAN is mostly undertaken by small farmers who cultivate less than 1 hectare and are resource poor, they are likely not able to afford the new GM plants. Given also that almost all farmers save seeds after crop harvest for planting in the succeeding cropping season, IPR regime may not allow farmers to save their seeds for successive planting. More troublesome, however, is the fact that there are no products developed to suit their particular needs. In addition, the high cost of GM seeds may discourage farmers from the use of these products.

Related to these issues and concerns is also the use of traditional knowledge and biodiversity. Since most biotechnology R&D work is conducted by developed countries, often by private companies, developing countries including ASEAN countries might have to pay for the use of new procedures, genes, promoters and terminators in future. IPR protection is crucial for the growth of the biotechnology industry, since huge investments are usually made in developing a product including its commercialization. The implication of this to trade, technical investment and access to products may put pressure on developing countries. Unfortunately, many developing countries are not yet ready to adopt IPR systems proposed mostly by developed countries. Obligated by WTO/ TRIPS, most countries in the ASEAN region are in the midst of drastic legal development. New intellectual property laws have been prepared and enacted. However, patent laws in existence do not protect plant and animal varieties. Plant Variety Protection Law (PVP) marks the highest point in intellectual property protection for agricultural biotechnology. Few research institutes in this region are well equipped with skills and knowledge concerning intellectual property management. During the past decade, developing countries have witnessed increasing disputes and cases resulting from the lack of effective intellectual property management. Therefore, additional legal measures need to be developed to address this need for IP management. Amongst these are material transfer agreement, confidentiality agreement and IP audit.

The current status of biosafety regulation in ASEAN reveals that only a few countries (Indonesia, Malaysia, Philippines, Singapore and Thailand) have developed some guidelines for R&D and field releases of genetically modified organisms, and none has a comprehensive legal framework to address commercial and consumers' concerns.

The most urgent need identified is building local and regional capacity. In most member countries lack of awareness at the political level coupled with weak management infrastructure, is the major hindrance to this development and should be improved. Other infrastructure such as IPR systems and biosafety are also in need of development albeit with less urgency.

Finally it was emphasized that the ASEAN countries must therefore, work together and utilize where appropriate, expertise from outside region to strengthen capacity in the following areas:

- Policy and decision making processes.
- Developing legal frameworks for biosafety.
- Training in and implementing risk assessment.
- Developing on data management and information sharing.
- Upgrading technology and preparedness to implement a biosafety regulatory framework.
- Developing biosafety clearing house mechanism, which should facilitate cooperation amongst ASEAN countries.
Session II: Biotechnology at National Level
Chairperson : Manju Sharma
Co-Chairman : D. Kirtisinghe

In this session 14 country reports and sub-regional report on ASEAN by Dr S. Bhumiratna were presented. The countries included Australia, Pacific Islands, Bangladesh, China, India, Indonesia, Iran, Nepal, Pakistan, Sri Lanka, Malaysia, Philippines, Republic of Korea and Thailand. A brief account of the country presentations is given below.

AUSTRALIA

Dr John Skerritt, presented a report that focused on ACIAR biotechnology initiatives. The meeting was informed that ACIAR worked through partnerships with NARS and is part of the Overseas Development Assistance programme. ACIAR currently has over 100 projects relating to biotechnology. Presently, ACIAR is involved in non-controversial programs covering diagnostics, vaccines for livestock, tissue culture and microbial fermentation. These technologies have had a profound effect on the agriculture of the developing countries of the region.

PACIFIC ISLANDS

Dr Mary Taylor, representing the Pacific Community, highlighted the biotechnological developments in the sub-region. She pointed out that the region covers a vast area composed of a large number of island countries, which range in size from Papua New Guinea, with a population of 4 million to Niue with a population of just two thousand. Agriculture in the island countries is predominantly of subsistence type, and is based on root crops as staple food. There are some exports of crops/commodities such as sugar, coffee, cacao etc but markets for these are fragile and susceptible to external influences. Concerns within the Pacific relate to agricultural intensification, rapid population growth, fragile economies and the environment, and resources limitations. Biotechnology is currently being used within the region, but mainly for micro-propagation of elite crop varieties, production of pathogen-tested plant material and for in vitro storage. The region makes use of other biotechnologies but through collaboration with overseas institutes. These include the use of molecular markers for germplasm management, and PCR-based diagnostics for viral disease detection. At present there is no biosafety legislation within any of the countries in the region. Decisions in this area are made within the confines of quarantine, and in some cases, by the department responsible for the environment. Similarly, intellectual property protection is lacking in all countries, the main problem being the lack of any system with which to protect traditional landraces. Biotechnology will continue to play an important role in agricultural productivity through tissue culture, and the possible adoption of molecular marker technologies and disease diagnostics. Any introduction of other more advanced technologies will have to be well considered and discussed with all stakeholders. As food security and sustainability are the key issues of consideration, any new technologies will have to be within this context. In addition, effective biosafety guidelines will have to be in place.

BANGLADESH

Dr M. Nurul Alam presented the country paper and flagged high population in Bangladesh as the main challenge before the agriculture. It was further mentioned that decreasing trends of per capita land available for increasing agricultural production while ensuring conservation of national resources were some of the important concerns. Therefore, to address these issues, R&D and commercialization of biotechnology is considered to be of high priority to supplement conventional modern technologies.

Having little national (both public and private) capacity for biotech R&D, at present Bangladesh is limited to tissue culture, biofertilizer (Rhizobium), biocontrol (pesticides), hybrid rice technology and mushroom cultivation. Modest number of trained manpower, which is not adequate, is available in BARC coordinated
NARS institutions. The locally developed disease free materials and one hybrid rice (by the public sector) and several imported hybrid seeds (mainly rice) are being marketed by the private seed companies/NGOs. However, in these marketing efforts several issues on the value (cost effectiveness) of the technologies, socio-economic issues, farmers’ rights, IPR and biosafety rules, etc remain unresolved. In spite of all these weaknesses Bangladesh has accorded high priority to harvest the potential of biotech products for food security, increased income, environment protection and human safety. For harnessing the benefits for the resource poor farmers, collaborative public/private/NGO partnership programmes under initiative and assistance of FAO and CGIAR are to be undertaken.

INDIA

Dr (Ms) Manju Sharma mentioned that in India biotechnology has been recognised as a most powerful tool for socio-economic development having a separate Department of Biotechnology in the Government. Since 1982, a systematic impetus has been given to Biotech research and application. There are many other scientific agencies in addition to DBT that support biotech research in India viz. ICAR, CSIR, DST. Universities and private sector organizations for knowledge generation, product and process development and technology transfer. To meet the growing demands of food from limited arable land, diversification of agriculture and value addition are some of the major challenges before Indian agriculture to achieve national goal of sustainable growth and development. Some aspects of the potential of GM crops, impact on environment and human beings, achievements in biotechnology research, bioprospecting and molecular taxonomy, biological software, bioresource development and edible vaccines were briefly projected. Concerns, new areas for research and future plan of action were highlighted keeping in view the needs of the society with special reference to the poor. Need for regional cooperation in this field for mutual benefits was especially highlighted.

INDONESIA

Dr (Ms) Ines H. Slamet Loedin from LIPI, Indonesia informed that biotechnology has been the national priority in Indonesia since 1985 and continued to be priority after the Indonesian economic crisis in 1998. Biotechnology is viewed as a cutting edge technology to improve agriculture, and together with other technologies, can eventually contribute to national food security.

In the first decade of biotechnology development in Indonesia, the intermediate technology was developed such as plant tissue culture for mass propagation and production of disease free plants, biofertilizers and biocontrols on commercial basis. While for livestock, biotech research focused on the embryo transfer for cattle technology and in the area of transgenic and molecular breeding. Plant transformation capacity has been developed in several crops such as rice, corn, sweet potato, and potato. Molecular assisted breeding using DNA markers was used to develop rice resistance to bacterial leaf blight, and several quantitative trait loci for abiotic stress have been identified and used in breeding programme in rice. In livestock, technology such as micro satellites to detect the genetic diversity of livestock, genetic study of resistance gene in thin tail sheep, proboscis, and production of diagnostics have been developed. Indonesia has already had patent law and PVP in place.

The richness of Indonesia’s biological diversity can serve as the competitive advantage in development of biotechnology. However, Indonesia urgently needs to develop capacity in genomics to take advantage of its richness in biological diversity. The issue of access of genetic diversity and benefit sharing has become national concerns. Capacity building in risk analysis and management of biotechnology products is required as well increased public participation in research through public awareness programmes. The existing national biosafety framework needs to be improved to include every stakeholder. Bioprospecting and establishment of microbial culture and other germplasm collection is the main target for research priorities together with improvement of the existing technologies.
IREN

Dr. A. Keshavarz informed in his presentation that there are 4 institutes and 15 laboratories in different universities and research organizations that conduct research in biotechnology. Iran has about 350 scientists engaged in biotechnology research and their efforts are supplemented to a limited extent by the private sector companies. As a result, bio-fertilizers, bio-insecticides and animal vaccines have been commercialized. The current biotechnology research programme has identified application of molecular makers to develop genetic maps and tagging genes for increasing improvements and time reduction and genetic transformation as major objectives. Developing hybrids/varieties with in-built resistance to biotic and abiotic stress in rice, cotton, wheat, sugar-beet, potato and maize have been given high priority. The transgenic crops are still at the test stage. Important constraints that impede the advancements of biotechnology are lack of human resources, capacity building, biosafety framework, sufficient protection of IPR, public investments and public awareness.

NEPAL

Dr Hari P. Bimb informed that agricultural biotechnology in Nepal is perceived essential to address food security and poverty alleviation. The perspective plan of the Ministry of Agriculture and Co-operation has targeted rice, wheat, maize, potato, sugarcane, banana, citrus, cardamom, tea and tomato as priority crops besides the conservation of agro-biodiversity including indigenous land races and their utilization. NARC is the apex agricultural research organization for the country and supports four laboratories. It has established Biotechnology Unit for implementing activities in biotechnology. There are 10 other public and private sector organizations that are involved mainly in tissue culture and micro-propagation of horticultural, medicinal and ornamental plants. NARC also conducts research on production of antigens, antisera and vaccines for livestock, pig, goat and fowl. Issues and concerns include declining and deteriorating trends in the natural resource base, environmental pollution, loss of biodiversity, ignorance of IPRs and biosafety, and limited access to food in addition to limited laboratory facilities and trained manpower. NARC strives to undertake marker-assisted selection, crops characterization and developing diagnostic kits for cereal, horticultural, fisheries, livestock and poultry. The annual capital investment from the Government is about US$ 25,000. NARC has effective linkages with IPGRI and NIAS in biotechnology in addition to AREP/WB. A national coordination framework is proposed to be developed by the Ministry of Science and Technology (MOST). Due to lack of a clear policy, regulation mechanisms and guidelines on biosafety and bioethics the promotion of biotechnology remains restricted.

PAKISTAN

Dr (Ms) Azra Quraishi mentioned that the biotechnology programme in Pakistan is developed to address several issues of national importance in the crops and the livestock sector, viz. increased yields, disease elimination/resistance, enhanced propagation rates of rare commodities, varietal improvement in reduced time span, development of varieties resistant to biotic and abiotic stresses and mitigation of environmental pollution due to agriculture. Main crops in the programme are rice, wheat, cotton, sugarcane, tomato, potato, banana, date palm, oil crops and a number of horticultural and ornamental crops. Key biotechnology techniques being tapped by various research institutes include tissue culture, genetic engineering, molecular markers' assisted breeding and animal biotechnology. The technologies, which have made a visible impact on the national economy, include virus free seed potato production through tissue culture, production of biofertilizers and embryo transfer. Genetic engineering is still in its developmental stages. The transgenics of cotton and rice are yet to go in for field-testing. Biosafety guidelines are being formulated and national commission on biotechnology is constituted. Biotechnology has been accorded a high priority by the Government in the IX FYP. Public sector research is conducted through agricultural universities and institutions whereas the private sector is not very prominent.
Session II: Biotechnology at National Level (contd.)
Chairperson : Nurul M. Alam
Co-Chairperson : John Skerritt

SRI LANKA
Dr Dhyan Kirtisinghe mentioned that the Council for Agricultural Research Policy of Sri Lanka (CARP) appointed a Committee of Specialists to identify priorities for Agricultural Biotechnology in the country. This Committee consisting of leading biotechnologists from all agricultural research institutes and the universities was instructed to prepare research priorities in Agricultural Biotechnology, prepare medium term plans (5-10 years), including training of scientists and technicians with assistance of international expertise.

To undertake production of transgenic plants and development of expensive techniques, such as DNA sequencing, the Agricultural Biotechnology Centre (AGBC) at the University of Peradeniya was selected as the National Centre. It was also decided that each of the National Agricultural Research Institutes should provide necessary resources. The upgrading of research laboratories and staff training were to be carried out concurrently.

National Biosafety Regulations were to be put in place prior to the production of transgenics. Documentation relating to biodiversity as well as IPR was to be formalized and encouraged. Universities were encouraged to collaborate with the Agricultural Research Institutes, and vis-à-vis in relation to applied research in biotechnology.

Finally, the CARP Committee of Biotechnologists is to monitor and evaluate progress in this activity and also inform on global developments to research scientists as and when necessary.

MALAYSIA
Dr Helen Nair reported that as biotechnology is recognized by the government as one of the flagship technologies to help Malaysia acquire developed status by 2020, it has received strong political support. Coordination is by National Biotechnology Directorate, under the Ministry of Science, Technology and the Environment. The Directorate was set up in 1995. In April 2001, a National Biotech Strategy was announced as a roadmap for future development. The strategy aims to harness the technology to the judicious exploitation of the country’s megadiversity in biological resources for wealth creation, while ensuring safe and responsible application within a sustainable environment. Cabinet support has been obtained and Eighth Malaysia Plan (2001-05) reflects it. This includes approval to set up BioValley Malaysia (BVM) — a geographical area in Multimedia Super Corridor (MSC), close to Kuala Lumpur. It will include three biotechnology institutes, in the following areas, viz: 1) Agricultural Biotechnology, 2) Pharmaceuticals and Nutraceuticals, 3) Genomics and Molecular Biology. The priorities for research in the proposed Institute of Agricultural Biotechnology have been identified from SWOT Analysis on research development up to the Seventh Malaysia Plan (till 2000). BVM will also include a Biotechnology Business Directorate. The synergy arising from integrating biotechnology and biodiversity with information technology, should provide an excellent environment for the development of clusters within the BioValley, between players from the public and private sectors. It is anticipated that such clusters will allow for a fast track approach towards a win-win outcome. With the National Biotech Policy targeted for parliament review by September, 2002 and the Biosafety Law expected to be in place by mid 2002, Malaysia as a late starter in Modern Biotechnology, hopes to catch up and provide some leadership in the Asia-Pacific region.

PHILIPPINES
Dr Reynaldo de la Cruz presented the status of agricultural biotechnology in the Philippines. He mentioned that the high population growth rate of 2.8% annually has put a tremendous pressure on agricultural lands and its productivity. R&D on modern biotechnology was found to be a good option in addressing the problem of agricultural productivity and food sufficiency. Planning, management and funding of biotechnology R&D are being addressed by three line agencies: Department of Agriculture (DA); Department of Environment and
Natural Resources (DENR); and Department of Science and Technology (DOST). Agricultural biotechnology programme was started in 1979 and was implemented by various institutes, specialized centres, and academic universities and colleges. By the year 1997, focus was made on modern biotechnology through the DOST-LEDAC, PCARRD and DA-AFMA funded programmes. The main thrusts of these programmes were on genetic engineering, capability building, awareness and advocacy campaigns. The programme embarked on the genetic engineering of important crops for improved quality traits and resistance to pest, livestock vaccines, diagnostic kits and biocontrol agent for the fisheries sector, micropropagation of genetically superior forest trees, biodiversity assessment, biosafety protocols, and commercialization of biotechnology products.

The future priority areas include genomics, proteomics, bioprospecting, bioinformatics, manpower development for regulatory work, and IP audit and management.

CHINA

Dr Sun Zongxiu informed that the agricultural biotechnology has become a strong impetus for the transition from conventional agriculture into modern agriculture in China. The Chinese government has given a high priority on agribiotech research through several state programmes. At present, a comprehensive R&D system has been formed, which includes the streamline from basic research, applied research to commercial production, and the close linkage of enterprises, universities, institutions and the government.

Chinese scientists have made enormous endeavours and advancement in cell engineering, gene transformation and genomics research. Combined with breeders, cell engineering techniques are being widely used for virus-free crop production and breeding. For gene transformation, Chinese scientists obtained transgenic plants of 95 species, involved 200 exogenous genes. Area grown under the transgenic Bt and Bt + CPT cotton was 600,000 ha in 2001. Research on gene transformation and genomics of rice are also moving fast. The strategy for developing agricultural GMOs was explained. It was stressed that with the efforts of scientists all over the world, agribiotech and its industrialization will become a strong drive for agricultural modernization and prosperity of common human being.

KOREA

Dr Suk-Chul Suh mentioned that agricultural biotechnology research and development activities in Korea are coordinated by National Institute of Agri-Biotechnology under the RDA and Ministry of Science and Technology (MOST) with a total annual investment of about US$ 330 million, of which 61.9% is by MOST. The major objectives are integrated management and utilization of bio-resources, development of source technology for agro-biotechnology, development and commercialization of novel bio-substances. The biotechnology research is undertaken through 7 institutions and 23 research laboratories on bioinformatics, genomics, plant biotechnology, molecular physiology, metabolic engineering and genetic resources. Korea has so far developed transgenics in 14 crops (35 species) 5 of which are at field trial level, and in 2 animal species (pig and chicken). A safety assessment support is being developed simultaneously.

THAILAND

Mr Songkran Chitrakon presented the R&D on Agricultural Biotechnology in Thailand. He informed that Thailand is a major exporter of agricultural products and in order to retain its competitive edge, the thrust will be on the innovative and creative research. By mid-seventies the country has already adopted the new tools, to apply to various practical problems. The area of Plant Transformation is expected to lead to production of transgenic plants with superior properties including resistance to diseases, insect pests and abiotic stress. Transgenic tomato carrying the coat protein gene of tomato yellow leaf curl virus was first developed. Development of transgenic rice varieties has been supported by the Rice Biotechnology Programme launched by BIOTEC and Rockefeller Foundation. Most of these plants are tested under the green house conditions in accordance with the Biosafety Guidelines. The country has an ambitious rice biotechnology programme. NCGEB on behalf of Thailand has
joined the International Collaboration for Sequencing the Rice Genome. Biotechnology interventions are expected to give a boost to shrimp production as biotech is expected to play a central role in helping to understand the shrimp and all aspects of its rearing. The major focus of BIOTEC is on shrimp disease and improvement of the seed supply. The Shrimp Biotechnology Service laboratory established in 1999 is designed to serve as the reference laboratory for major shrimp pathogen diagnosis based on molecular techniques. BIOTEC and Department of Agriculture have taken pilot scale initiatives on the bioculture of important insect pests. Finally it was mentioned that Thailand’s strategy is to keep biotechnology in a balanced perspective by undertaking activities within the framework of existing national research agenda and priorities.

The presentations – three sub-regional and different country-reports provided the status of agricultural biotechnology in the regional NARS. It was quite evident that all the NARS and agricultural research institutions in the region have recognized the importance of biotechnology to meet the future demands for food and to fight hunger and malnutrition and have taken initiatives matching their capacity. However, it was very clear that the agricultural research institutions in the region are at various stages of development and thus differ in their capacity to develop agriculture through biotechnological applications and also to handle the implications of new technology.

Concurrent with general acceptance to adopt biotechnology, there were several concerns that restrict application of biotechnology. A striking commonality in issues of concern was observed. These were primarily related to biosafety, bioethics, environmental conservation, human resources, capital investments, regulatory mechanisms, biosafety protocols, and IPRs, and information sharing.

Institutional capacity building and HRD programmes need to be undertaken. Networking of agricultural research institutions to address the common issues/needs was felt crucial for future development in agriculture using biotechnological tools. In this fast changing scenario, regulatory aspects being equally important call for formulation of framework of rules that are effective and expeditious.

Session III(a): Biotechnology Programmes of International Institutions/Organizations

This session consisted of presentations from the International Centres and Institutes on their biotechnology programmes.

Chairperson : Patricio S. Faylon
Co-Chairperson : Songkran Chitrakon

FAO

Dr Andrea Sonnino outlined FAO’s expectations of biotechnology. FAO considers that biotechnology has huge potential if it is properly integrated with other technologies and used to address food security and other key agricultural challenges. A systematic risk assessment and management must accompany its use. To assess whether biotechnology is addressing the needs of the developing countries, a worldwide inventory of applications is being compiled. From the findings to date, it was noted that there have been very few releases of GMOs in developing countries, with the major focus on commodities, and that these applications have made little or no contribution to food security. The survey has enabled gaps to be identified. From these gaps, priority areas have been identified, which include:

- Easy access to information. This is being addressed through the E-forum on biotechnology, the Biotech website, and FAO BiotechNews.
- Direct biotechnology research to meet key challenges. To meet this priority, the project ASIABIONET has been developed, involving 7 countries in Asia. This project will cover areas such as policy development, international cooperation and linkages, research priorities.
- Develop international instruments of governance to ensure biosafety. These include the Cartagena protocol, IPPC, Codex Alimentarius.
- **Build national capabilities:** FAO will present a paper at the upcoming WFS on policy development. Countries can make requests for assistance. A consultation meeting on IPR will also be held in Rome in June, 2002. Discussions will focus on using the ITPGR to ensure benefit sharing.

- Facilitate access to new technology to developing countries, poor producers and consumers.

The meeting expressed interest in the ASIABIONET project, and also requested distribution of the recommendations from the IPR consultation meeting to be held in June 2002.

**ICRISAT**

Dr Kiran K. Sharma described the work on biotechnology in ICRISAT. The semi-arid tropics (SAT) are home to one-sixth of humanity and house the poorest people in the world. Achieving sustainable food production in these fragile lands requires new tools in genetic enhancement. New biotechnologies, in addition to conventional plant breeding, are needed to boost the yields of food crops.

One of the global research themes at ICRISAT is to harness biotechnology for the poor, and to this end the institute has programmes in applied genomics, gene manipulation, bioinformatics, wide hybridization, and diagnostics. A significant investment has been made in the applied genomics programme under which there has been large-scale marker development in the mandate crops of ICRISAT. Over 1000 accessions of pigeonpea are being characterized by using SSRs; a subtractive EST library has been developed for drought tolerance; marker-assisted breeding for staygreen and striga is being utilized; HHB-67 is the first product of MAS for downy mildew resistance in pearl millet in farmers' fields.

ICRISAT has a specific strategy on GMOs, which is based on ICRISAT vision and strategy 2010 and guided by CGIAR policy, with an open door approach on the development and deployment of GM crops. A special feature of the policy is that ICRISAT works only in countries that have biosafety legislations.

It was stressed that biosafety legislation in the countries was an essential precursor to any activity in GMOs. The technologies for genetic transformation through Agrobacterium-based systems in groundnut, pigeonpea, chickpea, and sorghum are ready for transfer to NARS partners. Examples were given of various activities in the GMO area. Groundnut, in particular, was a good example with 50 to 60% transformation success.

ICRISAT has been carrying out studies with pigeonpea and chickpea to determine guidelines for the deployment of transgenic crops under field conditions. From these studies it was shown that there was no or unilateral gene flow in pigeonpea from cultivated to wild species and so the recommendation was that transgenics can be deployed based on information on the geographical distribution of the crop. More studies are underway to further substantiate such findings.

ICRISAT proposes to have a Biotech Science Park or an Agri-Biotech Incubator Park, which will bring in small and medium sized seed companies and other stakeholders with the aim of technology adoption and its transfer. They currently collaborate with the public sector, private sector, farmers groups, and NGOs. Training and technology exchange programmes are provided. Bottlenecks in research and deployment were discussed; these ranged from lack of efficient protocols for transformation to the lack of proper biosafety regulations in most countries of Asia and Africa.

ICRISAT firmly believes that biotechnology is too valuable to be ignored, and are working to promote this through a participatory approach, which utilizes indigenous knowledge, conventional research and cutting-edge technology.

**ISNAR**

Dr Jose Falck-Zepeda highlighted the biotechnology programme at ISNAR, which covers four main areas of work. These include 1) The socio-economic impact of biotechnology utilizing the DFID Sustainable Livelihood methodology. Five case studies have been used, the aim being to carry out an integrated social analysis of
the consequences of the changes brought about by new technology. ii) Developing biosafety frameworks for national implementation. It was stressed that this was not a common road map, and that only the basic elements would be defined, along with cost implications. iii) Measurements of agricultural biotechnology investments. The overall objective of this programme is to determine how relevant resources are mobilized, to record any research gaps and needs used to implement agricultural biotechnology research. The information generated would be disseminated to the policy makers. Six countries are involved in this study, and information has been collected over a number of years and from different institutes. Areas that have been considered relate to total expenditure in plant biotechnology research, how that has changed over time and what is the expenditure per researcher. Most of the expenditure is from the public sector. Observations to date show that most institutes or NARS cannot do any of the regulatory biosafety testing, political hurdles exist and cost of marketing is a limitation.

The policy implications of investment and public research studies show that given general funding decline, public commitment to investment and research for biotechnology is significant. Pressures from the EU have significant implications for trade and there is a need for coordination between the public and private sector. Therefore, an optimum funding level for public biotechnology needs to be determined.

Current and outreach activities include Biotechnology Policy and Management Seminars but there is a need to make these more issue-based events. The other initiatives include Web-based joint FAO/ISNAR biosafety decision platform. Biotechnology implementation policy decision platform and direct country support and consultation.

The future challenges for Asia-Pacific Agricultural Biotechnology as seen by ISNAR are that deployment is mainly by the public sector, and there is little private sector investment calling for an urgent need for collaboration/coordination. Further enhanced efforts are required for biosafety and finally augmenting national competencies.

ICGEB

Dr Madan Mohan presented the work of International Centre for Genetic Engineering and Biotechnology (ICGEB). The Centre was founded in 1987 as a special project of UNIDO. It now operates as an independent intergovernmental organization with offices in New Delhi, India and Trieste, Italy, with funding from the Governments of both countries. Funding is also provided by institutes such as the Rockefeller Foundation, Bill Gates, Wellcome, to name a few. There is no overlapping in activities between the two offices, with mainly training and workshops being conducted in Italy and the biotechnology work being carried out in New Delhi. Training is the key aspect of the Centre. Dissemination of information is also an activity through ICGEB-net, a computer resource for biotechnology. The main research activity is developing resistance to gall midge of rice. Resistant seeds have been generated, and will be tested shortly.

ILRI

Dr John Gibson presented on agricultural biotechnology capacity at ILRI. The Centre focuses on livestock because livestock are expected to increase to close to 50% of farm gate receipts in the developing world by 2020. In many smallholder systems throughout the world, livestock are the best means for income and capital generation, and women are the primary beneficiaries. Livestock also provide a good supply of micronutrients, and it has been shown that access to livestock products greatly improves health, and the physical and cognitive development of children.

Current biotechnology research includes: genomics, vaccine development and diagnostics (PCR and antigen ELISA). ILRI's capacity for genomics research is expanding with the installation of a bioinformatics computer. Expertise in this area covers a number of aspects ranging from QTL mapping to clone library development, to gene expression studies.
A number of projects are currently being implemented. For example, there is genome wide mapping of a livestock disease, which has located genome regions controlling tolerance of trypanosomiasis in crosses of African N’dama and Boran cattle. In addition to animal health programmes, there have been genetic diversity studies of African livestock, which have revealed global genetic variation, and enabled the history of human-livestock associations to be traced. This has implications for conservation, improvement and utilization.

ILRI now has a global mandate and specially to extend its services to Asia (there are already some activities in the Philippines). The services that ILRI can provide would cover a) Genomics research labs and expertise for biodiversity assessment, b) expertise for gene mapping, c) experience in training in characterization, conservation, utilization of livestock genetic resources, and d) development of diagnostics or vaccines.

**AVRDC**

Dr Meisaku Koizumi presented the work on biotechnology within AVRDC. He felt that ignoring biotechnology is not a viable option, as AVRDC’s partners, NARS, are increasingly using these new technologies. Therefore, AVRDC has embarked on biotechnology as part of its strategic research, and this is clearly illustrated by its 1998-2002 action plan. Recently AVRDC has been involved in a number of projects, which has facilitated its capacity building. Its major activities include:

- Development of DNA probes for virus and bacteria detection.
- Tissue culture for the production of virus-free garlic.
- Molecular markers to characterize genetic resources of certain vegetable crops, and to assist in the selection for resistance.

Gene transformation has been applied to tomato and pepper to achieve resistance to CMV. The transgenic tomato has been tested in the field.

The growing importance of biotechnology has led to AVRDC confronting the issue of IPR. AVRDC follows the principle that there has to be free access to technologies, and that IPR will only be sought in exceptional cases.

Despite on-going concerns about biotechnology, AVRDC is convinced of its benefits and will continue to move forward in this area. It also recognizes that conventional breeding and biotechnology have to work together; there cannot be a total reliance on biotechnology. Further, AVRDC will not release material to countries, which do not have the appropriate regulatory framework in place.

The meeting acknowledged the work of the International Centres and Institutes in the area of agricultural biotechnology. FAO’s leadership role is recognized, with the provision of information on the geographical distribution of biotechnology research. One important output of this process was the identification of gaps and needs, which required attention. FAO’s work in developing guidelines in IPR and biosafety was crucial, as this is proving to be a bottleneck in the actual utilization of biotechnology by the farmers. This was clearly shown by the country reports, and so the meeting was encouraged to note that FAO is working to provide guidelines on IPR and biosafety. The information support provided by ISNAR and ICGEB was valuable, especially the support given to countries by ISNAR to determine how appropriate biotechnology is to countries. Such assessment was useful in providing baseline information for countries from which they could move forward with developments in biotechnology. The meeting also greatly appreciated the input from ILRI and the offer of services relating to livestock. Similarly, the efforts of AVRDC in their work on vegetables were appreciated by the meeting.

It was recommended that the work of the International Centres needs to continue, especially that of policy and guideline development for IPR and biosafety. IPR and biosafety issues have to be addressed, and policies put in place before any real benefits of biotechnology can be achieved. As the country papers also demonstrated, it is not the technology, which is preventing the impact of biotechnology to be realized; rather it is the lack of appropriate guidelines and policies.
Session III(b): Biotechnology Programmes of Private Sector

Chairperson: Sutat Sriwatanapongse
Co-Chairperson: Paul S. Teng

SYNGENTA

Dr Partha R Dasgupta presented an overview of Syngenta’s work relating to GM crops in the region. He reiterated the reasons for regulation, namely health, environment, ethical, social, moral and economic. There is obviously a need to assess and whenever possible manage risks, so that the advantage of using transgenic plants is determined. Any regulatory framework should be comprehensive, and the US framework was given as a good example. Within the region, different regulations exist, which are hampering the development. In India, the system is going through reform with transparency being the key factor of the new system.

He indicated that there is a lot of optimism from farmers, and it is unfortunate that these potential beneficiaries are not reaping the benefits of this technology, largely because of the lack of regulatory frameworks. In many cases, a regulatory framework is not treated as a priority by countries. With IPR, there is pressure from WTO for countries to put some mechanism in place, but with biosafety there is no such pressure. Syngenta felt that there was a role for FAO to facilitate sharing of issues and information relating to biosafety and for the harmonization of protocols.

Other issues discussed in this presentation were the need for public awareness, but Dr Dasgupta raised the question as to who would be responsible for this. This must be well thought out to avoid any criticism of bias.

Finally, Syngenta reinforced the comment made by previous presenters, that there was an urgent need for more “gene flow” data, to clearly know the risks and thus facilitate commercialization.

The issue of the lack of collaboration between the private and public sector was raised from the floor, as to whether this was merely the result of lack of trust or were there other issues involved?

MONSANTO

Dr Paul Teng presented Monsanto’s commercial and non-commercial programmes in the Asia-Pacific region. Monsanto is now a restructured company dealing with conventional and GM seeds, chemicals (herbicides) and biotechnology traits. Monsanto commented on a lack of appropriate regulatory frameworks and systems, and also felt there was a need to distinguish between the theoretical and actual potential of biotechnology. In markets where poor penetration of hybrids has occurred, such as rain-fed marginal areas, it is highly unlikely that modern technology will make an impact; it is important to be aware of this. Monsanto has three commercialization strategies, namely direct seed sales, licensing of traits (little of this in Asia) and joint ventures (these can also be technology transfer, not solely business partnerships).

With regard to collaboration in research, the private sector is more likely to come on board after basic research has been completed. Non-commercial programmes are also a part of Monsanto’s strategy, such as the technology donation of PRV resistant papaya, and the sharing of the rice genome database. Partnership modes for non-commercial programmes are with international organizations and groups for technology sharing and transfer, with national institutions, and with NGOs. Monsanto acknowledged the role that ISAAA has played in transferring knowledge to the public sector.

In response to the backlash from Europe regarding GMOs, Monsanto have made a new pledge to help fulfill the promise of biotechnology for sustainable agriculture. It includes the following elements: dialogue, transparency, respect, sharing and benefits. They are involved in technology cooperation projects, in which they share fundamental scientific data, technology (genes and traits), know-how to move technology
to other crops, advice on environmental stewardship, and licenses to patented technologies. Current projects include the development of virus free sweet potato in Kenya, potato in Mexico and papaya in Southeast Asia.

Finally, Monsanto believes it has a role to play in reducing hunger in urban poor. Hunger in urban areas can lead to conflict, so to address urban hunger can alleviate the conflicts that occur within the urban environment.

\textbf{AVENTIS}

Dr Tawatchai Sitchawat presented the biotechnology initiatives by Aventis CropScience. He informed that Aventis is being taken over by Bayer AG and the new company will be called Bayer CropScience. Currently the organization has three groups of business, one of these, BioScience, addresses biotechnology. BioScience works with cotton, corn, soybean and rice; all are Basta tolerant crops. In Thailand, Aventis has tested varieties of hybrid corn and rice. However, for any further developments, they need to see more encouraging policies from the Government. IPR and confidentiality issues are also hampering development. There is a need for a public awareness programme, so that the consumer's attitude to biotechnology is more positive, and their understanding of its benefits is clear.

\textbf{APSA}

Dr J.S. Sindhu presented APSA’s programme on biotechnology. APSA is a regional forum to promote the enhancement of quality and trade of agri-horticultural seeds. As these seeds are carriers of genes, biotechnology is transferred in agriculture through seeds, and it is this concept that has determined APSA’s involvement.

APSA has a position paper on biotechnology, which will shortly be available on their website. APSA believes that biotechnology coupled with traditional methods can augment production and productivity to sustain agricultural growth. The organization aims to strengthen linkages between scientists, regulatory authorities, and the seed industry, to assist in the success of agricultural biotechnology in the region. However, issues of biosafety regulations and IPR have to be addressed.

The major aims of APSA are:
- Identify the problems and opportunities.
- Form linkages to translate the technology.
- Facilitate the marriage of technology and the seed industry.
- Develop strategies and technologies to implement programmes for the benefit of APSA members.
- Create awareness on IPR issues and arrange a platform for dialogue.

These presentations generated considerable discussion, and the main issue raised was that the papers had not addressed the problems that exist in collaboration between the private and public sectors. Investment from the private sector in the region is disappointing to say the least; at most it is 2% in some countries. Why is there this lack of investment? It was suggested that the priorities of the private sector are profits and not people. It could be that current IPRs are not genial for their investments, and similarly biosafety regulations are inadequate. If one considers the US, investment from the private sector is 95%.

The meeting recommended that collaboration between the private and public sectors in the Asia-Pacific region required urgent attention. Perhaps this could be resolved by the formation of a "body", which involves all the stakeholders, to facilitate dialogue, and establish trust. FAO could possibly drive the formation of this alliance. Such a combination of stakeholders could work at developing a strategic plan, aimed at attracting the private sector to collaborate in the development of biotechnology in the region.
Session IV: Regulatory Aspects (IPR, Biosafety and Ethical) of Development and Adoption of Biotechnology

Chairperson : Asis Datta
Co-Chairperson : Tanit Changthavorn

Dr Malee Suwana-Adth from Approtech Asia discussed the management issues associated with regulatory aspects of development and adoption of biotechnology. Generally the level of management that exists within adopting countries is weak, because this new knowledge/technology requires new management skills.

In countries where good governance and transparencies are still the issues, there is a definite need for more than one regulating agency. The US presents a good example, where three agencies, EPA, FDA, and PHS are all involved. In addition, management of good and appropriate farm practices is important. For example, in countries where there is a predominance of small farms, the buffer zone might not be applicable. In order to address this management problem, Approtech recommended the development of a biotechnology management training course. It was suggested that this could be a joint AIT-BIOTEC initiative at Thailand Science Park, with private sector involvement through the provision of fellowships.

The establishment of a biotechnology/GMO “clinic”, providing impartial and reliable biosafety/risk assessment services on key (unsettled or new) safety concerns, was another suggestion. This would be of great benefit to the community, and ICGEB/Delhi could play a role here in coordination with the national biotechnology centres.

Dr Suwana-Adth also made a request that the forum identifies the various issues within biotechnology, and then separates them, so that they can be dealt with efficiently and effectively.

Dr Tanit Changthavorn from BIOTEC, presented a paper discussing intellectual property protection (IPP) for agricultural biotechnology, from the South-East Asian perspective. He commented that IPR is an issue that has been mentioned frequently at this meeting, and is obviously one of the concerns to all participants. IPR has to be considered in all contexts; international, regional, national and institutional. Within the international context, there are several treaties, all with an impact on IPP.

- The TRIPs agreement under WTO has possibly the most influence on IPP, in that it is linked to membership of WTO. All members have to provide for protection of plant varieties, either by patents, or by an “effective sui generis system”, or by any combination thereof. This has been described as a “one size fits all” agreement, and is not a particularly suitable form of IPP for the South, thus encouraging a North-South polarization.
- UPOV is an international framework for the legal protection for plant varieties, and has 50 member states, but none from S.E Asian countries. Although TRIPs does not recommend UPOV as an acceptable sui generis system, there is general consensus that it does provide a ready-made solution. Unfortunately, it requires substantial infrastructure and is only suitable for improved varieties. Its acknowledgement of farmers’ rights and their entitlement to save and use seeds from one generation to another is questionable.
- CBD is an important framework recognizing the sovereign rights of nations to manage their own biological diversity. It also promotes fair and equitable sharing of benefits arising from the use of genetic resources.
- The FAO’s ITPGR is an effort to work in harmony with the CBD. The ITPGR recognizes farmers’ rights and the fair and equitable sharing of benefits arising from the use of genetic resources.
- WIPO is the UN arm for the protection of IP. It has little power and its interpretation of IP has changed over the years.

At a regional level, there is the conceived ASEAN Standard of IP System, and the ASEAN Intellectual Property Association (IPA), though the impact of both of these within the region appears minimal. At a national level, all of the countries are at a different stage of development, from Indonesia with PVPA Law No 21, 2000 in place, to Malaysia, with PVPA at the drafting stage. At the institutional level, the Southeast Asia Network
on IP/TT Management aims to provide sufficient knowledge to countries so that negotiations are facilitated. They also develop MTAs, confidentiality and licensing agreements.

IP management is of great importance, but perhaps there is an urgent need to understand that many of the disputes are due to misunderstanding, misconception and miscommunication. Much of this stems from a lack of knowledge. Countries should take every opportunity to seek advice and finance to assist the developments in this area. With this in mind, Dr Changthavoran drew the meeting’s attention to the first international conference on legal aspects of biotechnology in this region, Biolaw, 2002, which will take place in Bangkok in September, 2002. The objective of the meeting is to provide a forum for different groups to exchange and share their knowledge and opinions, in addition to developing professional linkages.

Devinder Sharma from Forum for Biotechnology and Food Security, made a presentation, which looked at the politics of food. He put forward a different argument, one in which biotechnology and hunger should not be linked together. Sufficient food is available to feed the global population, but the problem is distribution. He gave the example of India, where a surplus of 60 million tonnes of foodgrains exists, yet 320 million people are still hungry. He agreed that biotechnology will increase yields, and therefore production, but will it ensure better distribution of the product. He further argued that with GM foods there are no choices, as it would seem that there is pressure for this technology to dominate. However, the question is does it really benefit the poor of the region, for example, can poor people afford to purchase “Golden Rice”?

Mr Sharma gave an example of the problems that can result from new technologies. This was the introduction of pesticides in the mid-80s into cotton production in India. Initially there was increased production and good acceptance of this new technology, but eventually resistance built up to the pesticides, resulted in several problems (crop loss, increased financial pressure and the suicide amongst cotton farmers).

Where IPR issues are concerned, it was suggested that an IPR apartheid had been established with the poor countries being disadvantaged.

Roel Ravanera representing ANGOC, presented the perspective of NGOs on biotechnology. ANGOC is a network of NGOs from 11 countries in South and South-East Asia. It is a development NGO, concerned with the social side of technology. NGOs believe that there is a connection between GMOs and human rights. This necessitates consideration of the following:
- The right to adequate food (free from adverse substances and acceptable within a given culture).
- The right to informed choice.
- The right to democratic participation.

Poverty is a major concern in the region, and in addition, there are problems with rising inequality. Admittedly a significant number of poor people are located in urban areas, but these people originate from the rural areas. In trying to alleviate poverty, NGOs have identified three major initiatives:
- empowering of local communities.
- enhancing productivity and distribution.
- enhancing participation and demanding accountability.

From a survey carried out in seven countries it was shown that the Green Revolution did increase productivity, but did not increase income. So Mr Ravanera suggested that perhaps the issue is not to introduce new technology but to enhance what is there already. From experience, the NGOs within ANGOC believe that biotechnology does have its limitations, and is possibly not required in some countries.

Finally ANGOC agreed with many of the other speakers on the need to identify convergence areas, so that dialogue could be promoted and progress made in many of the areas, so far identified in this meeting.
Dr Maricelis Navarro informed that the International Service for the Acquisition of Agri-biotech Applications (ISAAA) established in September 2000, the Global Knowledge Centre on Crop Biotechnology to enhance the sharing of biotechnology among developing countries. She talked about enhancing the sharing of biotechnology information in the developing world. There is a wealth of experience and knowledge on crop biotechnology in the developing world. Unfortunately much is not known or shared with others. As a result, crucial information necessary for decision-making is not made available to those who stand to benefit from biotechnology the most.

Basically, the Centre serves as a global network for current knowledge on crop biotechnology. It supports national biotechnology programmes by providing information for decision-making and acts as an information broker for various stakeholders. The Centre links network members across Asia, Latin America and Africa. In Asia, three fully functional Biotechnology Information Centres are already operational in Malaysia, Philippines and Thailand. Partial support is being given to Indonesia and Vietnam while links are being maintained with India and China. Activities of the Centre include scanning of the agricultural biotechnology environment, expert networking with country nodes, information processing and packaging, information repository building, client feedback, and special projects.

These presentations further emphasized the need to identify the controversial debatable issues, and to establish a forum in which all stakeholders can be involved in dialogue. Without this dialogue, problems resulting from misunderstanding and miscommunication will continue. It was suggested that biotechnology being a “new technology”, training in its management was required among NARS partners. Along with this requirement, issues relating to IPR had to be resolved. This is a difficult area because of the agreements involved, and countries had to seek advice on this and collaborate where possible. GKC of ISAAA was meeting this requirement through the very effective dissemination of information, and the establishment of national biotechnology information centres in some countries. Also, there was a request from the NGOs to consider the relevance of biotechnology to some countries, and that it should not be seen as the sole means to solving the hunger and poverty.

Session V: Thematic Group Discussion to Identify Sectoral Needs and the Strategy for Future

Three groups from among the participants were constituted to deliberate on the following themes:

Group I: Institutional Research Framework and Capacity Building: Public, Private, NGOs and Civil Society
Facilitator: Dr (Ms) Manju Sharma

Group II: IPR, Biosafety and Ethics
Facilitator: Dr John Skerritt

Group III: Future Strategies: International/Regional Cooperation and Networking for Harnessing Biotechnology
Facilitator: Dr Patricio S. Faylon

Session VI: Presentation of Thematic Group Reports
Chairperson: Panjab Singh
Co-Chairperson: Qingfang Wang

Group I: Institutional Research Framework and Capacity Building, Public, Private, NGOs and Civil Society
Facilitator: Dr (Ms) Manju Sharma

The group recognized that biotechnology is a powerful tool for sustainable agriculture, especially keeping in view the needs of the small and marginal farmers. The group felt that a strong public sector support should be forthcoming to strengthen the research base and for enhancing the capability for novel innovations and discoveries leading to new products and technologies. This can be supplemented further by private sector partnership and by establishing functional linkages with other international agencies. The group identified priority areas
for sustainable agriculture that require biotechnological interventions for redressal; Resistance to biotic and abiotic stresses, integrated management of nutrients and pests, improved breeding methods, bioprospecting, biodiversity characterization, development of vaccines and diagnostics for animal health, micro-propagation techniques, value addition and preservation and socio-economic and impact assessment studies.

Capacity and institution building was the other important issue considered by the group. The role of public-private sector, inter-institutional partnerships and involvement of neutral bodies such as FAO, APAARI and GFAR was identified as of paramount importance. Some of the possible mechanisms suggested were South-South cooperation; North-South cooperation specially in the high tech areas; creation of centres of excellence; promoting public awareness on related issues; and organizing specialized training programmes.

The group suggested that strong networking using electronic media and synergy among the nations in the form of an Asia-Pacific Biotechnology Consortium or Asia-Pacific Network in Agricultural Biotechnology be established.

**Group II: IPR, Biosafety and Ethics**
Facilitator : Dr John Skerritt

The group deliberated on issues of IPR, biosafety and bioethics in relation to application of biotechnology and how best regional cooperation could be utilized in this endeavour. The developing country institutions are often poorly equipped to determine freedom to operate. The IP management and training needs were deemed to be of high importance so as to facilitate informed decision to be taken on commercialization and technology protection. Training is needed to provide clear understanding of IPRs, TRIPS, Patents, MTAs, PBRs etc.

Regarding biosafety issues, it was observed that major food safety issues relate to consumer perception that GM foods are unnatural and therefore could be a source for introducing allergens or toxins in the foods. Besides the food safety, main ecological risks relate to loss of genetic diversity in cropping systems, transfer of genes from herbicide resistant crops to wild relatives, and creation of new viruses from vector recombination. The biosafety needs, require first, a national policy framework that accommodates international conventions, be driven by domestic needs rather than those of the Western countries. The regulatory mechanism should be flexible and harmonized with the regulations prevalent in the region. The common opinion was that a national framework needs to be developed that not only addresses these concerns but also balances the needs of a wide range of stakeholders. Education of researchers and public are central issues as well. The scientists have a responsibility to communicate the broader implications of their research. The scientific community often hasn't really addressed IP, Biosafety at the project/national levels – there need to be individual institutional IP policies and culture developed as well as national frameworks. A more proactive role of APAARI was visualized being a neutral stakeholders’ forum rather than inter-governmental forum.

**Group III: Future Strategies: International/Regional Cooperation and Networking for Harnessing Biotechnology**
Facilitator : Dr Patricio S. Faylon

The group organized its discussion to undertake a SWOT analysis of the current scenario and assess the possible strategies to arrive at suitable recommendations.

Among the regional strengths, rich biodiversity, political commitment, strong regional capability in biotech and gradual building up of public-private sector partnership were identified. Co-existing also were the weaknesses in form of poor infrastructure to put products to market-mechanisms, inadequate public awareness, lack of efforts to promote awareness and understanding of the complete biotechnology situation, too much hype about simple problems, lack of financial and human resources in several regional NARS. Against the backdrop of the existing scenario, some exciting opportunities were seen to be forthcoming from the strong regional capability in biotech and willingness on part of countries to share expertise. The integration of biotechnology and ICT was recognized
as the most potential opportunity. Increased involvement of private sector in agricultural R&D was considered as a very positive development.

The main recommendations of this group relate to developing a functional mechanism of cooperation among the regional stakeholders. These were to recognize Asia BioNet in areas of biosafety, IP and public awareness by strengthening NARS. It was felt that involvement of private sector, CGIAR, GFAR and APAARI along with all other stakeholders was essential. It was further suggested to have in place transparent mechanism of collaboration between and among public and private sectors along with the existing systems such as GFAR and APAARI in the implementation of the priority projects identified in the action plan.

Finally, the group strongly mooted the idea to establish a consortium with a committed support and funding from the private sector and assured sustainability from the signatories of the various governments.

Session VII: Round Table Dialogue on Maximising Benefits and Minimising Risks of Biotechnology
Chairperson: Dr R.S. Paroda
Co-Chairperson: Dr Jose Falk-Zepeda

The chair emphasized that this session provided an opportunity for an in-depth dialogue, and to determine as to where despite differences in our perceptions, there could be a convergence. All the participants voiced a common desire to enhance application of biotechnological tools for increased agricultural productivity. However, it was felt that there is a need to separate the areas of biotechnology into those that are straight away acceptable and those that need further verification and discussion. However, many problems in agriculture such as: productivity, drought, salinity, and marginal lands, to name a few are, those which need to be addressed on priority. New technologies can help to address these problems effectively. Also it was stressed that there is an urgent need for required regulatory frameworks and testing procedures for biosafety. Also there is need to build the much needed partnerships involving all stakeholders. The lack of private sector’s involvement promoting biotechnology in the region is also of major concern.

Some important issues that were raised in the country papers presented were again discussed. These included:

- Need for collaboration and establishment of partnerships.
- Need for capacity building in a number of developing countries.
- Need for private sector involvement in the region.
- Lack of proper understanding at the Government level in many countries to provide the needed support in the field of agricultural biotechnology, both for research and development.
- Need for specific support to the less developing countries, still much behind in the field of biotechnology.
- Weak support for the IPR regime in most of the countries.
- Importance of having biosafety assessment mechanisms in place, based on scientific principles.
- Lots of mis-information needing information sharing and public awareness.

The discussion laid strong emphasis on biosafety assessments and the development of appropriate partnerships.

Dr Sonnino, FAO provided information from a meeting in Sub-Saharan Africa where 12 years experience in the risk assessment of GMOs was discussed. The infrastructure requirements for risk assessment are not all that demanding. He informed that the officer in charge of this activity coordinates with rather minimum infrastructure, and that all work is carried out in existing laboratories and the cost is charged to the applicant, not the host country. He further emphasized that risk assessment was a scientific matter, but that the decision-making was the responsibility of the politicians. It was important to ensure that any regulatory framework was not favouring the private sector because of lengthy evaluations and subsequent costs. As a further comment on biosafety, it was suggested that the information sharing can assist concerning biosafety assessment, in
that if genes have been tested in a specific ecosystem, trials need not be repeated again in similar ecosystems elsewhere.

On the issue of partnerships, Dr Gibson, ILRI stressed the need to identify as to what the Private sector might be interested in, so that specific negotiations can be based on mutual benefits. Similarly the scientists have to be active where policy is concerned and play a more proactive role to advise policy makers. In Asia-Pacific region APAARI can take a lead in this context for a regional approach and understanding. There must be an effort to convince the policy makers to adopt a “win-win” strategy for both the private sector and the society. On maximizing benefits, scientists must be clear on their objectives of research – what are the outputs, who gains and who might lose. To address this problem, a joint collaboration will indeed be helpful when resources are limited.

There had been considerable discussion on the issue of trust and the need to improve the public awareness. Presently, mistrust does exist regarding the risks associated with GMOs and hence it is proving to be a serious impediment towards adoption of this technology. Scientists must generate enough evidence to eliminate this mistrust from the minds of the public and the policy makers. There is also a mistrust concerning the present role of the private sector, and it is obvious that the public sector research will have to take the lead in this sphere to provide both an alternative as well as healthy competition. Also it is important that research collaboration is built among private and public research institutions in the field of GMOs and the transgenics. In this context, the initiative should start preferably with local companies first before establishing partnerships with the multinationals, wherever possible.

It became apparent that there is a need to establish a dialogue in order to converge on diverging views about the role that biotechnology can play in addressing the critical issues of poverty and malnutrition alleviation, food and/or income security and sustainable agricultural development. In addition, there is also a need to harness the “collective wisdom” and pursue actions, which will provide good options for the welfare of our society and proper benefit sharing by the farmers as well as consumers. All this will be possible through a dialogue and a trust building effort across the table involving key stakeholders as well as initiatives of neutral regional organizations such as APAARI and also the international organizations such as FAO and the CGIAR Centres.

From the presentations and above discussion, four main themes/recommendations emerged:

1. The need to evaluate the broader impact of biotechnology on society, and to identify bottlenecks and critical points, and what efforts can be made to provide new options/solutions?

In addressing these, the following points have to be considered:

• Who are the beneficiaries? Is biotechnology not benefiting the target population, and if not, how can this be resolved.
• Is biotechnology appropriate for every country? How can this be determined?
• Is there a possibility that one impact of biotechnology will be the monopolization of resources available to farmers? How can this be prevented?
• The environmental issues and the impact of biotechnology on biodiversity need to be addressed.
• There is also an urgent need to solve the problems of intellectual property rights protection.
• How can knowledge and information be effectively and efficiently disseminated?

2. Biosafety and regulatory frameworks have to be established, and a consensus reached on which comes first, the regulatory framework or the technology or should it be a hand-in-hand approach?

• There is a need to identify the necessary institutions, processes, capacity and organizations.
• What are the regulation costs? Does this favour any one sector, and therefore the beneficiaries?
3. Private and public sector partnerships have to be developed for any significant progress to be made.
   - What are the appropriate roles of the private and public sector within these partnerships? Is the public sector responsible for the initial research, with the private sector providing inputs to take the product to the market?
   - What should be the modes of collaboration?
   - How do we address the issues of trust, knowledge and mutual understanding so that negotiations can be on an equal basis?
   - Which types of research (basic versus applied) should be addressed by the different stakeholders and what are the investments possibilities.

4. Regional/International collaboration and capacity building is crucial so that progress is made, and all benefit.
   - Have to consider and involve all stakeholders, which include international organizations, IARCs and CGIAR system, NARS/NARIs.
   - Less resourceful countries with insufficient capacity to make informed decisions should be identified and strategies determined to assist, if required.
   - Information flow must be increased with emphasis on quality of information.
   - Public confidence on the public research sector must be raised. The public should continually be kept informed, so that they feel involved in the development process. The public sector is better placed to achieve this because there will be more trust than it is possibly with the private sector.
   - An important decision to address the promotion of agricultural biotechnology by pooling synergies, harnessing comparative advantages and ensuring judicious use of resources, was that a consortium approach be adopted by bringing together relevant partners and stakeholders in the region. A consortium approach was deemed to have better stability than that of donor-driven networks, which often continue as long as the donor support is available. The idea to establish a "Biotechnology Consortium for Asia-Pacific" received a unanimous acceptance from the participants. In this regional endeavour, the role expected of APAARI was to serve as a neutral facilitator/supporter for the establishment of such a consortium, in partnership with international agricultural research centres, FAO, GFAR and private, NGO and farmers organizations.

The Consultation concluded with the vote of thanks from Dr R.S. Paroda, Executive Secretary to all the delegates for their active participation. He expressed special thanks to Dr R.B. Singh, ADG and regional representative, FAO-RAP, Bangkok, for not only giving this opportunity to APAARI for organizing this meeting but also for providing valuable guidance to conduct the Expert Consultation.
FAO-APAARI Expert Consultation on the
Status of Biotechnology in Agriculture in Asia and the Pacific
21 to 23 March 2002
FAO Regional Office, Bangkok, Thailand

PROGRAMME

21 March 2002

08:00 – 09:00  Registration

INAUGURAL SESSION

Chairperson

09:00 – 09:10  Welcome

09:10 – 09:25  Objectives of the Expert Consultation

: Raghu N. Sapkota

: Malcolm Hazelman
Sr. Extension, Education and Communications Officer, FAO

: R.S. Paroda
Executive Secretary
APAARI

09:25 – 09:40  Chairperson’s address

: Raghu N. Sapkota
Chairperson
APAARI

09:40 – 10:10  Inaugural address

: R.B. Singh
Assistant Director General and Regional Representative
FAO, Bangkok

10:10 – 10:15  Election of Rapporteur

10:15 – 10:20  Vote of thanks

10:20 – 10:30  Group photograph

10:30 – 11:00  Tea

: P.K. Saha
Technical Officer, FAO and Liaison Officer, APAARI
11:00 – 12:00

Session I: Regional Status of Agricultural Biotechnology

Chairperson : R.B. Singh
Co-Chairperson : Abbas Keshavarz
South Asia : Asis Datta
China & East Asia : Qinfang Wang

12:00 – 13:00

Session II: Biotechnology at National Level

Chairperson : Manju Sharma
Co-Chairperson : Dhyan Kirtisinghe
Australia : John Skerritt
Bangladesh : Nurul M. Alam
India : Manju Sharma
Pacific Islands : Mary Taylor

13:00 – 14:00

Lunch

14:00 – 14:30

Session II: Biotechnology at National Level (contd.)

Indonesia : Ines H.S Loedin
Iran : Abbas Keshavarz

14:30 – 15:00

Tea

15:00 – 17:30

Session II: Biotechnology at National Level (contd.)

Chairperson : Nurul M. Alam
Co-Chairperson : John Skerritt
Nepal : Hari Prasad Bimb
Pakistan : Azra Quraishi
South East Asia : Sakarindr Bhumiratna
Sri Lanka : Dhyan Kirtisinghe
Malaysia : Helen Nair and Hassan Mat Daud
Philippines : Reynaldo de la Cruz

17:30 – 18:00

Discussion on Country Reports

19:30

Reception dinner hosted by ADG-FAO
22 March 2002

08:30 – 11:00  
Session III(a): Biotechnology Programmes of International Institutions/Organizations

Chairperson : Patricio S. Faylon  
Co-Chairperson : Songkran Chitrakon

China : Sun Zongxin  
Republic of Korea : Sukh-Chul Suh  
Thailand : Morakot Tanticharoen and Songkran Chitrakon

FAO : Andrea Sonnino
ICRISAT : Kiran K. Sharma
ISNAR : Jose Falck Zepeda
ICGEB : Madan Mohan
ILRI : John Gibson

11:00 – 11:15  
Discussion

11:15 – 11:45  
Tea

11:45 – 12:45  
Session III(b): Biotechnology in the Private Sector

Chairperson : Sutat Sriwatanapongse  
Co-Chairperson : Paul S. Teng

Syngenta : Partha R. Dasgupta  
Monsanto : Paul S. Teng
Aventis : Tawatchai Sitchawat
APSA : J.S. Sindhu

12:45 – 13:00  
Discussion

13:00 – 14:00  
Lunch

14:00 – 15:45  
Session IV: Regulatory Aspects (IPR, Biosafety and Ethical) of Development and Adoption of Biotechnology

Chairperson : Asis Datta  
Co-Chairperson : Tanit Changthavorn

Speakers : Malee Suwana-Adth  
: Tanit Changthavorn  
: Devinder Sharma  
: Roel Ravanova  
: Mariechel Navarro  
: Meisaku Koizumi

15:45 – 16:30  
Discussion

16:30 – 17:00  
Tea
23 March 2002

**Thematic Group Discussion**

09:00 – 12:00  Separate group discussion
10:30 – 10:50  Tea

12:00 – 16:00  

**Session VI: Presentation of Thematic Group Reports**

Chairperson  : Panjab Singh
Co-Chairperson : Qinfang Wang
12:00 – 12:20  Thematic group I  : Facilitator
12:20 – 12:40  Thematic group II : Facilitator
12:40 – 13:00  Thematic group III : Facilitator
13:00 – 13:30  General discussion
13:30 – 16:00  Lunch and break for finalization of recommendations

**Session VII: Round Table Dialogue on Maximizing Benefits and Minimizing Risks of Biotechnology and Final Recommendations**

Chairperson  : R.S. Paroda
Co-Chairperson : Jose Falck Zepeda
16:00 – 17:00  Presentation of synthesis report
17:00 – 18:00  Major recommendations and action plan
ANNEXURE-II

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RAP Ref.: LOA/RAP/__________

LETTER OF AGREEMENT

 Provision of funds from the
Food and Agriculture Organization of the United Nations to the
Asia-Pacific Association of Agricultural Research Institutions (APAARI)

1. Introduction

The Food and Agriculture Organization of the United Nations (hereinafter referred to as “FAO”), will make available to the Asia-Pacific Association of Agricultural Research Institutions (APAARI) (hereinafter referred to as “Recipient Organization”) a financial contribution in the amount of US$ 20,000 (Twenty thousand US Dollars) in support of studies relating to biotechnology within select countries in Asia in close collaboration with APAARI (including financial contribution).

2. Purpose

a) The activities for which the funds provided by FAO under this Agreement shall be used are the following:

1) Undertake studies to assess the needs and capacity of countries in Asia pertaining to biotechnology covering the following aspects:
   - assess the positive effects including the areas of potential concern.
   - types of policy advice, information and technical assistance required.
   - training and capacity-building support requirements including how and where to meet such needs.
   - assessment of technology options available and relevant for meeting the needs.
   - identify useful regulatory environments to ensure biosafety and harmonization with international standards.
   - identify important institutions and individuals involved in biotechnology including their specialties and strengths.
   - reconfirmation of the need for and requirements/arrangements for the establishment of a regional biotechnology network.

2) Organize a regional expert consultation.

3) Preparation of reports of findings including recommendations for national and regional attention, including by FAO.

4) Preparation of a synthesis paper/report on findings from the studies.
b) The background, the terms of reference, the inputs to be provided by the Recipient Organization and FAO, if any, the budget of the project and the identification of the Monitoring/Certifying Officer are given in detail in the attached Annex, which constitutes an integral part of this Agreement.

3. General Conditions

a) Funds provided by FAO under this Agreement are to be used by the Recipient Organization exclusively in support of the project.

b) The Recipient Organization will be responsible for the organization and conduct of the project. FAO will not be held responsible for any accident, illness, loss or damage, which may occur during the implementation of the project.

c) The use of the official emblem and name of FAO on any publication, document or paper is specifically prohibited without prior written approval from FAO.

d) All intellectual property rights (including copyright) in the work to be performed under this Agreement shall be vested in FAO, including, without any limitations, the right to use, publish, translate, sell or distribute, privately or publicly, any item or part thereof. Neither the Recipient Organization nor its personnel shall communicate to any other person or entity any confidential information made known to it by FAO in the course of the performance of its obligations under the terms of this Agreement nor shall it use this information to private or company advantage. This provision shall survive the expiration or termination of this Agreement. Any publication will be credited jointly to FAO and the RO.

e) The personnel assigned by the Recipient Organization for the organization and running of the project shall not be considered as staff members of FAO and shall not be entitled to any privilege, immunity, compensation or reimbursement by FAO. Neither the Recipient Organization nor its personnel shall be allowed to incur any commitment or expense on behalf of FAO. Nothing in this Agreement or in any document relating thereto, shall be construed as constituting a waiver of privileges or immunities of FAO, nor as conferring any privileges or immunities of FAO on the Recipient Organization or its personnel.

f) The present Agreement shall be governed by general principles of law, to the exclusion of any single national system of law.

g) If, after meeting the costs of the project, there are unexpended funds under this Agreement, the Recipient Organization shall return such unexpended funds to FAO.

h) FAO shall have the right to terminate this Agreement, by written notice to this effect, if it considers that the continued implementation of the Agreement is impossible or impractical:

i) for unforeseen causes beyond the control of FAO.

ii) in the event of a default or delay on the part of the Recipient Organization.

i) In the event of the Recipient Organization’s non-compliance or partial compliance with the terms of this Agreement, it will refund to FAO any payment already received in respect of activities that have not been performed by the Recipient Organization to a standard considered acceptable to FAO.

j) In the event of termination by FAO for unforeseen causes beyond its control, FAO shall complete all payments, which may be due up to the effective date of termination.

4. Reporting

a) The Recipient Organization shall submit to Mr Malcolm Hazelman, Senior Extension, Education and Communications Officer for the FAO Regional Office for Asia and the Pacific, Bangkok, Thailand a provisional programme and list of potential experts prior to releasing the second payment instalment.

b) The Recipient Organization shall submit to Mr Dong Qingsong, DRR, FAO Regional Office for Asia and the Pacific, Bangkok, Thailand an itemized “statement of expenditure” prior to receiving final payment for the works/services performed.

c) The Recipient Organization shall submit to Mr Malcolm Hazelman, FAO Regional Office for Asia and the Pacific, Bangkok, Thailand a final report within one month following the completion of the project.
d) The Recipient Organization shall submit to Mr Dong Qingsong, FAO Regional Office for Asia and the Pacific, Bangkok, Thailand a final audited statement of accounts showing the utilization of funds as determined under this Agreement within one month following the completion of the project. If the legal status of the Recipient Organization precludes the provision of audited financial statements, a statement certified as to its correctness by the officer responsible for maintaining them will be provided. In such cases the Organization shall have the right to review the relevant records.

5. Terms of Payment
a) For the execution of the project under this Agreement, FAO will make a financial contribution in local currency not exceeding the equivalent of US$ 20,000 (Twenty Thousand US Dollar).

b) The sum stipulated in paragraph 5a) above represents the full amount to be paid by FAO for all services and activities to be provided by the Recipient Organization under this Agreement.

c) FAO will make the above-mentioned payment in accordance with the banking instructions provided below by the Recipient Organization. Any dispute between FAO and the Recipient Organization arising out of the interpretation or execution of this Agreement shall be settled by mutual agreement. If FAO and the Recipient Organization are unable to reach agreement on any question in dispute or on a mode of settlement other than arbitration, either party shall have the right to request arbitration in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law (UNCITRAL), as at present in force. FAO and the Recipient Organization agree to be bound by any arbitration award rendered in accordance with the above, as the final adjudication of any such dispute.

6. Amendments
Any amendment to this Agreement shall be effected only on the basis of written mutual consent by the Parties.

7. Entry into Force
a) The Agreement will enter into force upon signature by both Parties.

b) The Recipient Organization must sign three copies of this Agreement and return two to

Mr Malcolm Hazelman, Senior Extension, Education and Communications Officer, FAO Regional Office for Asia and the Pacific.

Signed on behalf of the Food and Agriculture Organization of the United Nations:

Signature : ..................................................

Dr R.B. Singh
Assistant Director General and Regional Representative
FAO Regional Office for Asia and the Pacific, Bangkok, Thailand

Date : ..................................................

Signed on behalf of the Asia-Pacific Association of Agricultural Research Institutions (APAARI)

Signature : ..................................................

Dr R.S. Paroda
Executive Secretary
Asia-Pacific Association of Agricultural Research Institutions (APAARI)
New Delhi 110 003, India

Date : ..................................................

Detailed Banking Instructions (including: the name of the account holder, account number, bank’s name and its full address).
Status of Biotechnology Application in Agriculture and Allied Sectors in West and South Asia Region

Professor Asis Datta
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INTRODUCTION

The geographical region of West and South Asia has diverse agro-climates, while parts of it are suitable for intensive agriculture, the other parts pose stupendous problems for the improvement of agricultural productivity. Some parts of this region can increase area under cultivation. In certain other parts, the agricultural area may actually undergo contraction in future due to more populous inhabitation. Agriculture of several nations of this region has suffered from time to time from sudden weather changes, epidemics of crops, animal diseases and severe pest infestations. Indiscriminate deforestation for bringing new area into agriculture has adversely affected water regulation, soil holding, genetic diversity and cleanliness of atmosphere in some parts of this region. In the agriculturally self-sufficient countries, the match between growth of population and agricultural produce has been sustained by dependence on large input of fertilizers, irrigation and water in intensively cultivated fields. Several countries of the area import foodgrains in large quantities. There is no scope for mechanized agriculture in most of the countries covering this region due to small sized land holdings by bulk of farming community. However, the continued population growth dictates that agricultural productivity in the area must undergo progressive increase.

So far, the progress in agricultural productivity in South and West Asia has relied upon high yielding technologies requiring extensive inputs of water and fertilizers to crops. The environment change and population growth are already the cause of shortage of energy and water reserves. Therefore, there is urgent need to adopt new environment-friendly and low input agricultural technologies for high levels of crop productivity. The advent of biotechnology offers promise in meeting these objectives. Biotechnology uses molecular biological research discoveries to direct crops' field behaviour and quality of its produce. It also offers new kinds of bio-pesticides, bio-fertilizers, processed food and environment conservation. One of the main objectives of application of biotechnology in agriculture will be to improve seeds of crops so that the plants have resistance to diseases caused by bacteria, fungi and viruses, repellence for animal pests such as insects, mites and nematodes and tolerance to abiotic factors such as aridity, climatic variation, poor soil quality, crop rotation practices and other limitations. Since the modern biotechnology is a new development in the field of science and technology and its extensive application is awaited, presently the products and processes developed through its use need to be monitored locally, nationally and internationally for any unsuspected danger. On the whole it can be confidently predicted that the challenges posed by rising population in terms of requirement of increased food production, sustainable water and energy management and cleaner environment, despite practice of intensive agriculture and rapid industrialization, can be met through expanded use of biotechnology.

NATIONAL AGRICULTURAL RESEARCH SYSTEM/INSTITUTES

The current debate about the potential utility of modern biotechnology for food and agriculture presents a challenge to research and development. Since biotechnology offers sea changes, it can be seen that biotechnology research would revitalize the region. While the transformation takes place the objective to be met should remain that of integrating the science, technology and educational development with economic and social progress. If the
biotechnology R&D receives due attention in public research institutions, then the benefits of research can be readily passed on to small farmers at low cost or, through government agricultural extension services, even free of charge. Since this may be difficult to achieve with results of research sponsored by private enterprises, national agricultural research systems (NARS) of the region should be suitably funded for training of manpower and intensification of R&D in the biotechnology related area.

AGRICULTURAL BIOTECHNOLOGY INSTITUTIONS (PUBLIC AND PRIVATE SECTOR)

In order to maximize the use of new biotechnology knowledge, both public and private sector research is required to bring innovation and choices to farmers and consumers. These may be country specific, as the geographic factors, farming methods, etc vary from country to country. The private sector institutions would obviously focus on those areas of opportunity, which will repay their investment in innovation. The public sector must maintain the freedom to operate in an era of increasing proprietary technology. In South and West Asia, the public sector will need to develop technologies that meet the needs of the non-commercial sector, including the needs of resource-poor farmers and poor consumers. Public-private roles have been changing due to declining public sector investments in R&D, and increasing private sector investments especially in biotechnology. A number of factors are responsible for this change and they are:

- change in leadership in biological research (from public to private).
- change in ownership of technology.
- change in markets (the private sector is now more interested in developing country markets), etc.

Issues, Concerns and Challenges

Global food policy has been driven by the need to grow more food to meet the effective demand of increasing population. The agricultural systems that have been built over the past few decades have served their purpose up to a point. If the current system persists, the chance of bettering the lot of the majority of the world’s people will be diminished.

The planners and agricultural scientists of various nations in the South and West Asia have been engaged in alleviating poverty, improving food security, and reducing malnutrition, especially among children by using new technologies for environmentally sustainable agricultural development. The key components of agricultural biotechnology are:

Genomics: The molecular characterization of all species.

Bioinformatics: The assembly of data from genomic analysis into accessible forms.

Transformation: The introduction of one or more genes conferring potentially useful traits into plants, livestock, fish and tree species.

Molecular breeding: The identification and evaluation of desirable traits in breeding programmes by the use of marker assisted selection, for plants, livestock, fish and tree species.

The multi-faceted dimensions of biotechnology cover issues that are scientific and ethical, and those concerning safety, partnerships, economics, IPR and trade, and environment.

There is an urgent need for a more focused debate on the role of modern agricultural biotechnology in developing countries. While the arable land under cultivation is getting reduced due to human settlement like housing, non-agricultural use like industry, etc. and the availability of water for agricultural purposes are diminishing resources, there is but no option to increase food production and other agricultural commodities from less arable and irrigation resources. The need for more food has to be met through higher yields per unit of land, water, energy and time which is possible through new agricultural biotechnology. According to Prof M.S. Swaminathan, one of the renowned agricultural scientists and a person who played a major role
in the Green Revolution in India, we need to examine how science can be mobilized to raise further the biological productivity ceilings without associated ecological harm. Scientific progress on farms, as an evergreen revolution, must emphasize that the productivity advance is sustainable over time since it is rooted in the principles of ecology, economics, social and gender equity, and employment generation (Swaminathan, 2000).

Trends in Development of Biotechnology

Conventional biotechnology manipulated animals, plants and microorganisms, and selection was the major force behind production of desired quality. The new biotechnology uses basic molecular biological research discoveries to direct and manipulate the products it produces. Directed alterations in cellular DNA can convert the simplest of creatures into living biochemical factories of rare bio-chemicals, food and renewable energy sources. Sexual incompatibility barriers limit traditional plant breeding techniques.

Modern biotechnology arose when the technologies of gene engineering became available in the early 1970s. The first achievements of biotechnology were the cloning of DNA fragments or genes, which were then inserted into living cells to produce proteins of medical interest such as insulin, interferons or growth hormone. Today, large international research projects are underway, aiming at identifying and isolating all the genes that composite the heredity, or genomes, of micro-organisms, plants and animals. The analysis of genomic information necessitates the development of computer software and communication programmes creating a new field of Bio-informatics. Biotechnology contributes to agriculture by way of Agro-Bio, produces crops resistant to disease, parasites, herbicides or climate conditions. Modern biotechnology is the genetic engineering technology that results in the production of Genetically Modified Organisms (GMOs).

Aims and Objectives

1. To ensure the minimum food and nutrition needs of the growing population through agricultural technologies that are environment friendly.
2. To eliminate severe malnutrition and poverty.
3. To ensure comprehensive food and nutrition security at the household level.
4. To arrest environmental degradation and conservation of natural resources for enhanced sustainability and productivity of agriculture, and
5. To establish linkages among related sectors to promote agricultural diversification and to improve the quality of life.

Human Resources Infrastructure: Public and Private, University System Investment: Public and Private, University

Biotechnology in a globalizing economy involves the participation of all countries (developed and developing) in the interconnected web of trade liberalization in closed and open-market economies. The main objectives are to make known crop’s potential and its R&D requirements, to encourage a critical mass and synergy of advanced biotechnology research groups working on Agro-biotechnology and to provide a mechanism for voluntary focusing of resources and cost-effective use of existing facilities in biotechnology research. Linkages between strategic and applied research and users have to be developed. Moreover, university/institute-industry collaboration is an important factor in the bio-industrialization of developing countries.

The major concern for the biotechnology research and development is paucity of adequate investment. More funds should be diverted towards development of rural infrastructure, human resources and very importantly agricultural research and technology development and transfer in the long run. The continued efforts to increase investment would be required in order to develop science and technology, reform research institutes of applied science, increase technological innovation, reform managerial and distribution systems of science institutions, develop quality education, reform and develop higher education, and further improve working and living conditions of teachers/researchers. The private sector is likely to focus on those areas of opportunity, which will repay their investment in innovation. The public sector must maintain the freedom to operate in an era of increasing
propriety technology. In South and West Asian countries, the public sector will need to develop technologies that meet the needs of the non-commercial sector, including the needs of resource-poor farmers and the poor consumers.

Institutional Linkages (National and International); CGIAR Partnership

The Consultative Group on International Agricultural Research (CGIAR) assists national institutes in the application of modern biotechnology in the following areas:

Biosafety
1. Setting up regional linkages to share biosafety data and to pool information.
2. Providing training and guidance on risk assessment and risk management issues.
3. Providing technical training in biosafety reviews, prior to releases.
4. Building consensus among nations on biosafety protocols and guidelines.
5. Assisting in the development of media and information materials to increase public awareness.

Research and Development
1. Increasing CGIAR/NARS collaboration in biotechnology R&D.
2. Setting up programmes for the use and management of technology.

Intellectual Property Management
1. Increasing awareness on intellectual property and its fundamentals (copyrights, trademarks, patents, licensing, plant variety protection, plant breeders’ rights).
2. Establishing intellectual property policy and institutional policies.
3. Building capacity and human resources development in the field of technology transfer and intellectual property rights.

The future role of CGIAR is to enhance its role as protector of the interests of the poor and facilitator and bridge-builder in biotechnology partnerships, facilitating public policy and innovative institutional arrangements. CGIAR centres could develop, for the benefit of the South and West Asian countries, more comprehensive partnerships with the private sector and also with universities and other advanced research institutions. This would give these countries access to a minimum intellectual property platform that would guarantee that new products developed by their research institutes would reach farmers and consumers.

Donor Support: Bilateral, Multilateral Accomplishments

The commercial use in agriculture and animal husbandry has been increasing and, the species and the food products derived from them are gaining acceptability.

Crops

The new DNA manipulation techniques provide practicable means to overcome the limitations of plant breeders. Some of the commercially important plant species that have been modified are barley, cabbage, chickpea, cotton, maize, potato, rape/mustard, rice, soybean, tobacco, tomato and wheat. Five categories of innovations seem to be of particular importance to future agricultural needs.
1. Those that breed resistance against specific diseases and common pests and insects.
2. Those that reduce the environmental burden of fertilizers.
3. Those that reduce the demand for irrigation water.
4. Those that continue to improve crop production per hectare.
5. Those that improve the nutritive value of crops and vegetables.
Livestock

Animal biotechnology provides the means to take advantage of the huge numbers of sperms and oocytes from genetically superior animals that ordinarily are wasted by degeneration of oocytes and loss of sperm. Successes have been achieved through newly discovered techniques of embryo transfer and embryo splitting. As methods for genetic transfer of material in livestock are further developed, it will be possible not only to continue and accelerate the process of improving the reproductive performance of individual animals, but also to improve the quality of animal products produced. It seems technically feasible to introduce novel methods such as the production of high value proteins in lactating mammary glands and their secretion into milk. Through the application of recombinant DNA technology, specific genes controlling disease resistance are being identified. The identification, mapping, and cloning of these genes coupled with techniques in embryo manipulation offer dramatic potential for generating disease-resistant animals through gene transfer. Poultry is another area in which manipulation of composition of eggs from cholesterol-rich to cholesterol-free can be achieved.

Fisheries

Marine resources provide many goods and benefits including bioactive materials, drugs, and food items and must be characterized and conserved. In fact, aquaculture products are among the most used commodities in the world.

Forestry

Fast growing forestry and also trees of multiple uses have to meet the requirement of timber, conventional non-wood forest produce and also food and food materials. Forestry should be bred such that the sunlight is harvested at the various levels of the forest.

Natural Resources Management

Genetically engineered bacteria and fungi can provide hydrogen energy as an alternative to green energy.

PHT (Processing, Value addition, etc.)

Patents Obtained

The possibility that the new technology, or its products, might become subject to intellectual property protection rights, such as the patenting of genes and living organisms, will obviously have serious implications for the free exchange of genetic resources.

NATIONAL POLICY ON BIOTECHNOLOGY

There should be a detailed national policy on biotechnology. The policy should include scientific, ethical and safety issues, as well as regulatory, IPR and trade and economic issues. The relevant safety issues regarding geneflow and pest resistance concerns should be raised and reviewed during the application. The seed registration process should be streamlined properly. There should be a proper reporting at the end of field tests and a mechanism for public feedback and formulation of strategies in general for public relations. As far as priority in case of biosafety is concerned there should a definite legislative framework for enforcement and punitive mechanisms. The farmers’ associations and NGOs should be consulted in the biotechnology policy decisions. Biotechnology is to some extent inevitable, and has a great potential to accrue benefit to the developing countries through capacity building measures in research, industry, and biosafety regulations.

National Coordination Framework

Although many institutions are already actively involved, more coordination and work is needed at all levels that benefit the public especially the poor. Issues and areas that require further attention include:

- Ensuring public participation in the development of agricultural and resource use policies.
• Eliminating subsidies and credit policies for uniform high-yield varieties, fertilizers and pesticides, so as to encourage the use of more diverse seed types and farming methods.
• Providing policy support and incentives for effective agro-ecological methods that make sustainable intensification possible.
• Reforming tenure and property systems that affect the use of biological resources to ensure that local people have rights and access to necessary resources.
• Implementing regulations and incentives to make seed and agro-chemical industries more socially and environmentally responsible.
• Developing markets and business opportunities for diverse organic agricultural products.
• Developing legal systems and regulations to ensure the protection of intellectual property rights of indigenous peoples and farmers in developing countries in relation to genetic resources.

Investment Policy
The investment policy in agriculture may not be the same as in other sectors like banking, industry, etc. Towards this goal, an accelerated public investment is needed to facilitate agricultural and rural development. Even within agriculture, the investment should be crop-specific and should be made on high yielding crop varieties, environmentally sustainable production technologies, extension services, agricultural information systems, sustainable resource management, rural infrastructure and effective markets and social sectors like education, health, sanitation, water, etc. These investments need to be supported by good governance and an enabling policy environment, including trade, macroeconomic, and sectoral policies that do not discriminate against agriculture, and policies that provide appropriate incentives for the sustainable management of natural resources. Biotechnology needs to go hand-in-hand with investment in broad-based agricultural growth. There is considerable potential for biotechnology to contribute to increased yields and reduced risks for poor farmers, as well as more plentiful, affordable, and nutritious food for the poor consumers.

Research Partnership
Research and development in the areas of biotechnology and genetic engineering is currently proceeding at a striking speed leading to the discoveries and applications of new techniques. From traditional techniques of fermentation and tissue culture, biotechnology is now approaching the mature stage of ‘DNA technology’. This undoubtedly has a profound effect on agricultural development and food production and contributes to a long-term sustainable agricultural development. Biotechnology has now reached a stage from where it appears to offer technically feasible and viable solutions to many problems that were previously thought to be impossible. Genome research to develop highly improved varieties of plant and animal breeds has produced many genetically modified plants and animals. This technique is also being recognized as the enabling technology for sustainable agriculture development, and it could ensure a long-term conservation and sustainable use of biological diversity.

Bio-Safety/Bio-Ethics
In the context of the application of genetics and biotechnology in food crops of South and West Asia, the dilemma posed by technical change can be between political objective of national food security and the interests of poor farmers. There are tremendous ethical queries to avoid misuse of genetic testing and manipulations in medicine and in ecology. But the core promises for alleviating many illnesses and providing the food and necessities of a growing population. Bio-safety and risk assessment for the release of Genetically Modified Organisms (GMO) has been an issue of concern. Safety evaluations typically include identification of the composition and structure of the gene product; a quantification of the amount of gene product expressed in the edible portion of the food; a search for similarity to know toxins and anti-nutritional factors, allergens and other functional proteins; a determination of the thermal and digestive stability of the gene product; and the results of both in vivo and in vitro toxicological assays to demonstrate lack of apparent allergenicity or
toxicity. However, with adequate research and development, patience and foresight, suitable public policies and mechanisms could be developed to monitor, control and minimize the potential risks involved. A precautionary approach is highly essential for deriving maximum benefits from biotechnology while at the same time minimizing the potential risk factors involved. Recently, however, a protocol on bio-safety to the Convention on Biological Diversity has been adopted in Cartagena. This protocol proposes different mechanisms, including the establishment of a Bio-Safety Clearing House. This clearing house, in turn, aims at building national capabilities to assess the risks, if any, associated with the products of the new technology; and to ensure that trans-boundary movements of modified organisms and their products is according to internationally agreed principles that will ensure the safety of all users.

Ethics in the sense of moral philosophy analyses practices and activities with a view to their morality. The ethical challenges include the role of science, its risks, benefits, and impact on society. Moral and ethical standards are being used to develop laws governing some aspects of biotechnology. In 1998, the CGIAR system agreed to a statement of ethical principles underlying the work of the CGIAR centres in biotechnology. The relevant principles are those relating to honesty, intellectual rigour, openness and transparency, accountability, and precautionary approaches. In order to form opinion on whether a technology promises a balance to contribute to the common good or whether it may inflict significant harm to the society and its members, one must first analyze that technology’s potential and real benefits and risks. The bioethics committee of UNESCO established in 1993 has evolved guidelines for ethical issues associated with the use of modern biotechnology. Biosafety guidelines for genetically improved organisms need to be strictly followed to prevent harm to human health or environment. The time has arrived for a serious look at the ethical and biosafety aspects of biotechnology. New models of co-operation and partnership have to be established to ensure close linkages among government representatives, policy makers, researchers, NGOs, extension workers, industry, the farming community and consumers on environment safety, food and nutrition security, social and economic benefits, ethical and moral issues and regulatory aspects. Undoubtedly, greater public and political awareness is necessary, because the loss of biological diversity is immensely regrettable for aesthetic, ethical, philosophical, ecological and economic reasons.

In considering the potential risks and benefits of modern biotechnology, it is useful to distinguish technology-inherent and technology-transcending risks. Technology-inherent risks are those where the technology itself has potential risks to human health, ecology, and the environment. Technology-transcending risks include those that are not specific to the technology but where its use may have risks. For biotechnology these include the risk of increasing the poverty gap within and between societies, reducing biodiversity, and antitrust and international trade.

**IPR and Mechanisms of Accessing Technologies/Products by Public and Private Sectors**

Intellectual property rights are important for biotechnology, they can provide incentives for local researchers and firms, they have come to be required by international law, and they can assist in the international transfer of technology. Intellectual property rights (IPRs) such as patents are statutory rights which prevent imitation for a limited time. There are legal instruments to protect an inventor’s investments in his or her innovation. The research institution can own the IPRs and transfer of technology. However, a portion of the total revenue generated through exploitation of the technology, will have to be shared with the scientists or inventors connected with the development of the technology. This arrangement could result in profiting both the research institutions and the scientists involved in developing the technology. The duration of technology transfer deters small companies from searching for appropriate technology to commercialize. It is quite possible that links may be forged with disparate fields of technology. IPRs in the context of genetic engineering and biotechnology for food crops in South and West Asia do not differ basically from patents in developed countries. The outcome of an ethical analysis of IPRs will mainly depend on a benefit-risk analysis of genetics and biotechnology in agriculture.
GMOs/Transgenics/Molecular Breeding

Recombinant DNA biotechnology-derived foods are part of the continuing sequence of genetic improvement of the food supply. The techniques involve the introduction of one or a few defined genes into a plant. Although it is sometimes portrayed, as fundamentally new, the newness of rDNA biotechnology is best considered from a historical perspective. Genetic modification of plants began approximately 10,000 years ago when man first used what is referred to as selective breeding. This technique simply involved saving seeds from the most vigorous plants in an environment for replanting at a later time. Over a period of many years, this selection resulted in higher-yielding varieties of the crop.

The newer rDNA biotechnology techniques, in particular offer the potential to rapidly and precisely improve the quantity and quality of food available. Crops modified by rDNA technology pose risks no different from those modified by earlier genetic methods for similar traits. Because the molecular methods are more specific, users of these methods will be more certain about the traits they introduce into the plants. A 1991 joint Food and Agriculture Organization/World Health Organization consultation, addressed the question of the safety of rDNA biotechnology derived foods as follows:

“Biotechnology has a long history of use in food production and processing. It represents a continuum embracing both traditional breeding techniques and the latest techniques based on molecular biology. The newer biotechnological techniques, in particular, open up very great possibilities of rapidly improving the quantity and quality of food available. The use of these techniques does not result in food which is inherently less safe than that produced by conventional ones”.

The assessment of safety and nutrition of GM food focuses on the following:

- Toxicants known to be characteristic of the host and donor species.
- The potential that food allergens will be transferred from one food source to another.
- The concentration and bio-availability of important nutrients for which a food crop is ordinarily consumed.
- The safety and nutritional value of newly introduced proteins.
- The identity, composition and nutritional value of newly introduced proteins.
- The identity, composition and nutritional value of modified carbohydrates, fats or oils.

Patenting

Patent rights are justified as a means of encouraging investment in research and development that might not be profitable to firms that had not shared in the initial risk and cost and were free to copy successful new inventors. A patent confers the right to exclude others from making, using and selling the innovation within the territory of the nation granting the patent for a specified/limited period. In some circumstances, a patent on a process also confers a right to exclude sales within the nation of a product manufactured abroad through the use of the patented process. The basic requirements for patent protection are novelty, utility or industrial applicability, and non-obviousness or inventive step. The commercial value and significance of a patent depends on the scope of the patent claims which in turn depends on the breadth of the disclosure in the patent specification. The technological scope of a patent monopoly is determined by the language of the patent claims. For biotechnology-based breeding, however, the right to protect a gene under the regular patent system is essential. Otherwise the benefit of the protection can be lost to another breeder who breeds the inserted gene into his or her varieties.

Trade/Market Segmentation

Biotechnology will affect international trade with varying impacts in different areas of application. The impact on trade flows will be much larger in agriculture for two reasons:
1. Trade in agricultural products has more than the value of trade in other sectors, and

2. Social repercussions of shifts in international trade would be more important in the case of agriculture than in the case of other sectors.

A decline in agricultural exports could have serious consequences for those countries that rely almost exclusively on them for foreign exchange earnings. For example, the aquatic plant export industry of Sri Lanka has been developing rapidly. Its exports has increased from 4.2 million aquatic plants in 1997 to 8 million in 1998.

Future Priority Areas of Research and Development

Future research on biotechnology in agriculture will be on the exploitation of heterosis vigour and development of new hybrids including apomixis, genes for abiotic and biotic resistance, and developing plant material with desirable traits and genetic enhancement of important crops. Integrated nutrient management and development of new bio-fertilizers and bio-pesticides would be important from the viewpoint of sustainable agriculture, soil fertility, and a clean environment. There will be a switch to organic farming practices, with greater use of biological software on a large scale. It is scientifically well established that an environmentally benign way of ensuring food security is through bioengineering of crops.

Genomics, Proteomics

Plant genomics is the engine to drive trait discovery and help solve intractable problems in crop production. Genomics is a field of biology that has developed very rapidly over the last decade. It involves the large-scale sequencing of DNA, including entire genomes and the comparative analysis of the resulting sequences across species-barriers. To fully exploit the wealth of structural information obtained from the genome we must understand the specific biological functions encoded by a DNA sequence through detailed genetic and phenotypic analyses. Although no immediate spin-off for agricultural applications should be expected in the next 5-10 years, a detailed knowledge of plant and animal genomes will, in the long run, speed up breeding, also in tropical agriculture. Thus functional genomics requires diversity of scientific expertise as well as biological resources. In many important food crops the public sector has a large investment in biological resources and in plant breeding programmes through national and global crop networks.

Genetic Modification

Genetic modification, also termed as genetic manipulation, concerns the transfer of genetic information – in the form of DNA sequences – across sexual barriers between species, which under normal conditions would not exchange DNA. The resulting organisms are called Genetically Modified Organisms (GMOs) or transgenics. Genetic modification is currently used only to introduce a single new trait, which might be based on the activity of a single gene, or a small number of genes. The number of genes with known functions that has been isolated is still too small to allow for more complicated traits or combinations of traits to be introduced using genetic modification. In agriculture, genetic modification has been applied in major crops.

Social, Economic and Structural Aspects

New technologies have been developed and deployed, often with no consideration of the basic needs of the users. The prospective impacts of new technologies are matters of strong public concern. Gene transfers are considered exotic because genes from unrelated organisms are made to express in organisms which do not normally host them. Such mixing of genes from unrelated organisms might create a natural imbalance by the transfer of genetic traits into organisms, which nature has not so far ordained. It is important therefore, that all GMOs and their products should be monitored to assess not only technical merits but also agricultural, environmental and socio-economic impacts. Biotechnology is only one tool in addressing the challenges of food security and poverty. There is a need for biotechnology to be integrated with appropriate policies and other conventional
R&D programmes. The positive and negative impacts of biotechnology should be monitored over time in terms of should and what are affected and how they are affected. Monitoring impact will provide guidance for public policymakers in the future. Unless the South and West Asian countries have policies to ensure that small farmers have access to delivery systems, extension services, productive resources, markets, and infrastructure, there is a risk that the introduction of agricultural biotechnology could lead to increased inequality of income and wealth. In such cases, big farmers are likely to exploit most of the benefits through early adoption of the technology, expanded production, and reduced unit cost.

Country Profiles

Bangladesh

Research on biotechnology was initiated in 1977 in Bangladesh as tissue culture in various institutes under NARS, such as Bangladesh Agricultural Research Institute, Bangladesh Rice Research Institute, Bangladesh Institute for Nuclear Agriculture, Bangladesh Forest Research Institute, Bangladesh Jute Research Institute and Bangladesh Tea Research Institute. In addition to NARS, tissue culture facilities have been developed in many educational institutes such as Dhaka University, Chittagong University, Rajshahi University, Khulna University, Bangladesh Agricultural University, and the Institute of Post Graduate Studies in Agriculture.

The protocols of plant regeneration are available for five fruit species, fifteen forest species, three vegetable species, nine species of ornamental and medicinal plants and fifteen field crops. The new biotechnological research are found in the development of submergence tolerance in rice, salt tolerant coastal varieties, yellow mosaic virus resistant mungbean, and nutrition-improved varieties of jute and lentil. National Agricultural Research System (NARS) carry out research in four sub-sectors of agriculture such as crops, forestry, fisheries and livestock. There is a programme in ARMP for capacity building in the field of biotechnology by the NARS institutes. ARMP provides necessary funds for biotechnological research in all the four sectors. In Bangladesh, biotechnology effectively addresses the coastal salinity problem for possible rice cultivation through Marker-Aided Selection technique (MAS).

India

The Government of India considered the need for creating a separate institutional framework to strengthen biology and biotechnology research in 1980s. The premier research institutions are some of the laboratories under the Council of Scientific and Industrial Research (CSIR), Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR), and the funding agencies like the Department of Atomic Energy (DAE), the Department of Biotechnology (DBT), the Department of Science and Technology (DST) and the University Grants Commission (UGC). Biotechnology was given an important boost in 1982 with the establishment of the National Biotechnology Board. The success and impact of the National Biotechnology Board prompted the Government to establish a separate Department of Biotechnology in February 1986. There have been major accomplishments in areas of basic research in agriculture, health, environment, human resource development, industry, safety, and ethical issues. In India, the establishment of a Biotechnology Golden Jubilee Park for Women is a unique feature, which will encourage a number of women entrepreneurs to take up biotechnology enterprises that benefit women in particular.

The institutions under CSIR, ICMR, ICAR, DST and DBT have established in the identification of new genes, development of new drug delivery systems, diagnostics, recombinant vaccines, computational biology, and many related areas. India has a large research and educational infrastructure to carry out biotechnology research, comprising 31 agricultural universities, 204 central and state universities, and more than 500 national laboratories and research institutions.

The International Centre of Genetic Engineering and Biotechnology (ICGEB) at New Delhi, plays a vital role to link international institutions to conduct research on biotechnology. Intensification of agriculture and reliance in irrigation and chemical inputs in India has led to severe environmental degradation with problems
of salinity and pesticide abuse. Multinational and Indian public and private research companies are investing heavily in their industries encouraged by biotechnology-friendly policies. Politicians and policy makers believe that as well as creating wealth, the growth in biotechnology may bring medical and ecological breakthroughs. India's qualified and relatively cheap work force offers a real commercial advantage for biotechnology research. In India, by improving infrastructure and encouraging investment, socially beneficial biotechnology can flourish. The bio-piracy is a real concern of the research institutes. According to the Confederation of Indian Industry, the national market in biotechnology was valued at 2.5 billion, a five-fold increase since 1997. The International Rice Genome Sequencing Project (IRGSP) was launched in India in 1998. It has allotted large public resources towards infrastructure and human resources development in biotechnology. Under this project, scientists from the University of Delhi and the Indian Agricultural Research Institute (IARI) have been sequencing a part of chromosome 11 in rice. In order to develop transgenic crop plants with high nutritional value, a seed albumin gene (AmAl) encoding for a protein of high lysine and sulphur containing amino acids from amaranth seeds has been introduced in potato plants. The transfer of AmAl in potato results in significant increase in growth and tuber yield, besides higher protein content with increase in most essential amino acids. A number of Centres for Plant Molecular Biology (CPMBs) were set up under the university system for carrying out research. The Department of Biotechnology later set up the National Centre for Plant Genome Research (NCPGR). The National Bureau of Plant Genetic Resources, one of the gene bank, has a sizable collection. Efforts are initiated towards application in improving agricultural productivity, bioremediation in the environment, etc. Research and development priorities in agriculture include new regeneration protocols for rapid multiplication of cardamom, citrus, coffee, mangrove and vanilla. Yield of cardamom has increased 40 per cent by using tissue-cultured plants. India has regulatory systems in place at the national and institutional level to govern R&D programmes and commercial developments where appropriate. Intellectual property management was considered to be a difficult issue in India.

Pakistan

Public sector is the lone investor in biotechnology. National Institute for the Biotechnology and Genetic Engineering is an important research institution. The Government of Pakistan has not allowed the private sector to carryout research on biotechnology. It is necessity of the moment in Pakistan to commercialize agriculture for its growth.

Sri Lanka

In Sri Lanka, natural fresh water ecosystems are unique in their diversity and vulnerable like all other tropical rain-forest ecosystems. In Sri Lanka, women not only played a complementary but equally important role in the conservation and enhancement of plant genetic resources. Women were leaders in harnessing non-wood forest products for strengthening household nutrition, health and livelihood security. The growing commercialisation of agriculture is leading to the marginalisation of women in the intellectual aspects of biodiversity management. The feedstock for the modern biotechnology industry is biodiversity. Therefore, Sri Lanka is seeking the assistance of the Food and Agricultural Organization's Regional Office for Asia and the Pacific and the United Nations Development Programme to establish a Women's Biotechnology Park, on the basis of the one in Tamil Nadu, India.

Egypt

The Agricultural Genetic Engineering Research Institute (AGERI) was established in 1990 at the Agricultural Research Centre (ARC) to promote the transfer and application of biotechnology in Egypt. AGERI has collaborated with private companies especially MNCs as "BIOGRO International" to fulfill its commitments to bring research results into application and large-scale commercial distribution to the farmers. As one of the leading institutions in agricultural genetic engineering in West Asia, AGERI shares its know-how and experience with other countries within the framework of Technical Cooperation Among Developing Countries (TCDC). This institute also provides professional consultation in the field of molecular biology and agricultural genetic engineering. The private sector has access to biotechnology, and has invested heavily in research and development (R&D) of technology
and necessary ancillary expertise to bring a product to market. The competitive edge of a private company depends on the proprietary nature of its R&D and the protection offered by intellectual laws. Developing country's biotechnology institutions may be interested in working with private companies to gain access to important technology, develop managerial and business expertise, build intellectual capacity, or form a partnership with entity that has an existing capability of bringing a product to market. One of the major targets for biotechnology in Egypt is the production of transgenic plants conferring resistance to biotic and abiotic stresses, which are major agricultural problems leading to serious losses in many economically important crops.

**Israel**

Israel has a strong potential to take a leading place in the world of biotechnology. There are around 160 industrial enterprises active in the various sectors of Therapeutic pharmaceuticals, Diagnostics, Bio-informatics and Agro-Bio including plant and farm and animal products. The Biotech work force grew from 400 in 1988 to 4000 in the year 2000. The sale of products developed by Israeli Biotech sector which were 15 M$ in 1988, reached 800 M$ in 2000 of which 80 per cent is through export. The share of Israel is about 2.5 per cent of the total world Biotechnology sale. The Agro-Bio and veterinary products amount to 23 per cent of sales. Biotechnology research in Israel is carried out at seven universities, five technical colleges and other research institutes and hospitals. The Weizmann Institute of Sciences in Rehovot pioneered biotechnology in Israel. Kryat Weizmann Science Park has become the national centre of the country's biotechnology industry with largest companies based there.

**Jordan**

In the Biotechnology development, Jordan still lags behind many developing countries because of the lack of major funding to establish laboratories and to have the needed infrastructure, lack of national strategy for biotechnology and its application, lack of technical know-how and manpower and finally insufficient collaboration with international institutions. Despite these major shortcomings, Jordan has made some progress in fragmented biotechnology research and development, mainly of conventional biotechnology. Jordanian universities and private industries have succeeded in plant tissue culture, bio-fertilizers, and production of pesticides, developing some equipment used in biotechnology, yeast production and basic biotechnology research.

In general in the West Asia region the main constraints are inadequate resources, lack of qualified personnel, poor infrastructure, and insufficient regional and international collaboration. There is also a lack of clear strategy, policy, and regulatory framework to guide the use of modern biotechnology.

**EPILOGUE**

The fundamental challenge the world faces now is how to ensure that the people who are living in poverty have access to enough food to maintain a healthy life. Hunger is still a reality for 800 million poor people and food security still remains one of the most desirable objectives of sustainable development (FAO, 1996). According to FAO, the agricultural production will increase in order to meet the needs of the growing population, and it requires a virtual agricultural revolution through investments in new technologies and inputs as well as increased awareness of the need to preserve resources (FAO, 1981). The World Food Summit also stressed that the sustained improvements in the area of food security will necessitate poverty-oriented development policy, social reforms and appropriate technological innovation.

The Green Revolution has averted a world food crisis during the late 1960s and early 1970s. After the Green revolution, it is anticipated that advanced biotechnology and genetic engineering will play a major role in food production. Value addition to the conventional methods of agricultural development through the use of modern biotechnology acts as a driving force for the growth of the biotechnology industry, and investment is expected to increase in the coming years. Therefore, the industry should realize the potential long-term benefits of biotechnology and shape their business plans and activities accordingly. It is evident that biotechnology offers
technically viable solutions to our most urgent problems in the agricultural and environmental sectors. However, there are social, legal and economic problems arising from injudicious and uncontrolled use and application of biotechnology. Biotechnology inevitably helps to increase food self-sufficiency in densely populated countries in South and West Asia.

The new golden rice offers an exciting opportunity to complement Vitamin A supplementation programmes, particularly in rural areas. Biotechnology – one of the many tools of agricultural research and development, could contribute to economic development by helping to promote sustainable development centred on small farmers in developing countries. Agricultural biotechnology, especially genetic engineering, will play an important role in improving agricultural productivity, food, fibre, etc. At the same time it has been under debate, with opposing factions making strong claims of promise and peril. Concerns about biosafety as well as about intellectual property cannot be ignored. Effective regulatory mechanisms and safeguards need to be universal so that the impact of agricultural biotechnology is both productive and benign. There is a moral imperative to make GM crops readily available to developing countries that want them, to help combat world hunger and poverty.

The farmers should access improved agricultural technology through a participatory approach. The information and communication network has to reach the rural areas especially small farmers. The genetic engineering and biotechnology have the potential to increase agricultural production and productivity, enhance the environment, and improve food safety and quality. When poor small farmers have access to land, agricultural extension services, marketing opportunities, to working equipment and credit, then high yield variety seeds adapted to the biotope and resistant to pests can be developed with the use of genetics and biotechnology to bring more food to the small farmers. Sustainable agricultural development and sustainable food security will not be achievable without better governance and but also not without new technologies such as genetic engineering and biotechnology in the coming days.

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ASEAN Agro-Biotechnology: Overview and Recommendation on Regional Collaboration

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This paper presents an overview of biotechnology application in agriculture in the ASEAN region, assessing the positive effects and the areas of concern, the biotechnological options available and relevant to meet the basic needs, and the status of existing regulatory environments. The paper proposes possible mechanisms/arrangements for the establishment of a regional biotechnology network and recommends collaborative activity to strengthen Ag-Biotechnology as a tool for regional development.

ASEAN – THE IMPORTANCE OF AGRICULTURE

The Association of Southeast Asian Nations or ASEAN was established on August 8, 1967 in Bangkok by the five original Member Countries, namely, Indonesia, Malaysia, Philippines, Singapore, and Thailand. The group expanded to ten when Brunei Darussalam joined on January 8, 1984, Vietnam on July 28, 1995, Laos and Myanmar on July 21, 1997, and Cambodia on April 30, 1999. The ASEAN region has a population of about 500 million, a total area of 4.5 million square kilometers, a combined gross domestic product of US$ 737 billion, and a total trade of US$ 720 billion. Tables 1 & 2 show the GDP and the GDP growth of the region. The importance of agriculture to the member countries can be clearly seen in the attached Extra-ASEAN, Intra-ASEAN and other tables provided in Appendix 1. With the exception of Singapore and Brunei, ASEAN member countries are primarily agriculture based. All ASEAN member countries were invariably, but to differing degrees, affected when the economic bubble burst in the region in 1997. The event has brought about reassessment of the role of agriculture and, in most parts of the region, agriculture remains on top of the political agenda. Agriculture is seen as a critical factor for the rebuilding of economies and for employment of people from the depressed industrial sector. Thailand, for example, is implementing the “sufficiency” concept where agricultural activity plays a critical role in the process. To maintain a margin of trade balance, governments try to limit imports while improving export volume at this time of decreasing unit cost. Agriculture and agro-industry products, being of high local added value, are being looked upon to revive the economy. Analysis of the causes of the economic meltdown has also generated a much better appreciation of the need to upgrade technology levels in all sectors including the agriculture sector. To avoid returning to the commodity-based agricultural economy and to enhance yields and create value from the commodities, the region is trying to ride the fourth wave of the ‘Genomic Revolution’ in the hope of utilizing biotechnology to add value and create product differentiation, as well as building knowledge-based competitiveness. In other words, biotechnology has been identified as a critical key to accelerate agricultural development.

AGRICULTURAL BIOTECHNOLOGY – CONTRIBUTIONS AND CHALLENGES

Modern biotechnology is already making important contributions and poses significant challenges to agriculture, health and environment. Biotechnology is a new group of powerful tools for research and ultimately for accelerating development, and not an end in itself. Being research-based and multidisciplinary, successful development and application of biotechnology are possible only when a broad research and knowledge base in several subjects such as, microbiology, biochemistry, molecular biology and plant breeding exist. Biotechnological programmes
Table 1: GDP in Market Prices in US Dollar, 1996-2000 (in million US$)

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Sources: ASEAN Secretariat, ASCU Database; Updated: 17 May 2001

Table 2: Rates of Growth of Real GDP, 1996-2000 (in per cent)

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<td>5.86</td>
<td>9.88</td>
</tr>
<tr>
<td>Thailand</td>
<td>5.88</td>
<td>-1.45</td>
<td>-10.77</td>
<td>4.22</td>
<td>4.31</td>
</tr>
<tr>
<td>Vietnam</td>
<td>9.34</td>
<td>8.15</td>
<td>5.83</td>
<td>4.71</td>
<td>6.75</td>
</tr>
<tr>
<td>ASEAN°</td>
<td>7.29</td>
<td>4.12</td>
<td>-7.16</td>
<td>3.42</td>
<td>5.41</td>
</tr>
</tbody>
</table>

Sources: ASEAN Secretariat, ASCU Database

Note: ° As a proxy, the ASEAN GDP growth rate is computed as a weighted average of 10 ASEAN member countries’ figures, using PPP-GDP of the IMF-WEO of May 2001 as the weight

Updated: 17 May 2001

must be fully integrated into a research background and a continued commitment to basic research is a must to fulfill benefits offered by the emerging technologies.

Biotechnology has two principal applications in agriculture, namely increases in breeding efficiency (which includes quality traits) and in crop/farm productivity. Biotechnology itself is knowledge-based; it is inherently cultural because biotech essentially is “ideas” which both shapes the technology and is shaped by technology. The introduction of biotechnology, therefore, requires communication relating the technology to local cultural and societal values; much can be learnt from the recent experience in Europe.

Biotechnology has the capability to create modified plant forms tailored to meet specific agricultural needs and problems including high crop productivity, resistance to pests and diseases, tolerance to drought, heavy metals, and salinity, diagnostics of plant and animal diseases, effective vaccines and antibiotics, and more nutritious food and nutraceuticals. Thus many countries in the ASEAN have invested much in the development of R&D, human resources, and infrastructure support for biotechnology. There are many challenges, issues and concerns accompanying this knowledge-base and so close to the core of life itself, some of these will be explored later in this paper. ASEAN members' strategies are to keep biotechnology in a balanced perspective by undertaking activities within the framework of existing national research agenda and priorities.
A few specific examples will be given here to highlight the applications of molecular biology and genetic engineering to agricultural development in ASEAN.

**Plant Transformation**

The area of plant transformation leads to the production of transgenic plants with superior properties including improved quality traits, resistance to diseases, insect pests and abiotic stress. ASEAN scientists have developed transgenic tomato plants carrying the coat protein gene of tomato yellow leaf curl virus to control the serious virus disease of tomato. The same approach was taken to develop transgenic papaya and chili-pepper for resistance to papaya ringspot virus and chili vein-banding mottle virus, respectively. Being the most important stable grain, ASEAN nations are developing transgenic rice varieties, an example of which is transformation of an aromatic Thai rice with D1 pyrroline-5-carboxylate synthetase [P5CS] for salt and drought tolerance. Most of these transgenic plants are now being tested under greenhouse conditions in accordance with Biosafety Guidelines.

**Marker Assisted Selection**

Tomato production in the tropics and subtropics is facing serious constraints due to bacterial wilt, a disease caused by the bacterial pathogen recently reclassified as *Ralstonia solanacearum*. In ASEAN, an endemic outbreak of bacterial wilt [BW] in tomato, potato, pepper, ginger, and peanut occurs frequently, causing devastating yield losses. The programme in constructing BW resistant varieties cannot easily be accomplished due to the nature of the quantitatively inherited resistance that has several genes involved. Marker assisted selection (MAS), a breeding method of selecting individuals based on markers linked to target genes in addition to phenotypic measurement only is essential and useful for enhanced resistance to diseases. Tomato germplasm containing resistance genes and the location of the genes in a tomato molecular map allow the use of DNA markers located near the resistance genes as a tool in selection for the resistant traits. Currently, the breeding project for resistant tomato has conducted marker assisted selection not only for wilt disease caused by *Ralstonia solanacearum* but others such as, nematode, tobacco mosaic virus and powdery mildew.

A second example to demonstrate the use of molecular techniques to assist conventional plant breeding is the development of corn variety in Thailand. A long research effort started in the early 1950’s resulted in the first officially approved maize variety, Suwan-1 which was released in Thailand in 1973. The research was initiated to overcome drought stress and other production constraints, most notably, sorghum downy mildew disease. Breeding for downy mildew resistance is based on selection and hybridization of selected plants in a screening nursery. The effectiveness of selection depends highly on environmental conditions of the nursery. The molecular techniques such as Simple Sequence Repeat (SSR) are being used to define marker positions which link to QTLs of sorghum downy mildew for the application of breeding programs through marker assisted selection.

Molecular genetic markers can now find direct application and should greatly assist selective breeding programmes of commercially important marine species in Thailand. Species-specific markers found in several marine species are used for identification of correct broodstock and seed species and for quality control of commercial trading of oyster, mud crab and abalone seed. A population-specific RAPD marker found in the black tiger shrimp, *P. monodon*, from the Andaman Sea can be used to verify growth and survival performance among different *P. monodon* stocks in commercial culture settings. Due to powerful application of DNA-based technologies to identify DNA markers which are associated with nuclear loci that control economically important traits (quantitative trait loci, QTLS), marker assisted selection has great potential and gains more attention in breeding programmes for plants and animals, for example, rice resistance to bacterial leaf blight and leaf/neck blast.

**Status of Agricultural Biotechnology Applications in the ASEAN**

In terms of trade, ASEAN is in the process of setting up necessary infrastructure to regulate and control the research, commercialization and trade of GMO products. Although only a few ASEAN countries have clearly
approved the use of GM food crops as human and animal feed. ASEAN as a whole has imported products such as GM-soy, GM-maize and processed food-products. It is clear that both soybeans and corn are imported from countries which allow the commercial production of GM crops and are widely used either as food or feed ingredients in the food processing industry. Thailand has approved the use of GM soybean and corn for human consumption and animal feed. Malaysia has also approved GM soybean. Indonesia imports nearly 900,000 tonnes of soybean and about 1.2 million tonnes of corn each year. Most come from the USA, Argentina and Brazil, where a high proportion of transgenic crops are grown. Most of the soybean destined for human consumption would go through such soy-based products as sauces, beverages, tempah, tofu and soy-bean oil (Tables 3 & 4). The imported corn goes into, or is in the form of, flour, starch and oil. Maize and soy meal also would be used as animal feed.

Table 3: Import by Commodity in 2001 (in Thousands of US $)

<table>
<thead>
<tr>
<th>Items</th>
<th>Indonesia</th>
<th>Malaysia</th>
<th>Singapore</th>
<th>Thailand</th>
<th>Vietnam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soya sauce</td>
<td>16,404</td>
<td>36,870</td>
<td>556,005</td>
<td>1,179</td>
<td>-</td>
</tr>
<tr>
<td>Corn (grain)</td>
<td>2,567</td>
<td>50,890</td>
<td>-</td>
<td>106,096</td>
<td>3,423</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>-</td>
<td>5,483</td>
<td>53,247</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pop Corn</td>
<td>-</td>
<td>-</td>
<td>6,732</td>
<td>17,021</td>
<td>-</td>
</tr>
<tr>
<td>Corn Oil</td>
<td>28,634</td>
<td>236,137</td>
<td>571,500</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Corn Flake and prepared food</td>
<td>287</td>
<td>134,464</td>
<td>8,478</td>
<td>220,537</td>
<td>-</td>
</tr>
<tr>
<td>Corn prepared or preserved by vinegar</td>
<td>-</td>
<td>3,875</td>
<td>87,080</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: Bureau of Export Trade Promotion

Table 4: Countries of import by Commodities in 2001

<table>
<thead>
<tr>
<th>Items</th>
<th>USA</th>
<th>South Africa</th>
<th>Argentina</th>
<th>Brazil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn</td>
<td>1,113,733</td>
<td>426,876</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Corn Flour</td>
<td>1,315,946</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Soy bean</td>
<td>95,267,701</td>
<td>-</td>
<td>110,012,000</td>
<td>11,002,286</td>
</tr>
<tr>
<td>Soya oil cake</td>
<td>30,469,980</td>
<td>-</td>
<td>168,867,990</td>
<td>60,085,286</td>
</tr>
</tbody>
</table>

Source: Bureau of Export Trade Promotion

For production, Indonesia is the only country that has allowed limited (spatial and time) production of Bt-Cotton. Most field trials are of technologies developed by multinationals such as Monsanto, AgroEvo, Pioneer Seeds, Cargill Seeds, and Novartis. Some locally developed GMP has also been tested in contained field trials. Crops that had been introduced for testing are Bt corn, Bt soybean, Roundup Ready Soj, Bt Cotton, Flavor Saver Tomato, Viral resistant papaya and tomato. There are cases where requests for field trials were turned down, this exemplified the working mechanism of guidelines and voluntary measures, but at the same time there have been reported cases of Bt-cotton grown without proper authorization and clearance. Besides limited commercial production in Indonesia; Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam have conducted limited GMO field trials. There has been no report of field trials in Brunei Darussalam, Cambodia, Laos or Myanmar.

In support of capacity building, Singapore has announced her intention to be the Asian Centre on Health related Bio-industry. Singapore plans to build up an additional 7,000 biotechnology researchers and to invest another 2.5 billion dollars by the year 2005. This is along the line of other Asian nations demonstrated by the announcement by Japan to have 1,000 new biotechnology companies with 217 billion investment by 2010 and China's plans to double its 3,000 biotechnology research centres in 10-15 years. Malaysia has announced its "Bio-valley" plan with 12 billion dollars investment in 10 years. BIOTEK, the National Biotechnology Directorate, under the Ministry of Science, Technology and Environment was established with the mission to
spearhead the development of biotechnology in Malaysia. The Philippines started its biotechnology programmes in 1979 with formal creation of the National Institutes of Molecular Biology and Biotechnology (BIOTECH) at the University of Philippines at Los Baños (UPLB). In 1995, three other biotechnology institutes were established within the UP system. There are also organizations active in biotechnology-related research such as the Philippine Rice Research Institute (PhilRice). Thailand’s capacity building in biotechnology is coordinated through the National Centre for Biotechnology and Genetic Engineering (BIOTEC) of NSTDA which is launching a new Science Park this year with state-of-the-art research facilities.

Except for Singapore, where salary and conditions are conducive to draw foreign scientists, mostly from China, India and Europe, the number of scientists and laboratories in the region are still very low, relatively. Nevertheless, the following crops/plants have been the focus of research in the region:

<table>
<thead>
<tr>
<th>Crop</th>
<th>Research Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthurium</td>
<td>Disease resistance</td>
</tr>
<tr>
<td>Banana</td>
<td>Resistance to BBTV, Regulation of ethylene production</td>
</tr>
<tr>
<td>Bell pepper</td>
<td>Virus resistance</td>
</tr>
<tr>
<td>Cacao</td>
<td>Stem borer</td>
</tr>
<tr>
<td>Caladium</td>
<td>Foliage color</td>
</tr>
<tr>
<td>Cauliflower</td>
<td>Resistance to insects</td>
</tr>
<tr>
<td>Chili pepper</td>
<td>Resistance to potato virus Y, Cucumber mosaic virus</td>
</tr>
<tr>
<td>Chinese cabbage</td>
<td>Insect and disease resistance</td>
</tr>
<tr>
<td>Coffee (arabica)</td>
<td>Tolerance to rust</td>
</tr>
<tr>
<td>Coconut</td>
<td>Modification of fatty acid composition</td>
</tr>
<tr>
<td>Corn</td>
<td>Resistance to Asian corn borer</td>
</tr>
<tr>
<td>Cotton</td>
<td>Fibre/flower promoter isolation</td>
</tr>
<tr>
<td>Cucumber</td>
<td>Virus resistance</td>
</tr>
<tr>
<td>Mango</td>
<td>Delayed ripening</td>
</tr>
<tr>
<td>Mungbean</td>
<td>Improvement of nutrition</td>
</tr>
<tr>
<td>Oil Palm</td>
<td>Oil quality improvement, Insect resistance, Fungal resistance</td>
</tr>
<tr>
<td>Oilseed rape</td>
<td>Disease and herbicide resistance</td>
</tr>
<tr>
<td>Orchid</td>
<td>Regulation of flower development, Improved flower color, Improved shelf life, Disease resistance</td>
</tr>
<tr>
<td>Papaya</td>
<td>Resistance to PRSV, Improved shelf life, Delayed ripening, Resistance to PRSV</td>
</tr>
<tr>
<td>Peanut</td>
<td>Resistance to peanut stripe virus</td>
</tr>
<tr>
<td>Potato</td>
<td>Resistance to potato virus Y, Protein production, Fluorescence, Bacterial resistance</td>
</tr>
<tr>
<td>Rice</td>
<td>Resistance to rice stem borer and blown hopper, blast, tungro, sheath and blight; Herbicide, Drought &amp; Salt tolerance; and Gene sequencing &amp; discoveries activities</td>
</tr>
<tr>
<td>Rubber</td>
<td>Specific proteins, Resistance traits</td>
</tr>
<tr>
<td>Soybean</td>
<td>Resistance to peanut stripe virus; Resistance to pod borer</td>
</tr>
<tr>
<td>Sugarcane</td>
<td>Drought tolerance, Resistance to stem borer, Control of ripening/maturation</td>
</tr>
<tr>
<td>Sweet potato</td>
<td>Sweet potato feather mottle virus</td>
</tr>
<tr>
<td>Watermelon</td>
<td>Virus resistance</td>
</tr>
<tr>
<td>Tobacco</td>
<td>Herbicide tolerance</td>
</tr>
</tbody>
</table>

Other agricultural biotechnology areas include bio-control, bio-fertilizers, tissue culture, inoculants, plant-microbe interactions, and animal production (vaccines, diagnostics, pro-biotics and feed additives). In February 2002, an embryo technology service company was set up in Thailand, the first in ASEAN.
Issues and Concerns about Biotechnology – Regional Status

Biotechnology, the forerunner of the genomic revolution, arrives on the scene at the time when society has had opportunities to experience both the good and the bad effects of the previous three technological revolutions — from the green revolution, industrial revolution, to computer (or IT) revolution. Moreover, the technology, arising from our understanding of biology, touches the core of our own self-definition.

For these and several other reasons, the technology raises more troubling issues than any other technology revolution in our history. Bio-ethical issues will be debated on for many more years to come, not only from the concern of “playing God” but also the concern of the possible effect on the biosphere and the consequences of reducing the world’s gene pool to patented intellectual property. Disturbing trends emerge from the development and commercialization of biotechnologies in the industrialized countries where most of the biotechnology R&D presently takes place. The high cost of research invested by the private sector, coupled with domination of TNCs through university-industry complexes and acquisition and increasing proprietary hold, suggest that commercial prospects rather than the urgency of needs of the have-nots or have-less will determine the priorities. The biotechnology gap will further diminish the position of the developing countries, increasing vulnerability and dependence.

For our interest here we will explore only some of these issues and concerns which are being considered at the ASEAN regional level. These are the biosafety, public awareness, access for small farmers and IPR.

Biosafety

Many countries in ASEAN are actively involved in biotechnology research and have made substantial investments in agricultural biotechnology. Biotechnology is recognized as one of the tools to improve crop productivity and product quality, and better manage environmental resources. In order to harness this technology and benefit from it, it is important that regulations are in place to address those concerns such as the potential effect of GMOs on health and the environment. The objective is to maximize the benefits and minimize the risks when harnessing the technology. It is expected that more genetically engineered crops and other food products will come into the market over the next few years. Some of these products would come from developed countries while others are developed by researchers within ASEAN. Movement of GMOs for research and trade between countries would be a matter of concern for ASEAN. There is therefore an urgent need for ASEAN to take a regional approach to develop standard procedures for regulating these products.

The two biosafety issues are environmental safety and human health. Because of the potential risks of GMOs, there is a need for the creation of an efficient regulatory body in each country. This is particularly so because GM food such as soybean is important as a whole food or food component of the ASEAN food processing industry. The ASEAN member countries rely almost totally on imported soybean and if the producer does not distinguish the source of the product, it becomes almost inevitable not to accept GM soybean.

ASEAN member countries are at various stages of developing their regulatory mechanisms. Table 5 shows clearly that ASEAN members are at different stages of development in biosafety. Indonesia has clearly stated regulations, but has not yet been able to implement them. Malaysia has drafted a biosafety bill and is in the process of having it legislated into law. Only Indonesia and Singapore had developed guidelines for labeling of GMO products. Most other countries in ASEAN have developed guidelines; except for Brunei, Laos, Myanmar and Vietnam. The scope covered is from laboratory work to commercial release. Those with guidelines, namely, Indonesia, Malaysia, Philippines, Singapore and Thailand have developed them largely using UNEP, UNIDO, CBD, MAFF, UK, GMAC and FAO guidelines as the basis. The most popular one being the Australian GMAC’s Guidelines for the Planned Release of GMOs. Invariably the member countries plan to adopt the product-based rather than process-based approach for the evaluation of GMOs. The focus would be on the properties of the GMOs rather than the molecular techniques by which they are made. One of the recommendations from the several regional task force, is to look at the possibility of applying the concept of substantial equivalence in
the safety assessment of the GMO. Evaluations of GMOs in these member countries are on a case-by-case basis. It is recognized that different organisms would behave in different ways and pose different problems when released.

Table 5: Status of GMO in ASEAN

<table>
<thead>
<tr>
<th>Country</th>
<th>GMO Planting</th>
<th>Food</th>
<th>Biosafety Legislation/ Status</th>
<th>Food</th>
<th>Guidelines Environ</th>
<th>Lab</th>
<th>Field Trials</th>
<th>GMF Approved</th>
<th>Public Education</th>
<th>Labeling (threshold)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei</td>
<td>N</td>
<td>L</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N (not decided)</td>
</tr>
<tr>
<td>Cambodia</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Laos</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Y with restriction</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y (5%)</td>
</tr>
<tr>
<td>Malaysia</td>
<td>N</td>
<td>Y</td>
<td>Expected June 2002</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y (3%)</td>
</tr>
<tr>
<td>Myanmar</td>
<td>N</td>
<td>L</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Philippines</td>
<td>N</td>
<td>L</td>
<td>Expected 2002</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Singapore</td>
<td>N</td>
<td>Y</td>
<td>???</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Thailand</td>
<td>Y</td>
<td>Y</td>
<td>Expected 2003</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y (5%)</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Y/N</td>
<td>Y</td>
<td>Expected 2002</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N (not decided)</td>
</tr>
</tbody>
</table>

Note: N = no; L = likely and Y = yes

Regulatory Policy and Institutional Framework of ASEAN Member Countries

Of the 10 members in ASEAN, at least 4 countries, Indonesia, Malaysia, Philippines and Thailand, have successfully conducted field trials of GMOs. Indonesia is the only country which has approved the environmental release of Bt cotton. However, the release comes with restrictions. First, the farming area is restricted to 7 districts in South Sulawesi province, the cotton seeds are to be exported only and the remaining plant parts must be destroyed. Moreover, the approval came with a time restriction of 1 year, subject to review for annual renewal. The Indonesian authorities also have completed field trials for soybean and corn which would be the next likely candidates for commercial release. Thailand has concluded three years of environmental studies on Bt cotton and the genetically modified viral resistance papaya is currently being field studied. In the past, Thailand has also conducted environmental impact studies on several lines of GM food crops such as tomato, rice, corn, cotton and papaya. Malaysia has also concluded the environmental assessment of GM soybean. Soybean is the only GM commodity approved for food and animal feed in Malaysia. The Philippines also have completed the field trial studies of Bt corn but have not approved it for commercial release yet. Singapore has approved commercial sale of GM blue cut carnation but not for growing. There have been reports of illegal planting of GM crops, particularly Bt cotton by farmers in Thailand, Vietnam and Indonesia.

ASEAN can be classified into two groups based on their GMO policy. The first group has not yet developed a policy on GMOs yet. These include Cambodia, Laos, Myanmar, Brunei and Vietnam. Among these countries, Laos is setting up the National Biosafety Framework and the government has designated the Science, Technology and Environment Agency as the national focal point. Brunei is establishing a National Authority on Genetic Modification (NAGM) to oversee the regulatory control of GMOs. Vietnam has formed a working group (see country report) and drafted the Biosafety Bill which is being approved by the Ministry of Science, Technology and Environment. As for Cambodia, an interview with an official at the Cambodian Import and Export Inspection and Fraud Repression Department of the Ministry of Commerce stated that as long as the safety of GM food has been substantiated by scientific evidence, Cambodia will not change its policy on GMOs. In Myanmar, due to poor infrastructure and communication, the government appears not to have taken up the issue yet.

The second group is countries which exercise regulation over GMOs either through their existing systems or new regulations. Of these countries, Malaysia and Thailand are expected to have biosafety legislation in force by 2002. The Philippines has the Biosafety Guidelines published in 1991. The two guidelines cover laboratory
approval and environmental release. Indonesia is the only country to have the provisions on biosafety of genetically engineered agricultural biotechnology products released under the Ministerial Decree No. 85/kpts/HK 330/9/1997. The Decree of the Minister of Agriculture does not have law enforcement power. Furthermore, there is Law No. 5/1994 for the Ratification of the UN Convention on Biological Diversity and Law No. 7/1996 on food.

Singapore also enforces biosafety using the guidelines for “Release of GMOs Used in Agriculture”. The control of GMO imports into the country and the commercial release of GMOs for culture and cultivation or for agricultural production are through the existing Acts administered by the Agri-Food and Veterinary Authority of Singapore (AVA), formerly the Primary Production Department. Once approval is granted, the product (GMO) will be registered with GMAC. As for commercial and academic research, NSTB would advise the project managers to seek clearance from GMAC before any GMO is released and field-tested.

The Philippines have established and implemented guidelines for laboratory and environmental release. Malaysia and Indonesia have national guidelines for the release of genetically modified organisms into the environment. Both are expected to release the guidelines for safety assessment of GM food in 2002. Thailand has released guidelines for laboratory, field trial and safety assessment of GM food. This year, it is expected to revise all three guidelines and release a new guideline for industrial production of chemicals or biological materials using GMO.

The lead agencies in most member countries for the approval of agricultural products derived from biotechnology would be the Ministry of Science and Technology and/or the Department of Agriculture. Approval for importation of GMOs for agriculture would most likely go to the Genetic Manipulation Committees or National Committee for Biosafety, through the Ministry or Department of Agriculture, in ASEAN.

The existing legislation in ASEAN generally uses the sanitary and phytosanitary requirements, and Acts enacted in these areas, to regulate importation of GMOs. Examples of these are the Plant Quarantine Act, Animal Control Act and Fisheries Act. Other legislation includes the Food Act and Hazardous Substance Act.

Stakeholders/Key Players
The key players for biosafety regulations in ASEAN are relevant government departments. Brunei plans to establish NAGM under the Ministry of Industry and Primary Resources. Most other countries, Indonesia, Laos, Malaysia, Thailand and Vietnam, have their biosafety central bodies in the Ministry of Science, Technology and Environment. The Philippines has appointed the National Biosafety Committee of the Philippines (NBCP) as an independent body. Singapore and Malaysia also have GMAC, which operates under a governmental office. The Philippines system seems to have greater community involvement for most of the laboratory work and field trials. Singapore also has some industrial representative in their GMAC while Thailand’s NBC and associated subcommittees have some members from the general public or NGO representatives.

Public Awareness and Information
The recent studies by AFIC Market Research between 1998-1999 in ASEAN (Thailand, Philippines, Malaysia and Indonesia) showed that the public in general, was not very aware of food biotechnology. In Thailand, 12% of the respondents were “very to quite” aware, 38% in Philippines and 8% in Malaysia and Indonesia. The response to the question of “ordinary soybeans don’t contain genes but GM soybeans do” also indicated the limited knowledge of biotechnology in all five countries where more than 50% answered either “yes” or “don’t know”. From the survey, most countries do not have structured nor organized public education programs on GMOs. The Thailand Biodiversity Centre and the National Centre for Genetic Engineering and Biotechnology have conducted several public forums, seminars and have several publications available such as cartoons on GMOs and GM food. Thailand’s Food and Drug Administration also runs an educational programme using mass media. The Malaysian National Biotechnology Directorate is stepping up efforts to implement their public awareness
programme. The programmes include school and public forum lectures, preparation and distribution of pamphlets and promotion of understanding through mass media. Most countries have information such as frequently asked questions on their websites.

Many countries have a built-in system of public awareness for field trials or commercial release. Some have public participation in the decision making level. Indonesia requires the proponents to announce plans for use/release of GMOs in newspapers circulating in the vicinity of the utilization areas upon submission of application or upon receiving directives from the Ministry of Agriculture. Malaysia requires national authorities, industry and researchers to disclose or make available safety information to the public, particularly to the communities where field trials or planting is to take place. In Malaysia, GMAC must inform the local community of planned release and national authorities should provide appropriate information to the public. The Philippines has a similar approach, but more public involvement than Malaysia in that, there must be two community representatives in NCBP and in IBCs and a public information sheet (PIS) must be posted in target field test sites, allowing 60 days for public comment. Thailand has a member of the general public in the policy making body of NBC. Singapore also has an industrial representative in GMAC and the decision to inform the public of planned release of GMOs is vested in GMAC.

Directly related to information issue is that of labeling of GM products which was “demanded” on the basis of the public’s “right to be informed”. It appears that countries have three choices in terms of labeling: mandatory, voluntary or no labeling (status quo). In the US where opposition to any form of labeling had been the norm, some form of voluntary labeling may be required in the future by the Food and Drug Administration (FDA). Japan, Canada, Australia, and New Zealand have already adopted mandatory labeling. In the European Union, most countries adopted mandatory labeling if the content of GMO had reached a threshold level. Food products containing more than 1% GMO should be labeled.

Many concerns are inherent in labeling. For example, labeling involves additional cost to producers. The same cost will be incurred even if products will be labeled "Non-GMO" or "GMO free". A study done in Canada on the cost of labeling showed a cost equivalent to at least 9-10% of the retail price of processed food products, and 35-41% of the producer prices. The study also concludes that biotechnology and non-biotechnology food (labeled biotechnology free) would be equally affected by this price increase, which amounts to $700-950 million per year in Canada alone. Another study jointly done in Australia and New Zealand came out with an additional cost to industry estimated at 6% of turnover sales in the first year of implementation and 3% in subsequent years. The producers however will have no choice but to pass this cost on to the consumer, thus prices of GM plants and food will increase.

Access to GMOs by Small Farmers

Agriculture in ASEAN is mostly done by small farmers who cultivate areas of less than 1 hectare. Many of them are resource poor, and may not be able to afford the new GM plants. Almost all farmers save seeds from present harvest to be planted during the succeeding crops. In the future, IPR may not allow farmers to save their seeds. More troublesome, however, is the fact that there are no products developed to suit their particular needs. In addition, the high cost of GM seeds may discourage farmers from the use of these products.

Related to this issue and concern is also the use of traditional knowledge and biodiversity. The ASEAN region is rich in biodiversity and traditional uses thereof; however, since the WTO’s Agreement on Trade-Related Intellectual Property (TRIPS) does not include specific provisions related to the protection of traditional/indigenous knowledge (systems, practices, naturally-occurring plants, products), new methodologies/instruments need to be developed. This was one of the recommendations on ‘Biodiversity, Biotechnology, Traditional/Indigenous Knowledge, and Traditional Medicine,’ coming out of an ASEAN regional working group meeting in Jakarta, Indonesia (May 2-4, 2000) on the TRIPS Agreement and its Impact on Pharmaceuticals.
Intellectual Property Rights (IPR)

Since most biotechnology R&D work is conducted by developed countries, often by private companies, developing countries including ASEAN countries may have to pay for the use of new procedures, genes, promoters and terminators. IPR protection is crucial for the growth of the biotechnology industry, since huge investment is usually made in developing a product to the commercial stage. The World Trade Organization (WTO) requires IPR protection. The implication of this to trade, technical investment and access to products may put a lot of pressure on developing countries. Unfortunately, many developing countries are not yet ready to adopt IPR systems proposed mostly by developed countries. Although technology transfer processes have been taking place for centuries, biotechnology has brought in a different perspective. What is new with biotechnology is the extent to which the transferring parties are claiming rights in what is being transferred. The cultural factors are very important and patentability is at the heart of the issue. Aside from the cultural issue, institutional IP management strategies of public and private entities vary significantly for reasons related to R&D capacity, critical mass, cost, legal aspects, strategic objectives, and public opinion. With respect to patent protection, developed countries, especially the US tried to include protection for every kind of living thing, beginning with microorganisms, in the framework of the WTO, specifically in TRIPS. Developed countries went further, asserting that the existing intellectual property regimes in most countries should be reformed to include the protection of biotechnology, and that the new intellectual property rights should be extended to developing countries like Thailand as well in order that the rights granted will be recognized worldwide. The law of trade secrets may also be a practicable form of protection for particular forms of biotechnology. When the biotechnology invention cannot be effortlessly reverse engineered the law of trade secrets may be preferable to a patent. Trade secrets may also be an alternative, if patent protection is not available for an invention. Also, the limited ability for legal mechanisms and the law itself to keep up with technology development has been well recognized.

An Overview of Intellectual Property Protection for Biotechnology in ASEAN: (Contribution of Dr Tinit Changthavorn, Department of Business Development and BioLaw-BIOTEC)

The current status of IP protection for biotechnology can be seen as follows:

International level: There are a number of international legal frameworks involving IP and biotechnology. Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), an agreement under the umbrella of the World Trade Organization (WTO) agreement, is the most important international regime for intellectual property protection. In general, the agreement imposes all member countries to introduce or improve their intellectual property protection to comply with agreed standards. WTO/TRIPS plays a major role in the development of IP in ASEAN since most countries including Thailand, Indonesia, the Philippines, Malaysia and Vietnam, are WTO member states. The most crucial provision of TRIPS for biotechnology is Article 27(3)(b) where legal protection for plant varieties, either by patents or effective sui generis system or by any combination thereof, shall be introduced. The Convention on Biological Diversity and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture have significantly influenced perspectives in intellectual property management for biotechnology.

National level: Obliged by WTO/TRIPS, most countries in this region are in the midst of drastic legal development. New intellectual property laws have been prepared and enacted. Most patent laws in ASEAN do not protect plant and animal varieties. Plant Variety Protection Law (PVP) marks the highest point in intellectual property protection for agricultural biotechnology. The protection has been introduced in Thailand and Indonesia while the Philippines and Malaysia are working on PVP drafts. Gene patent has also been an issue of discussion and whether genes should be patented remains unanswered.

Institutional level: Few research institutes in this region are well equipped with skills and knowledge concerning intellectual property management. During the past decade, developing countries have witnessed increasing disputes and cases resulting from the lack of effective intellectual property management. Therefore, additional legal measures
need to be developed to address this need for IP management. Amongst these are material transfer agreement, confidentiality agreement and IP audit. With assistance from international organizations, a number of intellectual property activities have been introduced in ASEAN. Capacity building is the most urgent and vital activity. Launched in October 2001, Southeast Asia Network on IP/TT Management is a joint effort amongst biotechnology research organizations in five countries and the International Service for the Acquisition for Agri-Biotech Applications. The network aims to establish cooperation amongst network organizations and other organizations in the area of management of intellectual property and technology transfer.

ASEAN COLLABORATION IN AGRICULTURE AND BIOTECHNOLOGY

ASEAN Vision 2020 indicates "... a concert of Southeast Asian nations, outward looking, living in peace, stability and prosperity, bonded together in partnership in dynamic development and in a community of caring societies". To achieve this vision ASEAN has adopted the Hanoi Plan of Action, with a six-year time frame (1999-2004), and ten major programme areas. The 10 priority programme areas are in food, agriculture and forestry, in environment and in science and technology. Under these there are a number of cooperation programmes/projects pursued amongst ASEAN members in biotechnology, especially in agriculture, environment and biosafety. There are three ASEAN sectoral bodies that deal with biotechnology and biosafety issues.

1. ASEAN Ministers for Agriculture and Forestry (AMAF).
2. ASEAN Committee on Science and Technology (COST).
3. ASEAN Senior Officials on Environment (ASOEN).

AMAF has dealt with the issues from the perspective of ASEAN trade promotion of food products and food safety. The implementation body for the cooperative programmes in food, agriculture and forestry is handled by a Senior Officials Meeting on Food, Agriculture and Forestry (SOM-AMAF), which has been active in trade issues concerning crops. Their recent activities included the harmonization of phytosanitary measures and harmonization of minimum residue limits of pesticides for vegetables, and the development of ASEAN standards for animal vaccines. SOM-AMAF has organized a Task Force on the Harmonization of Regulations for Agricultural Products Derived from Biotechnology. There are also some R&D and technology transfer programmes to improve agricultural productivity. COST is involved with the overall development of science and technology capability within the region through joint research and development, human resource development, regional networking of science and technology infrastructure and programmes, and promotion of technology transfer. These activities are implemented in economically significant sectors and disciplines such as food science and technology, marine science, non-conventional energy and biotechnology. The priority areas for the Sub-Committee on Biotechnology for 2001-2004 are in food and horticultural crops, improvement of livestock production, value-addition to natural products and bioinformatics. ASOEN is concerned with policy measures and institutional development. These promote the integration of environmental factors into national and regional development planning, establishment of long-term goals on environmental quality and work towards harmonization of environmental quality standards, and joint actions to address common environmental problems in the region. ASOEN deals with biotechnology from the environmental protection perspective. The Working Group on Nature Conservation and Biodiversity has taken interest in the issues in the context of international conventions and protocols. SOM-AMAF, COST and ASOEN have organized a series of workshops on capacity building and regulations for agricultural products derived from biotechnology starting in 1997. In the same year, ASOEN has agreed to develop a common protocol on access to genetic resources and related intellectual property rights.

The current status of biosafety regulation in ASEAN reveals that few member countries (Indonesia, Malaysia, Philippines, Singapore and Thailand) have developed some guidelines for R&D and field releases of genetically modified organisms, and none has a comprehensive legal framework to address commercial and consumers' concerns. The key weaknesses were the lack of the force of law, and the standard S&T infrastructure for most
operational procedures in risk assessment and risk management is weak. ASEAN still needs to build up the institutional and legal framework, as well as developing the scientific and technical capacity to implement the framework. In September 1997, the ASEAN Ministers of Agriculture and Forestry (AMAF) endorsed Singapore’s initiative on a regional programme to harmonize regulations for agricultural biotechnology products. An “ASEAN Workshop on Regulations for Agricultural Products Derived from Biotechnology” was organized in April 1998 so that ASEAN member countries could learn from the experience of countries in the Asia-Pacific region. The private sector was also invited to give their perspectives to the government regulatory agencies during the workshop. In October 1999, the task force was completed and AMAF adopted the ASEAN Guidelines on Risk Assessment of Agriculture-Related GMOs. The guidelines call for the establishment of a National Authority on Genetic Modification in each member country, to oversee the implementation of the guidelines. The task has not been accomplished in many ASEAN countries, particularly the less developed economies. After the adoption of the harmonized guidelines, SOM-AMAF will proceed with a public awareness programme on GMOs. Currently, the national bodies have publications or brochures in the format of FAQs on GMOs, which are readily accessible by Internet.

There are other issues, which were not taken up by the harmonized Guidelines such as labeling of GM food. Since the issue has not yet been resolved at the Cartagena Protocol and many if not most ASEAN members are not ready technologically and do not have the infrastructure to monitor and control, the issue was left to individual countries for further consideration.

A workshop on “Capacity Development for the Integrated Approaches to Biosafety of Genetically Modified Organisms (GMOs): Southeast Asia Workshop” was organized by the Institute of Advanced Studies, United Nations University from 6-8 November 2001 in Jakarta, Indonesia. The focus was to increase understanding in relation to field trials for transgenic crops, build up clearing house mechanisms for information nationally and regionally and promote regional approaches to biosafety. In the country report of the ten ASEAN members, the need for effective biosafety regimes to protect the richness and diversity of the flora and fauna in the SEA region was called upon. The member countries share common needs due to their geographical vicinity and similar biodiversity, the current level of biosafety development varied considerably as highlighted in the country section of this report. Hence it was proposed in the workshop that the capacity building efforts be targeted at three different levels: the national, sub-regional and regional.

POLICY RECOMMENDATIONS FOR ASEAN

The most urgent need for ASEAN is in building local and regional capacity, and human resource is the key to this development. Transferring of technology and skilled scientists can help speed up the process, but technology imbedded in the products will do little in strengthening the capabilities. In most member countries lack of awareness at the political level, coupled with a weak management infrastructure, is the major hindrance to this development and should clearly be improved. Other infrastructure such as IPR systems and biosafety are also in need of development albeit with less urgency. Following are some policy recommendations for ASEAN collaboration.

Human Resource Development

There is a clear need for ASEAN to take initiatives to build autonomous capability to pursue high priority biotechnology research without any further loss of time. In a highly skill-intensive area like biotechnology, training of scientific and technical manpower is a crucial element of any strategy to build local capability. Building local capability in biotechnology is essentially a national effort with strong supportive input provided by mutual co-operation within the region and international agencies. The key to building local capacity is human resource development. The number of scientists doing biotechnology R&D in the region is still very low, particularly when compared with other regions. Thus, there is a need to increase the number of scientists in the region,
particularly in countries such as Brunei Darussalam, Cambodia, Myanmar, and Laos. Regional collaboration on ASEAN-help-ASEAN can be coordinated through the functional committees and other ASEAN mechanisms. Human resource development should also include training of personnel in the regulatory systems to increase their capability in doing risk assessment and evaluation of GMOs. Political awareness and will is needed to make resources available and to facilitate the flow of people across national boundaries for the training and collaborative S&T activities.

S&T Policy, Planning and Organizational Structure

Biotechnology research requires rather relatively sophisticated infrastructure facilities, including identification of appropriate areas, strong management and funding systems, and appropriately equipped research facilities. The weak S&T infrastructure is one of the main hindrances to the building up of S&T capabilities and thus the competitiveness in knowledge-based technology. S&T infrastructure is complex and in most of the region requires a subtle cultural change. Such processes take time and perseverance. Regional collaboration can be an excellent tool to help push members over the hurdle and the resistance to change. High-level Heads of State, Ministerial, and Senior Official Meetings can help to pursue the much needed political support. This would make resources available and create environments necessary to foster infrastructure development. This necessary structure will bring about clear and flexible policy which will help in the identification and implementation of priority areas. Supporting management mechanisms, excellence and competitive research will evolve to generate innovation. Only in this way can we hope to lift the reliance on R&D in TNCs and research results of the developed nations making it possible to attach due importance to the development of low-input sustainable farming systems to benefit marginal and small farmers. ASEAN must work within ASEAN to foster the linking of the excellent/specialized centres, forming networks, combining to build strengths and combining strengths to work on regional issues of importance. The linking of excellent/specialized centres or any other agencies requires commitment in cost sharing and making travel and meeting/workshop costs available. Funding has been difficult, but more difficult has been the priority accorded to regional commitment. ASEAN nations can only hope to compete well in this world of globalization through "real" regional collaboration. Some workshops and meetings have been sponsored or co-sponsored by various International and Regional organizations such as ISAAA, ILSI, and UN organizations (FAO, UNU, UNIDO etc.)

Peripheral infrastructure development is also of importance; for example ASEAN needs to focus on capacity building to fully implement the biosafety policy. The legal expert must be competent enough to translate protocol into laws. As a strategy for consumer protection, it must develop the capacity to conduct risk assessment, risk management and field trials. Many ASEAN countries also do not have the capacity to develop the biosafety clearing house mechanism. ASEAN should quickly develop the coordination amongst governments on biosafety, the capacity for data management and information sharing and strengthen the research network system. ASEAN should work together and bring in expertise from her regions to strengthen capacity in the following areas:

- Policy and decision making process.
- Developing legal framework for biosafety.
- Training in and implementing risk assessment.
- Development on data management and information sharing.
- Upgrade technology and preparedness to implement a biosafety regulatory framework.
- Developing biosafety clearing house mechanism which should facilitate cooperation amongst ASEAN.

Information Exchange, Regulatory and Harmonization

Not only because information exchange creates better understanding, leads to more active interactions, and thus a stronger region, it is also critical to the success of a harmonization process which is required to allow free movement and facilitate trade within ASEAN under the AFTA agreement. Standards and regulations need to
be harmonized to reduce any possible friction and ensure fair practice. This is in line with ASEAN Vision 2020 which aims to harness technology to develop a competitive agriculture sector within the ASEAN Free Trade Area framework. Free intra-ASEAN trade will strengthen the competitiveness of the region’s agricultural products while addressing concerns of these products on health and the environment. In order to harmonize regulations, there is a need for open communication between the various regulating agencies to ensure that the task can be completed expeditiously. Moreover, as experience and knowledge on the introduction of GMOs to the environment are limited in this region, together with the fact that technology is changing dynamically, there is a need for exchange of information to understand the requirements of each country and to keep pace with new knowledge and experiences gained. There is a need to speed up the implementation of ASEAN Guidelines on Risk Assessment of Agriculture-related Genetically Modified Organisms (GMOs). The guidelines in their present form may not be perfect, but improvements can be introduced later as more scientific data becomes available. SOM-AMAF, ASOEN and COST have to innovate meaningful ways to work together in this and many other areas.

Misinformation and the lack of scientific understanding can lead to poor judgment, mismanagement and missed opportunities. ASEAN must work together to increase public awareness and understanding of S&T, and particularly, biotechnology.

**Intellectual Property Rights**

Most ASEAN countries recognized that IPR protection is crucial for the growth of the biotechnology industry, since huge investment had been made in developing a product. World Trade Organization (WTO) requires IPR protection. The implication of this to trade, technical investment and access to products put a lot of pressure on developing countries. ASEAN should think through carefully, especially in the post-genomic era, as to what role would intellectual property rights be playing in order to enhance the progression of the region’s biotechnology industry so as to scale up the overall economic development and the betterment of science and technology sector. Cultural and traditional practices are being tested and put under various constraints due to globalization forces. ASEAN needs to work together to make the requisite change as painlessly as possible. Moreover, being the region well endowed with rich biodiversity, ASEAN countries should come together to develop national legislation on protection of indigenous and/or traditional knowledge and on that basis formulate an ASEAN collective position to be advocated at international level. Countries should develop an inventory and registry of their biological resources and traditional/indigenous knowledge, taking into account the intellectual property implications of such inventories and registries. There should be a network of information exchange and networking among the ASEAN member countries for this purpose. The workshop also recommended collaboration on the various aspects on intellectual property rights through the approach of R&D. The issue of patentable subject matters is indeed not only the question of law but also the consideration of policy.
Agricultural Biotechnology Development, Policy and Impacts in China

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INTRODUCTION

Biotechnology has the potential to address problems not solved by conventional research. At the same time, biotechnology may speed up research processes and increase research precision (Conway, 2000). Proponents of biotechnology consider that GMOs (genetically modified organisms) have the potential to be healthier, and more nutritious and productive than organisms derived through conventional means. Biotechnology proponents indicate that the technology has the potential to revolutionize medicine and agriculture, and that it will help solve poverty and environmental problems. Conversely, critics of biotechnology claim that genetically modified (GM) crops will affect human health and damage the environment (Altieri and Rosset, 2000) and may do very little to alleviate poverty and income insecurity in developing countries.

In spite of the highly conflicting views on biotechnology, GM crops have been developed rapidly since the early 1990s. The global area of GM crops increased from 1.7 million hectares in 1996 to 44.2 million hectares in 2000 (James, 2001). An estimated 3.5 million farmers from industrial and developing countries grew and significantly benefited from planting biotech crops in 2000. A recent annual global review of GM crops by James further indicates that the number of farmers planting GM crops in 2001 is expected to grow substantially to 5 million or more, and global area planted to transgenic crops is expected to continue to grow by 10 per cent or more in 2001 over 2000 (James, 2002). Most GM crops are planted in USA, accounting for more than two-thirds of the global total in 2001 (James, 2002). Although only 3 per cent of the global GM crops were planted in China in 2001, the share of the number of farmers planting GM crops in the world is much larger as the average farm size is only about 0.5 hectare. Recently, we estimated that there were at least 3 million farmers who have adopted Bt cotton in 2000 in China and this number might increase to 5 million in 2001.

China was one of the first countries to introduce a GM crop commercially and currently has the fourth largest GM crop area sown, after the USA, Argentina, and Canada. Although commercialization of major food crops has proceeded at a cautious pace in China, the official policy of the Chinese government has been to promote biotechnology as one of the national priorities in technology development since the 1980s (SSTC, 1990; Huang, Rozelle, Pray and Wang, 2002). The Chinese government views agricultural biotechnology as a tool to help China improve the nation’s food security, raise agricultural productivity, increase farmer’s income, foster sustainable development, and improve its competitive position in international agricultural markets (MOA, 1990).

A recent survey of China’s plant biotechnologists by the author and his collaborators confirms this objective (Huang, Rozelle, Pray and Wang, 2002), which shows that China is developing the largest plant biotechnology capacity outside of North America. The list of GM crops in trials is impressive and differs from those being worked on in other countries. The first commercial release of a GM crop in the world occurred in 1992 when transgenic tobacco varieties were first adopted by Chinese farmers.1 GM varieties in four crops have been approved

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* This paper is prepared based on several recent studies conducted by the author and his collaborators, Scott Rozelle, Carl Pray, Qinfang Wang, Ruifa Hu, Fangbin Qiao, José Falck Zepeda, James Keeley and researchers from biotech policy programme at the Centre for Chinese Agricultural Policy (CCAP), Chinese Academy of Sciences.

1 Chinese farmers have not been allowed to grow GM tobacco since 1995. This policy measure is a response to strong opposition from tobacco importers from the USA and other countries.
for commercialization in China since 1997. These include GM varieties in cotton, tomato, sweet pepper, and petunias. Cotton varieties with the **Bacillus thuringiensis** (Bt) gene to control bollworm have spread widely. We estimate that Bt cotton covered an area of 1.48 million hectares in 2001. GM varieties in crops such as rice, maize, wheat, soybean, peanut and others are either in the research pipeline or are ready for commercialization (Chen, 2000; Li, 2000; Huang, Rozelle, Pray and Wang, 2002).

On the other hand, there is a growing concern among policy makers regarding the impacts of the ongoing global debate over biotechnology on China's agricultural trade, biosafety, and the potential opposition derived from consumer concerns on the environmental and food safety of biotechnology products. Under this situation, despite GM crops have continued to be generated in public research institutes and the number of imported GM crop varieties for field trial and environmental releases has been rising, the approval of GM crops, particularly food crops, for commercialization has become more difficult since late 1998. This reflects the influence of the global debate on GM crops, and particularly restrictions on imports to EU countries, on Chinese policymakers.

China, like many other developing countries, now faces a dilemma as to how to proceed on the further commercialization of GM crops. The objectives of this paper are to review the status of biotechnology application in China's agriculture and current findings on the impacts of plant biotechnology, and to identify the area for policy intervention. In order to achieve these objectives, the paper is organized as follows. In the next section, a general review of agricultural biotechnology development programme, research capacity and financing in China is provided. The third section discusses the priority and products of agricultural biotechnology. The fourth section examines biosafety management and regulations in China. The impacts of biotechnology are discussed in the fifth section. The final section provides concluding remarks and areas for policy actions.

Statistics on biotechnology research investment and human capacity presented in this paper are based on our primary survey of 29 leading plant biotechnology research institutes reported in Huang, Wang, Zhang and Zepeda (2001) and Huang, Rozelle, Pray and Wang (2002). The 29 institutes reviewed in the above study together account for more than 80 per cent of plant biotechnology programmes in China. The study concentrates on the development of plant biotechnology though contact information about leading animal biotechnology institutes is also included (Table-A). It is important to note that all the institutes surveyed are mostly publicly funded entities. Investments in biotechnology research by the private sector are very limited in China. The issues related to biotechnology policy process discussed in this paper are reported in details in Huang, Wang, Zhang and Keeley (2001). The discussions on the economic, environment and health impacts of plant biotechnology research are from several recently published and unpublished papers by the authors (Pray et al., 2001; Huang, Hu, Rozelle, Qiao and Pray, 2001; and Huang, Hu, Pray, Qiao and Rozelle, 2001). The impact study is based on a primary survey of 282 Bt cotton farmers in North China in 1999.2

**AGRICULTURAL BIOTECHNOLOGY PROGRAMS IN CHINA**

**An Overview**

Biotechnology in China has had a long history. Yet, systematic scientific research in modern biotechnology has been conducted only recently. Several research institutes within CAAS (the Chinese Academy of Agricultural Sciences) and CAS (the Chinese Academy of Sciences) as well as in public universities, initiated their first agricultural biotechnology research programmes in the early 1970s. The research focus of biotechnology in the 1970s was cell engineering, tissue culture, and cell fusion. Research in cell and tissue culture covered crops including rice, wheat, maize, cotton, vegetable and others (KLCMCB, 1996). Several advanced rice varieties were generated through anther culture in 1970s and 1980s.

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2 This impact study has been continued since 1999. The analyses based on the data collected from 2000 and 2001 surveys that covered more provinces and cotton farmers are under going.
The most significant progress in agricultural biotechnology was made following the development of transgenic techniques after 1983. The pace of biotechnology research increased significantly after China started a bold national policy supporting biotechnology programmes in 1986. Since then, agricultural biotechnology laboratories have been established in almost every agricultural academy and major universities. By the late 1990s, there were over 100 laboratories in China involved in transgenic plants research (Chen, 2000). Chinese research institutes and laboratories have generated advanced biotechnology applications that have been utilized in medicine, chemistry, environment, the food processing industry, and agriculture.

Bt cotton is one of the most often cited examples on the progress of agricultural biotechnology in China. Six transgenic cotton varieties with resistance to bollworms had been produced by Chinese institutions by 2000 and have been approved for commercialization in China since 1997 (BRI, 2000a). Huang, Hu, Pray, Qiao, and Rozelle (2001) estimated that since the first Bt cotton variety was approved for commercialization in 1997, total area under Bt cotton reached 0.7 million hectares in 2000. Our recent survey shows that Bt cotton area reached 1.48 million hectares in 2001, which accounted for 31 per cent of China's cotton area. In addition, other transgenic plants with resistance to insects, disease, herbicides or that have been quality-modified have been approved for field release and are ready for commercialization. These include transgenic varieties of cotton resistant to fungal disease, rice resistant to insect pests or diseases, wheat resistant to barley yellow dwarf virus (Cheng, He, and Chen 1997), maize resistant to insects or with improved quality (Zhang, et al., 1999), soybeans resistant to herbicides, transgenic potato resistant to bacterial disease, and so on (MOA, 1999; NCBED, 2000; Li, 2000).

Progress in plant biotechnology has also been made in recombinant microorganisms such as soybean nodule bacteria, nitrogen-fixing bacteria for rice and corn, and phytase from recombinant yeasts for feed additives. Nitrogen-fixing bacteria and phytase have been commercialized since 1999. In animals, transgenic pigs and carp have been produced since 1997 (NCBED, 2000). China was the first country to complete the shrimp genome sequencing in 2000.

Current Agricultural Biotechnology R&D System

Agricultural biotechnology research and development in China is predominantly financed and undertaken by the public sector. Several supra-ministries and agencies are involved in the design of research strategies, priorities, and the approval and allocation of budgets. The supra-ministries and agencies include the Ministry of Sciences and Technology (MOST), State Development Planning Commission (SDPC), and the Ministry of Agriculture (MOA) among others (Figure 1).

Ministry of Sciences and Technology (MOST)

At the national level, MOST establishes overall agricultural biotechnology R&D plans in collaboration with the Ministry of Agriculture. Overall agricultural biotechnology R&D plans are finalized through five-year and long-term plans. In addition, MOA and MOST propose R&D legislation and implement-approved policies. MOST supervises, coordinates, and evaluates biotechnology R&D plans, projects and budgets. MOST also runs the 4 largest biotechnology programmes in China. These are the ‘863’ Plan, ‘973’ Plan, Special Foundation of Transgenic Plants (SFTP), and Key Science Engineering Programme (Figure 1 and Table-A).

The ‘863’ Plan, also called High-Tech Plan, was initiated in March 1986 as a result of the recommendation from 4 leading scientists in China. The ‘863’ Plan supports a large number of applied as well as basic research projects with a 10 billion RMB yuan budget over 15 years to promote high technology R&D in China. Biotechnology is one of 7 supporting areas of the “863” Plan, having a budget of 0.7 billion RMB yuan over the life of the plan. Interviews from our survey suggest that actual budget for biotechnology research may be higher than the figures presented here.

The ‘973’ Plan was initiated in March 1997. This plan was established to support basic science and technology research. Life sciences, with biotechnology as priority, constitute one of the key supporting areas. The Special
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Foundation of Transgenic Plants is a unique Foundation, being a 5-year-programme launched in 1999 by MOST to promote research and development of transgenic plants in China. The total budget of this programme during its first five years is 500 million RMB yuan (8.26 yuan = 1 US$). The Key Science Engineering Programme (KSRP) is a large programme started in the late 1990s under the supervision of MOST and SDPC to promote basic research, including biotechnology. The first project on agricultural biotech, crop germplasm and quality improvement, was funded with 120 million RMB yuan in 2000.

State Development Planning Commission (SDPC)

The State Development Planning Commission makes annual, five-year and longer-term plans. SDPC ultimately determines national level financial budgets for all ministries in the Chinese government. SDPC authorizes the Ministry of Finance (MOF) to transfer funds to MOST for later transfer to the various ministries and their research institutes, and the Chinese Academy of Science (CAS). SDPC runs directly the High-tech Industrialization Programme, a programme promoting the commercialization and extension of biotechnology in both agriculture and non-agriculture areas (Figure 2). SDPC also co-manages with MOST other important agricultural biotechnology programmes, including the Key Science Engineering Programme.

Ministry of Agriculture

In principle, the MOA coordinates national level agricultural biotechnology research within the Ministry’s research system and biosafety management overall in China. In the research programme, the MOA directly manages only one Foundation, the China Agricultural Sciences and Education Foundation (CASEF) initiated in the late 1990s. The budget for CASEF is small relative to the budget allocated to biotechnology programmes administered by MOST and SDPC. Moreover, biotechnology is one of the several components of CASEF.

MOA contributes to agricultural biotechnology research programmes mainly through its involvement in formulation of overall agricultural biotechnology R&D plans and legislation, and implementation of legislated
policies that are coordinated by MOST. Activities of research institutes outside the domain of MOA are largely uncoordinated with MOA’s own R&D (Huang, Wang, Zhang and Zepeda, 2001). On the other hand, the national agricultural biosafety management is primarily led by MOA.

Other Ministries and Agencies

There are about 150 laboratories at the national and local level located in more than 50 research institutes and universities across the country working on agricultural (plant and animal) biotechnology. China initiated a programme with large capital investments in biotechnology in the mid-1980s. Laboratories that were evaluated and selected as National Key Laboratory (NKL) have been equipped with advanced instrumentation and also received extra operating funds to strengthen the biotechnology research programme at the recipient laboratory. Both SDPC and MOA administrated the laboratory selection programme. NKLs are denominated “Open Laboratories” because of the mandate that they should train and allow usage of both domestic and foreign guest researchers. In China, a total of 30 NKLs working in biotechnology have been established. Among them, fifteen NKLs focus their efforts on plant, animal, and agriculturally related biotechnology (Table-B).

At the national level, the MOA, CAS, State Forestry Bureau (SFB), and Ministry of Education (MOE) are the major authorities responsible for agricultural biotechnology research (Figure 1). Under the MOA, there
are 3 large academies, the Chinese Academy of Agricultural Sciences (CAAS, about 8000 research and support staff), Chinese Academy of Tropical Agriculture (CATA), and Chinese Academy of Fisheries (CAFi).

Among the 37 institutes within CAAS, there are 12 institutes and 2 National Key Laboratories (NKL) that conduct biotechnology research programmes. CAFi and CATA also have biotechnology laboratories or programmes, and each has one NKL performing research in biotechnology.

National institutes outside the MOA system also undertake agricultural biotechnology research. These include 7 research institutes and 4 NKLs under CAS, research institutes within the Chinese Academy of Forestry (CAFo) directly supervised by the State Forest Bureau, and universities under the Ministry of Education (MOE). There are 7 NKLs located in 7 leading universities conducting agricultural biotechnology or agriculturally related basic biotechnology research. In addition, institutes in the State Bureau of Petro-chemical Industry conducts biotechnology research efforts in the agro-chemicals (e.g., fertilizer). Structural and functional analyses are conducted in several leading National Key Laboratories in biotechnology (SPC and NSFC, 1995). In addition to the NKLs, numerous laboratories in the medical academies at the national and provincial level, universities, and in CAS have been established since 1985.

A similar organizational structure is followed at the local/provincial level where the Provincial Science and Technology Commission (PSTC) is the key agency administering biotechnology programmes (Huang, Wang, and Keeley, 2001). Each province has its own provincial academy of agricultural sciences and at least one agricultural university. Each academy or university at the provincial level normally has 1 or 2 institutes or laboratories focusing their work on agricultural biotechnology. Because of human capacity, physical equipment, and research investment constraints, contributions of local and/or provincial level biotechnology programmes are small compared to the overall national biotechnology system, although the number of local level institutions is quite large. Each programme is individually unable to make the necessary investments to produce viable biotechnology outputs. Cooperation and coordination among local or provincial level agricultural biotechnology programmes is limited.

Summarizing, the institutional framework of agricultural biotechnology programme in China is very complex, having a large number of participating institutions engaged in agricultural biotechnology. However, multiple sources of funding (MOST, SDPC, MOA, local and province), combined with the large number of biotechnology research institutes and laboratories, and the lack of coordination and collaboration among research institutes both at the national and the provincial level, have led to large overlaps of the agricultural biotechnology research programmes and has contributed to unnecessary and inefficient duplication of efforts, particularly at the local level.

**Agricultural Biotechnology Research Capacity**

Our recent survey, the results of which were published in Science (Huang, Rozelle, Pray and Wang, 2002), shows that China is developing the largest biotechnology capacity outside of North America. To create a modern and internationally competitive biotechnology research and development system, China has made great efforts to improve the innovative capacity of its national biotechnology programmes since the early 1980s. In contrast to the stagnating (or even declining) trend of agricultural research expenditure and research staff in the late 1980s and the early 1990s (Huang and Hu, 2001), R&D investments and the number of research staff in biotechnology has increased significantly since the early 1980s. Based on our primary survey of 29 research institutes in plant biotechnology, the number of researchers more than doubled in past 15 years, and total investment in real terms nearly doubled every five years (Huang, Wang, Zhang and Zepeda, 2001).

**Human Resources**

China's public agricultural research system, the largest in terms of research personnel in the world, employs more than 130,000 persons with about 70,000 professional staff (Huang and Hu, 2001). Table 1 shows the
Table 1: Numbers and composition of plant biotechnology research staff in sampled institutes, 1986-99

<table>
<thead>
<tr>
<th>Year</th>
<th>Professional staff</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mgt</td>
<td>Research</td>
<td>Sub-total</td>
<td>Staff number</td>
<td>Technical</td>
<td>Other</td>
<td>Sub-total</td>
</tr>
<tr>
<td>1986</td>
<td>82</td>
<td>203</td>
<td>285</td>
<td>80</td>
<td>276</td>
<td>356</td>
<td>641</td>
</tr>
<tr>
<td>1990</td>
<td>114</td>
<td>295</td>
<td>409</td>
<td>98</td>
<td>301</td>
<td>399</td>
<td>808</td>
</tr>
<tr>
<td>1995</td>
<td>164</td>
<td>371</td>
<td>535</td>
<td>111</td>
<td>322</td>
<td>433</td>
<td>968</td>
</tr>
<tr>
<td>1999</td>
<td>207</td>
<td>484</td>
<td>691</td>
<td>133</td>
<td>381</td>
<td>514</td>
<td>1205</td>
</tr>
<tr>
<td>1999a</td>
<td>264</td>
<td>705</td>
<td>969</td>
<td>233</td>
<td>455</td>
<td>688</td>
<td>1857</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Composition (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>13</td>
</tr>
<tr>
<td>1990</td>
<td>14</td>
</tr>
<tr>
<td>1995</td>
<td>17</td>
</tr>
<tr>
<td>1999</td>
<td>17</td>
</tr>
<tr>
<td>1999a</td>
<td>16</td>
</tr>
</tbody>
</table>

<p>| Staff number by Institute and University in 1999a |</p>
<table>
<thead>
<tr>
<th>University</th>
<th>Research Institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>52</td>
<td>212</td>
</tr>
<tr>
<td>72</td>
<td>633</td>
</tr>
<tr>
<td>124</td>
<td>845</td>
</tr>
<tr>
<td>15</td>
<td>218</td>
</tr>
<tr>
<td>27</td>
<td>428</td>
</tr>
<tr>
<td>42</td>
<td>646</td>
</tr>
<tr>
<td>166</td>
<td>1491</td>
</tr>
</tbody>
</table>

Note: All data are from 22 biotechnology research institutes except for those with 1999a that includes 29 institutes in 1999. These 29 institutes account for about 80% of research staff, about 85% of research expenditure, and more than 90% of research output in China's plant biotechnology.


number and composition of plant biotechnology research staff in the institutes included in our survey. Results from 22 institutes with complete information show that the number of total staff3 involved in biotechnology doubled within 13 years increasing from 641 in 1986 to 1205 in 1999 (Table 1). Of total professional staff, 484 where involved in research directly, whereas 207 were in management positions. Total professional staff increased 142% since 1986. The total number of professional staff in all the 29 plant biotechnology institutes reached 691 in 1999. Based on the above information, Huang, Rozelle, Pray and Wang (2002) estimated the human resource for China as a whole (Table 2). This study concluded that China's agricultural biotechnology research staff has become one of the largest in the developing world (Table 2, columns 4 and 5). The number of scientists and professional staff reached nearly 2000 in 1999. A marked improvement also has occurred in the formal education and training of those engaged in biotechnology research (Huang, Wang, Zhang and Zepeda, 2001).

Similar to other agricultural research programme in China, plant biotechnology research primarily is built around the research institutes. In the 29 institutes surveyed in this study in 1999, there were 633 researchers employed at research institutes (Huang, Wang, Zhang and Zepeda, 2001). Total staff in universities sum 166.

Financial Resources

Government funding puts Chinese plant biotechnology second only to US public sector (Huang, Rozelle, Pray and Wang, 2001). According to our recent research report in Science, unlike the rest of the world, in which most plant biotechnology research is financed privately, China’s government funds almost all of its plant biotechnology research. MOST has increased plant biotechnology project funding in the sample institutes from $8 million (in PPP $) in 1986 to $48 million in 1999 (Table 2). After a number of adjustments (see notes to Table 2), China’s total investment in plant biotechnology in 1999 was estimated to be $112 million.

Expenditures of this level demonstrate the seriousness of China’s commitment to plant biotechnology. Government research administrators allocated about 9.2% of the national crop research budget to plant

3 Total staff includes professional and support staff. Professional staff includes researchers and management. Support staff includes technical and other personnel.

4 All values are report in US dollars in real PPP terms by dividing all figures that were initially reported in yuan (Chinese currency) by the official exchange rate (8.25 yuan: 1 dollar) and multiplied by the purchase power parity multiplier (1.4.2933).
biotechnology in 1999, up from 1.2% in 1986. China's level far exceeds the 2.5% levels of other developing countries (Byerlee and Fisher, 2000).

The developing world's other large biotechnology programmes, in Brazil and India, fall short of China's (Huang, Rozelle, Pray and Wang, 2002). The Brazilian central agricultural research system, EMBRAPA, spends $2 million annually on genetic engineering (Paarberg, 2001). Foreign life science firms in Brazil spend approximately $1-2 million on plant biotechnology research. The Sao Paulo research foundation, FAPESP, spends $5-10 million annually. The Indian government allocates $15 million (Qaim, 2001). Even after adding the investment of private firms (an estimated US $10 million), plant biotechnology research expenditures in India are only around 20% of China's. Given these spending levels, China accounts for more than half of the developing world's expenditures on plant biotechnology (Huang, Rozelle, Pray and Wang, 2002).

Compared to the developed world, China's spending has been relatively small, less than 5% of total annual expenditures in industrialized countries, about $2.3 billion (Byerlee and Fisher, 2000). Such an assessment changes, however, when comparing China to the public research spending of other countries and when considering its future plans. Globally, the public sector makes about 45% of plant biotechnology research expenditures (Huang, Rozelle, Pray and Wang, 2002). China currently accounts for more than 10 per cent of this amount. In early 2001, China's officials announced plans to raise plant biotechnology research budgets by 400% before 2005. If achieved, China could account for nearly 1/3 of the world's public plant biotechnology spending.

The main source of investments in biotechnology research in China is the national government. Donor agencies contributed between 1.5 per cent in 1986 to 6.9 per cent of the total plant biotechnology budget for 22 institutes studied in 1999 (Huang, Wang, Zhang and Zepeda, 2001). Funds from competitive grants supporting research projects accounted for two thirds of the total budget. The increasing share of competitive grants reflects the change in priority from capacity building to an increase in specific research projects.

Table 2: Plant biotechnology research budget and research staff in China, 1986-99

<table>
<thead>
<tr>
<th>Year</th>
<th>Expenditures by sample institutes (PPP million US dollars)a</th>
<th>Estimates for all China</th>
<th>Plant biotech as per cent of total public ag. Research budget</th>
<th>Total staff working full time on plant biotech for sample institutes (number of scientists)</th>
<th>Estimates for total staff working full time on plant biotech for all China</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>8</td>
<td>17</td>
<td>1.2</td>
<td>641</td>
<td>740</td>
</tr>
<tr>
<td>1990</td>
<td>14</td>
<td>31</td>
<td>2.7</td>
<td>808</td>
<td>1057</td>
</tr>
<tr>
<td>1995</td>
<td>17</td>
<td>40</td>
<td>3.1</td>
<td>986</td>
<td>1447</td>
</tr>
<tr>
<td>1999</td>
<td>48</td>
<td>112</td>
<td>6.4/9,2b</td>
<td>1205</td>
<td>1988</td>
</tr>
</tbody>
</table>

Source: Huang, Rozelle, Pray and Wang, 2002.

a Data for columns (1) and (4) are from 22 research institutes. Estimates for total plant biotechnology investments in China (column 2) were calculated by taking the sum of investment in core, project, equipment and other expenditure categories for 22 institutes (treated in column 1) and multiplying by a factor of 1.30 (in 1986) to 1.41 (in 1999), which adjusts for the fact (based on the ratio of staff) that the historic data were missing the 7 institutes (of the 29 institutes that provided data for 1999) and multiplying by a factor of 1.20, which adjusts for the fact that the surveyed sample only covered 80 per cent of all institutes doing plant biotechnology work. This number (total project and staff funding) was multiplied by 1.25 to account for the fact that China's research expenditure figures do not include charges for facilities. A final adjustment (5% before 1995 and 10% in 1995 and 1999) accounts for private sector research (including that from foreign sources -reference 12). To go from our survey number of 92.8 million yuan in project expenditures in 1999 to our total estimate of research investments of $112 million, one multiplies 92.8 by 1.41*1.2*1.25*1.108.25*4.2933. Details of the survey and a copy of the survey instrument can be found on the Science website.

b The number 9.2 is plant biotech as per cent of total public plant research budget.

PRIORITIES AND PRODUCTS OF AGRICULTURAL BIOTECHNOLOGY RESEARCH

Research Priorities

In 1985, MOST developed a five-year Biotechnology Development Outline (BDO). A BDO also proposes policy measures and research priorities in each research field. Based on the BDO, each biotechnology programme develops its own guideline that specifies research priorities within its programme for both the whole 5 year period and for each individual year. Huang, Wang, Zhang and Zepeda (2001) summarized research priorities of plant biotechnology identified in various Biotechnology Development Outlines for the past 15 years in China (Table 3). In the selection of major crops to be included in the biotechnology programmes, cotton, rice, wheat, maize, soybean, potato, and rapeseed have been consistently listed as priority crops for research funding from the national biotechnology programmes since the mid-1980s. Total area sown to crops listed as priorities was over 100 million hectares, accounting for more than two-thirds of the total crop area sown in China in the 1990s (SSB, 2000).

Cotton has been consistently selected as a top priority crop not only because of its importance due to area sown and its contribution to the textile industry and trade, but also because of the serious problems with the associated rapid increase in pesticide applications to control insects (i.e., bollworm and aphids). Per hectare pesticide expenditures in cotton productions in China increased considerably in the past decades, reaching RMB yuan 834 (approximately US$ 100) in 1995. This amount is much higher than comparable expenditure in grain crops production but lower than in horticultural production (Huang, Qiao, Zhang, and Rozelle, 2000). Cotton production alone consumed about US$ 500 million annually in pesticides in recent years.

Rice, wheat and maize are the three most important crops in China. Each accounts for about 20 per cent of the total area planted. Production and market stability of these three crops are the primary concern of the Chinese government as they are central to China's food security. National food security, particularly related to grains, has been a central goal of China's agricultural and food policy and has been incorporated into biotechnology research priority setting. Grain crops have been prioritized not only for biotechnology and non-biotechnology research programmes (Huang and Hu, 2001), but also for irrigation investment and other government support programmes in agriculture (Huang and Ma, 2001).

Table 3: Research focus of plant biotechnology programmes in China

<table>
<thead>
<tr>
<th>Crops/traits</th>
<th>Prioritized areas</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Crops</strong></td>
<td>Cotton, rice, wheat, maize, soybean, potato, rapeseed, cabbage, tomato</td>
</tr>
<tr>
<td><strong>Traits</strong></td>
<td></td>
</tr>
<tr>
<td>Insect resistance</td>
<td>Cotton bollworm and aphids</td>
</tr>
<tr>
<td></td>
<td>Rice stem borer</td>
</tr>
<tr>
<td></td>
<td>Maize stem borer</td>
</tr>
<tr>
<td></td>
<td>Soybean moth</td>
</tr>
<tr>
<td></td>
<td>Potato beetle</td>
</tr>
<tr>
<td>Disease resistance</td>
<td>Rice bacteria blight and blast</td>
</tr>
<tr>
<td></td>
<td>Wheat yellow dwarf and rust</td>
</tr>
<tr>
<td></td>
<td>Soybean cyst nematode</td>
</tr>
<tr>
<td></td>
<td>Potato bacteria wilt</td>
</tr>
<tr>
<td>Stress tolerance</td>
<td>Rapeseed sclerotinia</td>
</tr>
<tr>
<td>Quality improvement</td>
<td>Drought, salinity, cold</td>
</tr>
<tr>
<td></td>
<td>Cotton fibre quality</td>
</tr>
<tr>
<td></td>
<td>Rice cooking quality</td>
</tr>
<tr>
<td></td>
<td>Wheat quality</td>
</tr>
<tr>
<td></td>
<td>Maize quality</td>
</tr>
<tr>
<td>Herbicide resistance</td>
<td>Rice, soybean</td>
</tr>
<tr>
<td>Functional genomics</td>
<td>Rice, rapeseed and arabidopsis</td>
</tr>
</tbody>
</table>

Genetic traits viewed as priorities may be transferred into target crops. Priority traits include those related to insect and disease resistance, stress tolerance, and quality improvement (Table 3). Pest resistance traits have top priority over all traits. Recently, quality improvement traits have been included as priority traits in response to increased market demand for quality foods. Quality improvements have been targeted particularly to rice and wheat, as consumer income rises in China. In addition, stress tolerance traits — particularly resistance to drought — are gaining attention particularly with the growing concern over water shortages in northern China. Northern China is a major wheat and soybean production region with significant implications to China’s future food security and trade.

Table 4 presents the available plant events in China up to 1999. A plant event is the specific combination of a genetic transformation construct and a plant host. This list also includes the stage in which each plant event is in the biosafety approval process. There are 18 crops with events that have entered the biosafety approval process. There are 39 events, of which 9 are for insect resistance, 20 for disease resistance, 2 for herbicide resistance, 5 for agronomic or quality modification, and 3 for stacked insect or disease resistance and quality modification.

In 1997 there were 57 applications for field trial, environmental release, and commercialization (Table 5). Of these China approved 46 requests for agricultural biotechnology products. The total number of approved cases for field trials, environmental release or commercialization reached 251 in 1999. Of the 251 approved cases, 92 were approved for field trials, 74 for environmental release and 33 for commercialization.

Among the approved releases for commercialization, sixteen approvals were granted to Bt cotton (varieties developed by CAAS and by Monsanto), 5 to tomatoes with resistance to insects or improved shelf-life, a petunia with altered flower color, and sweet pepper resistant to diseases.

Products in the Research Continuum

There are over 120 different genes and more than 50 different plant varieties that have been used in plant genetic engineering in China since the middle 1980s (Huang, Rozelle, Pray and Wang, 2002). Plant biotechnology research has emphasized the development of new varieties for major crops which seemed as high priority by the Chinese government such as cotton, rice, wheat, maize, soybean, potato and rapeseed. Traits introduced into these crops include insect resistance, disease resistance, herbicide resistance, stress tolerance and quality bacterial wilt (ecocropin B) (MOA, 1999; NCBD, 2000). These genes have been applied in plant genetic engineering since the late 1990s. Significant progress has also been made in the functional genomics of Arabidopsis and in plant bioreactors, especially in utilizing transgenic plants to produce oral vaccines (BRI, 2000b).

Transgenic Plants Resistant to Insects

- Cotton: Insect-resistant Bt cotton was developed by the Biotechnology Research Institute (BRI) of the Chinese Academy of Agricultural Sciences (CAAS), a leading institute on crop biotechnology in China. The Bt gene's modification and plant vector construction technique was granted a patent in China in 1998. The Bt gene was introduced into major cotton varieties using the Chinese-developed pollen tube pathway (Guo and Cui, 1998 and 2000). Five transgenic, open-pollinated varieties and one transgenic hybrid Bt cotton variety have been registered with the new plant variety registration authorities. Bt cotton has been approved for commercialization in 9 provinces since 1997 (BRI, 2000a). The area planted to Bt cotton reached around 700,000 hectares, nearly equally shared by Chinese and Monsanto Bt varieties (Huang, Qiao, Rozelle and Pray, 2001).

- Rice: Several research institutes and universities have been working on transgenic rice resistant to insects since the early 1990s. Transgenic hybrid and conventional Bt rice varieties, resistant to rice stem borer and leaf roller were approved for environmental release in 1997 and 1998 (Zhang, 1999). An additional transgenic

---

5 Applications were made after the creation of the Office of Genetic Engineering Safety Administration (OGESA) which was established in the MOA in 1996.
<table>
<thead>
<tr>
<th>S.No.</th>
<th>Crop</th>
<th>Introduced traits</th>
<th>Field Trial</th>
<th>Environmental release</th>
<th>Commercialized</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cotton</td>
<td>Insect resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bollworm (Bt)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bollworm (Bt+CpTI)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bollworm (CpTI)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bollworm (API)</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disease resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Viricillium &amp; Fusarium (Chili)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Viricillium &amp; Fusarium (Glu)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Viricillium &amp; Fusarium (GlueChili)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Rice</td>
<td>Insect resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stem borer (Bt)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stem borer (CpTI)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rice plant hoper</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disease resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bacterium blight (Xa21)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fungal disease</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rice dwarf virus</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Herbicide resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salt tolerance (BADH)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AceDs (rice mutant)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>Wheat</td>
<td>BYDV resistance &amp; quality improvement</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>Maize</td>
<td>Insect resistance, (Bt) &amp; quality improvement</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>Soybean</td>
<td>Herbicide resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>Potato</td>
<td>Disease resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bacterium wilt</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PVY resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Viroid resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disease resis. &amp; quality improv.</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>Oil rape</td>
<td>Disease resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>Tobacco</td>
<td>Insect resistance (Bt or CpTI)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes&gt;Yes*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TMV resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td>9</td>
<td>Peanut</td>
<td>Stripe virus resistance</td>
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<td>Yes</td>
<td>No</td>
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<tr>
<td>10</td>
<td>Chinese cabbage</td>
<td>Turnip mosaic virus resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>11</td>
<td>Tomato</td>
<td>CMV resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TMV &amp; CMV resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Time-altered shelf life</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cold tolerance (stip)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td>Melon</td>
<td>CMV resistance</td>
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<td>No</td>
<td>No</td>
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<tr>
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<td>Sweet pepper</td>
<td>CMV resistance</td>
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<td>Yes</td>
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<td>14</td>
<td>Chilli</td>
<td>CMV/TMV resistance</td>
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<td>Yes</td>
<td>No</td>
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<tr>
<td>15</td>
<td>Papaya</td>
<td>PRSV resistance</td>
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<td>Yes</td>
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<td>16</td>
<td>Poplar tree</td>
<td>Insect resistance</td>
<td>Yes</td>
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<tr>
<td>17</td>
<td>Petunia</td>
<td>Flower colour altered</td>
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<td>Yes</td>
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<td>18</td>
<td>Pogostemonium</td>
<td>Bacterium wilt resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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</tbody>
</table>


* Commercialized in 1992 but stopped in the middle 1990s due to trade issues.
Table 5: Agricultural biotechnology testing in China, 1997-2000

<table>
<thead>
<tr>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Total (plants, microorganisms, animals)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submitted</td>
<td>57</td>
<td>68</td>
<td>126</td>
<td>102</td>
<td>353</td>
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<tr>
<td>Approved</td>
<td>46</td>
<td>52</td>
<td>94</td>
<td>59</td>
<td>251</td>
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<tr>
<td>Approvals for Plants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field trials</td>
<td>29</td>
<td>8</td>
<td>28</td>
<td>na</td>
<td>46</td>
</tr>
<tr>
<td>Environmental release</td>
<td>5</td>
<td>9</td>
<td>30</td>
<td>na</td>
<td>65</td>
</tr>
<tr>
<td>Commercialization</td>
<td>4</td>
<td>2</td>
<td>24</td>
<td>1</td>
<td>31</td>
</tr>
</tbody>
</table>


A rice variety that expressed resistance to rice plant hopper has been tested in field trials. Through anther culture, the CpTi gene and the Bar gene were successfully introduced into rice, which expressed resistance to rice stem borer and herbicide (NCBDE, 2000; Zhu, 2000).

- **Maize:** A transgenic Bt maize resistant to maize stem borer was developed by the China Agricultural University, which was approved for environmental release in 1997 (OGESA, 1999).

- **Soybean:** The Jinlin Academy of Agricultural Sciences recently developed a transgenic Bt soybean that expresses resistance to the soybean moth. The transgenic lines Jilin 27 and Heilong 35 have already been approved for field trials and environmental release in 1997 (NCBDE, 2000).

- **Others:** Transgenic tobacco, papaya, poplar tree, and a few others now are either in the stages of field trials or environmental releases (OGESA, 1999; Wu, Sun, and Yao, 2000). Research in transgenic wheat resistant to insect (i.e. aphids) is in the research pipeline.

**Transgenic Plants Resistant to Disease**

- **Cotton:** BRI of CAAS recently made a breakthrough in plant disease resistance by developing cotton resistant to fungal diseases. Glucomanase, glucosidase and chinatinase genes were introduced into major cotton varieties. Transgenic cotton lines with enhanced resistance to *Verticillium* and *Fusarium* were approved for environmental release in 1999 (BRI, 2000a).

- **Rice:** Transgenic rice with *Xa21*, *Xa7* and *CpTi* genes resistant to bacteria blight or rice blast were developed by the Institute of Genetics of CAS, BRI, and China Central Agricultural University. These transgenic rice plants have been approved for environmental release since 1997 (Zai and Zhu, 1999; NCBDE, 2000).

- **Potato:** Synthesized cecropin polypeptide genes and transgenic potato lines resistant to bacterial wilt were developed by BRI in the mid-1990s. These genetically modified potato lines resistant to bacterial wilt were approved for environmental release in Beijing and Sichuan province in 1997 (Jia and Tang, 1998).

**Other Plant Biotechnologies**

Significant progress has been made with transgenic plants expressing drought and salinity tolerance in rice and wheat. Transgenic rice expressing drought and salinity tolerance has been in field trials since 1998. Genetically modified nitrogen fixing bacteria for rice and maize, as well as phytase for feed additives, were approved for commercialization in 2000. In addition to plant genetic engineering, tissue culture techniques have also been often applied in horticulture, to produce virus free potatoes and strawberries. Several adopted rice and sugar beet varieties were developed by anther culture (Authors' survey, 2000). Progress has also been made in molecular marker assisted selection of plant varieties. For example, a new soybean line with high yield and resistance to cyst nematode disease was produced in 1998. In microbial research, several valuable insecticidal genes were isolated and cloned.
BIOSAFETY MANAGEMENT AND REGULATIONS*

Principles of Biosafety Management

The principles that have been set by Chinese government in biosafety management are summarized as follows (Huang, Wang and Keeley, 2001):

1. Equal attention should be paid to both biotechnology R&D and to safety management. The government actively supports and encourages biotechnology R&D through preferential policy measures, at the same time it pays great attention to biosafety issues. Promotion of biotechnology and its related industries must guarantee human health and environmental safety.

2. In safety issues, prevention should be the priority. Based on the particular biotechnology product, negative ecological and environmental effects and potential dangers to human health in the period of experimental research, field trials, environmental release, commercialization and processing, storage, utilization and waste treatment, etc. should be prevented.

3. There should be cooperative management between related ministries. Biotechnology products are associated with many fields, such as agriculture, forestry, pharmaceuticals and health, and food processing etc. Biosafety management involves not only human health and ecological and environmental protection, but also export and import management and international trade activities. Therefore, the cooperation among related ministries and agencies is necessary.

4. Management should be based on fair and scientific principles. Biosafety assessment must be based on science, the related manipulation techniques, monitoring processes, monitoring methods and results must be up to scientific standards. According to regulations, all released biotechnology products should be monitored regularly and corresponding safety measures should be adopted regarding monitoring data and results. A system of national biosafety assessment standards and monitoring of technology should be established.

5. Public participation. Consumers have the right to know the facts about the products of biotechnology. The public should be aware of similarities and differences between biotechnological and traditional products. The consumers have choice as to whether to use new genetically modified products or not.

6. Assessment should be on a case by case basis. Genetic information exchange during processes of genetic manipulation is complex, so specific analysis and assessment must be taken for every particular product. Based on required information, appropriate safety measures should be taken according to the progress of genetic engineering. On the other hand, these scientific measures will be gradually improved and perfected with the development of technology, accumulation of experience, public opinion and acceptance (Liu and Zhu, 2001)

Biosafety Management System

So far, biosafety management is implemented at 3 levels: national, ministries and research institutes. The Ministry of Science and Technology (MOST) represents the national level and is responsible for the general management of biosafety. Recently, a new division for biosafety management has been set up within the National Centre of Biological Engineering Development (NCBED, Figure 2). It is responsible for the administration of new regulations, for promoting academic exchange on biosafety, and coordinating different ministries involved with biosafety issues (Huang, Wang and Keeley, 2001).

At the ministry level, the Ministry of Agriculture (MOA) is in charge of the formulation and implementation of biosafety regulations for agricultural biotechnology. Within the MOA, the Office of Agricultural Genetic Engineering Safety Administration (OAGESA) under the Department of Science and Education is responsible for the implementation of regulations. The Biosafety Committee on Agricultural Biological Engineering (BCABE) composed of officials from MOA and scientists from different disciplines including agronomy, biotechnology, plant protection, animal science, microbiology, environmental protection and toxicology, nominated by the MOA, is responsible for the biosafety assessment of experimental research, field trials, environmental release and

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*This section is mainly from a research report by Huang, Wang and Keeley (2001).*
commercialization of GMOs. The Ministry of Public Health is responsible for the food safety management of biotechnology products. The Appraisal Committee consisting of food, health, nutrition and toxicology experts, nominated by MPH, is responsible for reviewing and assessing GM foods since it has been designated as a New Resource Food. The State Environmental Protection Agency and MOA assume responsibility for environmental safety.

Within every biotechnology or research institute, there is usually a biosafety management group led by the director of the particular research institute. The group is in charge of the reviewing application documents and biosafety related consulting services. The Biosafety Division of Agricultural Genetic Engineering (BDAGE) under the Centre of Science and Technology Development, MOA, takes responsibility for accepting and pre-reviewing applications for biosafety assessment.

Since 2001, the government has been planning to set up the biosafety management system at provincial and country levels in order to enhance the local capacity on managing this novel technology. The policy to set up local biosafety committee will be effective by March 20, 2000. This implies that after full implementation of the policy, there will be 31 biosafety committees and government offices at provincial level and about 2500 at the country level. Establishment of the lower level biosafety management system will require substantial human capacity building investment.

**Biosafety Regulations**

The first biosafety regulation in China, “Safety Administration Regulation on Genetic Engineering” was issued by MOST in 1993, aiming at promoting the R&D of biotechnology in China. This regulation is a general guideline for implementing regulations of related ministries. The regulation consists of general principles, safety clauses and evaluation, application and approval, safety control measures, and legal responsibilities. MOST required the related ministries to draft and issue corresponding biosafety regulations on biological engineering, but only MOA has issued the Implementation Regulations on Agricultural Biological Engineering in 1996.

According to this general regulation of MOST, MOA has organized an Expert Panel of 10 eminent professors and experts to draft the Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering (hereinafter referred to as the Regulation) during the period of June 1994 to October 1995. The Regulation was reviewed and approved at the Conference of the Standing Committee of MOA, and issued by the Minister of Agriculture as an order of MOA in July 1996.

In May 2001, the State Council issued new biosafety guidelines: Agricultural GMO Safety Regulations. Three detail regulations corresponding to this general Guideline were announced in January 2002 and will be effective on March 20, 2002. There are several important changes to existing procedures included in these guidelines, and also details of regulatory responsibilities after commercialization. These include the addition of an extra production trial stage prior to commercial approval; new processing regulations for GM products; labeling requirements for marketing; new export and import regulations of GM products; and local and provincial level monitoring guidelines. A more detailed biosafety process may also strengthen China’s hand where it will invoke the Cartagena Biosafety Protocol to deal with future trade issues on certain GMOs. It also may be possible to avoid WTO trade disputes where it can be shown that an adequate transparent and non-discriminatory national biosafety process has happened.

The National Environmental Protection Agency also recently published a biosafety framework, funded by UNEP. This document has not however been followed by any change in institutional mandates: biosafety assessment continues to be managed by the MOA where institutional capacity resides. This is clearly felt to be the most realistic option in the Chinese context given resource constraints and the complexity of the issues.

Regarding food safety policy, “The Food Health Law of the People’s Republic of China” was issued by the Ministry of Public Health (MPH) in 1982, and amended in 1995. This is a general law for food health
monitoring and management, and a major legal basis for other food health related regulations and standards. Transgenic food has been included in the wider category of “novel foods” in China, so the management of GM food has been added to the existing “Management Regulation of Novel Foods”, which was issued in 1990 by MPH. According to this regulation, any trial production or commercial production of a new food must be approved by MPH.

Other regulations related to biotechnology and safety issue are “Quality control guideline of recombined DNA products for humans” issued by MPH in 1990 and “Administrative measures for biological veterinary products” issued by MOA in 1996.

On the other hand, although the biosafety regulation and implementation system have been established in China, several problems have emerged during practice, for example, the monitoring system and consulting service at local and farm levels is relatively weak, and collaboration and coordination between ministries needs to be further strengthened.

**Intellectual Property Rights**

There are several agencies responsible for IPR management in China. These include the State Patent Office, The Trademark Office (the State Administration for Industry and Commerce), and the National Copyright Administration. China Patent Law was issued in 1984, amended in September 1992 and in 2000, and the new amended Patent Law became effective on July 1, 2001. The Regulations for implementation of the newly amended Patent Law were issued in 2001 too. With the development of biotechnology in China, a biotechnology division was set up under the State Patent Office, to promote and manage applications for and granting of biotechnology patents. In addition, an IPR Affair Centre under the Ministry of Science and Technology was set up, this is a government consulting agency for IPR processing in China (SIPO, 1999).

From April 1, 1985 to the end of 2000, about 1265,974 applications for invention patents were filed with the State Patent Office, and 687,541 cases have been granted. Genetic engineering is ranked among the top 20 groups. But the amount of patent on genetic engineering accounted for only 1.1% of total patents granted in the 1990s (SIPO, 2000). Among the applications for genetic engineering patents, 75% of applications were made by foreign companies and research institutes. Applications submitted by Chinese scientists only accounted for 25%. Chinese scientists are facing great challenges from biotechnology companies and institutes of developed countries.

Regarding New Plant Variety Protection, the Regulations of PRC on the Protection of New Varieties of Plants were issued in 1997 and became effective on 23 April 1999 when China became the 39th member country of UPOV. Detailed regulations on the implementation of PVP have been put in effect thereafter. The use of new plant variety for propagating purposes by farmers on their own holdings is protected by the PVP policy (SIPO, 1997). The Plant New Variety Protection Office under MOA and SFA (State Forest Agency) has been established since 1999 and is responsible for granting PVP. The Seed Law was issued in 2000, the IPR of a new transgenic plant variety can now be doubly protected by PVP and the Seed Law.

In addition to protecting intellectual property and plant breeders rights, policymakers are also concerned to protect farmers rights. Balancing the IPR and farmers’ rights is a challenging issue that the policy makers will face in the future, particularly after China’s accession to WTO.

Capacity building in relation to IPRs is an emerging challenge for China. This challenge may include several dimensions. Increased incentive mechanism and awareness of IPR within the Chinese scientific community are frequently mentioned issues by Chinese scientists and research administrators. A particular concern of IPAC in MOST is how to encourage Chinese scientists to identify more opportunities to seek patents on products and processes they develop. Scientists in the public sector have not traditionally seen patents as an important peer recognition. The on-going policy allows the research institutes or the patent holders to have up to 35%
shares in the profit generated from the technology. However, so far most research institutes have neither human capacity nor financial ability to manage the issues related to IPR.

Another area is the process of inspecting patent applications. This has become substantially more complicated following advances in biotechnology science, particularly functional genomics. The volume and complexity of patent applications is particularly demanding. International linkages contribute to building capacity in this area, including for example, links to WIPO where the former DG of the State Patent Office holds a key position.

Finally, China has been also increasing interest in looking for new ways of using patented technologies from private sector in national biotech research programme. The focus of capacity building efforts is on evaluating the costs and benefits of different models of collaboration and technology transfer, including licensing, MTAs and collaborative agreements.

**Impacts of Plant Biotechnology**

GMs are the centre of an increasingly rancorous debate about the value of agricultural biotechnology. The champions of biotechnology such as Monsanto and the Biotechnology Industry Organization see agricultural biotechnology as a tool to help solve problems of hunger and excessive pesticide use. The critics of biotechnology such as Altieri and Rosset (2000) say that plant biotechnology is not needed, will be bad for consumers’ health, will impoverish small farmers, will erode the profits of companies like Monsanto, will increase pesticide use, and reduce biodiversity.

This debate is particularly important for developing countries most of which have not yet decided whether to allow the use of GM plants or not. GM cotton, soybean, and corn varieties have increased yields and profits and decreased pesticide use of farmers in the US (Gianessi and Carpenter 1999; Fernandez-Cornejo, Klotz-Ingram and Jans 1999). Few ex post studies of farm level impact of biotechnology so far have been published about countries outside the US. This section tries to summarize our recent studies that provide evidence on the farm level impact of biotechnology with a case study of Bt cotton production in China.

In response to rising pesticide use and the emergence of a pesticide resistant bollworm population in the late 1980s, China’s scientists began research on GM cotton, launching the nation’s most successful experience with GM crops. Starting with a gene isolated from the bacteria, *Bacillus thuringiensis* (Bt), China’s scientists modified the cotton plant using an artificially synthesized gene that was identified with sequencing techniques. Greenhouse testing began in the early 1990s. When area sown to cotton decreased due to pest losses in the mid-1990s, in 1997, the commercial use of GM cotton was approved. During the same year, Bt cotton varieties from publicly funded research institutes and from a Monsanto joint venture (with the US seed company Delta and Pineland and the Hebei Provincial Seed company) became available to farmers. The release of Bt cotton began China’s first large-scale commercial experience with a product of the nation’s biotechnology research programme.

Response by China’s poor farmers to the introduction of Bt cotton eliminates any doubt that GM crops can play a role in poor countries (Huang, Rozelle, Pray and Wang, 2002). From only 2,000 hectares in 1997, Bt cotton’s sown area grew to around 700,000 hectares in 2000. By 2000, farmers planted Bt varieties on 20% of China’s cotton acreage. The average farm size of the typical cotton farmer in the survey sample was less than 1 hectare (of which the cotton area was less than 0.5 hectare). Currently, Bt cotton in China is the world’s most widespread transgenic crop programme for small farmers.

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7 This section is mainly from Huang, Rozelle, Pray, and Wang (2002); Pray, Ma, Huang and Qiao (2001); and Huang, Hu, Pray, Qiao and Rozelle (2001).
Farmers are receiving the greatest benefit from Bt cotton's reduced pesticide need. Bt cotton farmers reduced pesticide use by an average of 13 sprays (49.9 kg) per hectare per season (Table 6). This reduced costs by $762 per hectare per season. Farmers also significantly reduced labour for pest control. After holding the incidence of pests, pesticide price, and farmer's age and education constant, regression analysis finds that Bt cotton adopters use significantly less pesticides when pesticide use is measured by the number of sprays, the quantity of pesticide used, or total cost.

The decrease in pesticide use has increased production efficiency. Although yields and the price of Bt and non-Bt varieties were the same, the cost savings and reduction in labour enjoyed by Bt cotton users reduced the cost of producing a kilogram of cotton by 28%, from $2.23 to $1.61 (Table 6). Multivariate production efficiency analysis demonstrates that the results are statistically valid (Huang, Hu, Qiao, Rozelle, and Pray, 2001).

China's experience with Bt cotton demonstrates the direct and indirect benefits of its investment in plant biotechnology research and product development. According to our research, the total benefits from the adoption of Bt cotton in 1999 were $334 million (Huang, Rozelle, Pray and Wang, 2002). Ignoring the benefits created by foreign life science firms, the benefits from the main variety created and extended by one of China's publicly funded research institutes were $197 million. Farmers captured most of the benefits since government procurement prevented cotton prices from declining (which would have shifted some of the benefits to consumers). Hence, the social benefits from research on one crop, cotton, in only the second year of its adoption were enough to fund all of the government's crop biotechnology research in 1999. As Bt cotton spreads, the social benefits from this crop will easily pay for all China's past biotech expenditures on all crops.

Our survey showed that farmers reduced use of toxic pesticides, organophosphates and organochlorines, by more than 80% and that this reduction appears to have improved farmer health. The survey asked farmers if they had suffered from headaches, nausea, skin pain, or digestive problems after applying pesticides. If the answer was "yes," it was registered as an incident of "poisoning." Only 4.7% of Bt cotton growers reported poisonings; 11% of the farmers using both Bt and non-varieties reported poisonings; while 22% of those using only non-Bt varieties reported poisonings.

Our field interview also showed that biodiversity of insects appears to have been enhanced by the adoption of Bt cotton. Local government authorities in Hebei province in 1997 found 31 insect species in Bt fields of which 23 were beneficial while non-Bt fields contained 14 species of which 5 were beneficial (Pray, Ma, Huang and Qiao, 2000).

CONCLUDING REMARKS

China considers agricultural biotechnology a strategically significant tool to improve its national food security, raise agricultural productivity, and create a competitive position in international agricultural markets. China also intends to position itself as a world leader in biotechnology research. This objective also addresses the perception

<table>
<thead>
<tr>
<th>Variety</th>
<th>Yield (kg/ha)</th>
<th>Total production costs per kg cotton (US$/kg)*</th>
<th>Pesticide use per hectare</th>
<th>Cost (US dollars)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Number of applications</td>
<td>Quantity (kg)</td>
</tr>
<tr>
<td>Bt cotton</td>
<td>3371</td>
<td>1.61</td>
<td>8.6</td>
<td>11.8</td>
</tr>
<tr>
<td>Non-Bt</td>
<td>3196</td>
<td>2.23</td>
<td>19.8</td>
<td>60.7</td>
</tr>
</tbody>
</table>

Source: Huang, Rozelle, Pray and Wang, 2002.

* Converted from yuan at 8.25 exchange rate and to PPP terms by multiplying by 4.2933.
that policy makers have of the risk associated with the dependence of national food security on imported technologies. Despite the growing debate worldwide on GM crops, China has developed agricultural biotechnology decisively since the mid-1980s. China was the first country to commercialize a GM crop and was the fourth country in terms of GM crop area in 2000. China has about 20 genetically modified plants that are in the pipeline for commercialization.

The institutional framework for supporting agricultural biotechnology research programme is complex both at national and local levels. However, our review of the current institutional arrangements also show that the coordination among institutions and consolidation of agricultural biotechnology programmes will be essential for China to create a stronger and more effective biotechnology research programme in the future.

China's efforts in promoting biotechnology research have increased over time. Most efforts have been made to improve research capacity, increase the stock of knowledge and technology, and promote commercialization of the biotechnology that are significantly needed by farmers (i.e. Bt cotton). Research capacity in terms of both quantity and quality has improved significantly. On the other hand, human capacity may need further improvement if China intends to establish an internationally competitive biotechnology research programme and to achieve the overall goal of promoting agricultural biotechnology in China.

A remarkable event has been the growth of government investments in agricultural biotechnology research. In contrast to stagnating expenditures on agricultural research in general, investments in agricultural biotechnology have increased significantly since the early 1980s. In spite that the number of researchers increased rapidly over the past 15 years, investment measured as expenditure per scientist more than doubled.

Examination of the research focuses of agricultural biotechnology research reveals that the food security objective and the current farmers' demands for specific traits and crops have been incorporated into priority setting. Moreover, the current priority setting of investments in agricultural biotechnology research has led to the investment in favour of the commodities in which China does not have relative comparative advantage in the international market such as grain, cotton and oil crops, which implies that China is targeting its GMO products at the domestic market.

The review on the impact studies shows that small farmers obtain increased incomes from adopting Bt cotton. Farmers who grew most popular Bt varieties reduced their costs of production by 20 to 23 per cent over new non-Bt varieties while prices of cotton were about the same for Bt and non-Bt varieties. In addition it may allow some farm families that did not have enough food to increase their food purchases and food consumption. More important, the use of Bt cotton has substantially reduced pollution by pesticides in the regions where it was adopted. Farmers' and farm labourers' exposure to pesticides has been reduced. Biodiversity of insects also appears to have been enhanced by the adoption of Bt cotton.

Although China is still struggling with issues of consumer safety and acceptance, many competing factors are putting pressures on policy makers to decide whether or not to continue commercializing transgenic crops. The demand of producers (for productivity-enhancing technology) and consumers (for cost savings), the current size and rate of increase of research investments, and past success in developing technologies suggest that products from China's plant biotechnology industry will one day become widespread inside China. China also could become an exporter of biotechnology research methods and commodities as opportunities for contract research, the sales of genes, markers and other tools, and exporting GM varieties are expanding in both industrialized and developing countries. Globally, China has several advantages; it has many well-trained scientists, a low cost research environment, and large collection of germplasm.

Does the China example provide lessons for other Less Developed Countries? The answer appears to be yes. Many LDCs have the same problems as China's. Bt cotton appears to be just what the critics of the Green Revolution wanted. Although there are still uncertainties about how durable current Bt cotton resistance to boilworm
and about environmental impacts of Bt cotton, when compared to the known environmental and health problems caused by pesticides, it would seem that Bt cotton is a desirable alternative. Particularly in countries like India which have major bollworm problems and no longer have effective ways of fighting them. In conclusion, China’s case suggests that more developing countries should seriously consider allowing the cultivation of GMOs such as Bt cotton because it offers an effective way of controlling a serious pest of cotton, reducing pesticide use, and improving the health of farmers and farm workers. In addition LDC governments should be open to other biotechnology that passes their environmental and safety standards and allow farmers to choose the technologies that best fit their farming systems.

References


Key Laboratory of Crop Molecular and Cell Biology (KLMCCB), Ministry of Agriculture, 1996. In The Research and Prospects of Crop Genetic Engineering, Chinese Agricultural Science and Technology Press.


## Major policy measures related to biotechnology in China

<table>
<thead>
<tr>
<th>Key Breakthrough S&amp;T Projects</th>
<th>Started in 1982 by SDPC. Updated every five years. One of major components of these projects is biotechnology R&amp;D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Biotechnology</td>
<td>Prepared by scientists and officials led by MOST, SDPC, and others in 1985. Formally issued by the State Council in 1988. The Outline defined the research priorities, development plan and measures to achieve targets.</td>
</tr>
<tr>
<td>Development Policy Outline</td>
<td>National Key Laboratories (NKLs) on Biotechnology Started in 1985 under MOST. Thirty National Key Laboratories in biotechnology (15 on agriculture or agriculture related) have been established. NKLs are open laboratories, inviting both domestic and international visiting fellows.</td>
</tr>
<tr>
<td>The Climbing Programme</td>
<td>A National Programme for Key Basic Research Projects, including biotechnology programme, initiated in the early 1980s.</td>
</tr>
<tr>
<td>High Technology Plan (863)</td>
<td>Established in 1986 with 10 billion RMB for 15 years to promote high technology R&amp;D in China. Biotechnology is one of 7 supporting areas with a total budget of 0.7 billion RMB.</td>
</tr>
<tr>
<td>Natural Science Foundation of China</td>
<td>Established in 1986 to support basic science research. Life science and Agronomy are two support areas related to the agro-biotechnology.</td>
</tr>
<tr>
<td>Biosafety regulations</td>
<td>MOST issued the Biosafety Regulations on Genetic Engineering in July of 1993, which include the biosafety grading and safety assessment, application and approval procedure, safety control measures, and legal regulations.</td>
</tr>
<tr>
<td>Agricultural biosafety regulations</td>
<td>MOA issued the Safety Administration, Implementation, and Regulations on Agricultural Biological Genetic Engineering in July 1996.</td>
</tr>
<tr>
<td>&quot;973 &quot;Plan</td>
<td>Initiated in March 1997 to support the basic science and technology research. Life science is one of the key supporting areas of the Plan.</td>
</tr>
<tr>
<td>Safety Committee</td>
<td>Biotech Safety Committee was set up in MOA in 1997. The committee is in charge of the implementation of agricultural bio-safety regulations</td>
</tr>
<tr>
<td>Special Foundation for</td>
<td>A 5-year-programme launched in 1999 by MOST to promote the research and development of transgenic plants in China. The total budget of this programme in the first 5 years is 500 million RMB.</td>
</tr>
<tr>
<td>Transgenic Plants</td>
<td>Key Science Engineering Programme Started in the late 1990s under MOST and SDPC to promote basic research, including biotechnology programme. The first project on biotech (crop germplasm and quality improvement) was funded in 2000 with 120 million RMB.</td>
</tr>
<tr>
<td>Special Foundation for</td>
<td>A programme supported by the SDPC to promote the application and commercialization of technologies, started in 1998</td>
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<tr>
<td>High-tech Industrialization</td>
<td>Seed Regulation and Law Regulation on the Protection of New Varieties of Plants was issued in 1999. The first Seed Law was issued in 2000.</td>
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<tr>
<td>Amended Agricultural Biosafety</td>
<td>1996 MOA’s biosafety regulation was amended and issued by the State Council in May 2001.</td>
</tr>
<tr>
<td>Regulation</td>
<td>“Three Regulations” on Agri-biotech products MOA announced three regulations related to agri-biotech: risk assessment, import safety management, labeling.</td>
</tr>
</tbody>
</table>

Source: Huang, Wang, Zhang and Zepeda, 2001 and the author’s recent survey.
<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Affiliation</th>
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</thead>
<tbody>
<tr>
<td><strong>Applied Plant Biotechnology</strong></td>
<td></td>
</tr>
<tr>
<td>1. National Key Lab of Agricultural Biotechnology</td>
<td></td>
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<tr>
<td>2. National Key Lab of Crop Genetic Improvement</td>
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<tr>
<td>3. National Key Lab of Plant Disease and Pest Biology</td>
<td>Institute of Plant Protection, CAAS</td>
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<tr>
<td>4. National Key Lab of Tropical Crop Biotechnology</td>
<td>Institute of Tropical Crops, CATA</td>
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<td><strong>Applied Animal Biotechnology</strong></td>
<td>Haerbin Veterinary Institute, CAAS</td>
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<tr>
<td>1. National Key Lab of Veterinary Biotechnology</td>
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<tr>
<td>2. National Key Lab of Freshwater Fish Germplasm and Biotechnology</td>
<td>Changjiang Aquatic Product Institute, CAFI</td>
</tr>
<tr>
<td><strong>Other Applied Biotechnology</strong></td>
<td>Institute of Zoology, CAS</td>
</tr>
<tr>
<td>1. National Key Lab of Membrane Biology &amp; Engineering</td>
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<tr>
<td>2. National Key Lab of Biochemistry Engineering</td>
<td>Institute of Chemistry and Metallurgy, CAS</td>
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<tr>
<td>3. National Key Lab of Enzyme Engineering</td>
<td></td>
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<tr>
<td><strong>Basic Biotechnology (Plant, Animal, Microorganism, and others)</strong></td>
<td>Institute of Plant Physiology, CAS</td>
</tr>
<tr>
<td>1. National Key Lab of Protein &amp; Plant Genetic Engineering</td>
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<tr>
<td>2. National Key Lab of Genetic Engineering</td>
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<tr>
<td>3. National Key Lab of Plant Molecular Genetics</td>
<td>Institute of Genetics, CAS</td>
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<tr>
<td>4. National Key Lab of Plant Cell and Chromosome Engineering</td>
<td>Institute of Aquatic Biology, CAS</td>
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<tr>
<td>5. National Key Lab of Freshwater Ecology and Biotechnology</td>
<td>Institute of Biochemistry, CAS</td>
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<tr>
<td>6. National Key Lab of Molecular Biology</td>
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<tr>
<td>7. National Key Lab of Preliminary Development of Microorganism Resources</td>
<td>Institute of Microbiology, CAS</td>
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<td>8. National Key Lab of Biological Control</td>
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<tr>
<td>9. National Key Lab of Drought Agro-ecology</td>
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<tr>
<td>10. National Key Lab of Bioreactor</td>
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<tr>
<td>11. National Key Lab of Microbial Biotechnology</td>
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</tbody>
</table>

**Medical Biotechnology**

<table>
<thead>
<tr>
<th>Laboratory</th>
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<th>University</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. National Key Lab of Pharmaceutical Biotechnology</td>
<td></td>
<td>Nanjing University</td>
</tr>
<tr>
<td>2. National Key Lab of Virus Genetic Engineering</td>
<td>Institute of Virus, Chinese Academy of Preventive Medical Sciences</td>
<td>Beijing Medical University</td>
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<tr>
<td>3. National Key Lab of Natural and Bionic Pharmaceuticals</td>
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<td></td>
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<tr>
<td>4. National Key Lab of Cancer Gene and Related Gene</td>
<td>Shanghai Carcinoma Institute</td>
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<tr>
<td>5. National Key Lab of Molecular Tumorology</td>
<td>Tumor Institute, Chinese Academy of Medical Sciences</td>
<td></td>
</tr>
<tr>
<td>6. National Key Lab of Experimental Blood</td>
<td>Blood Research Institute, Chinese Academy of Medical Sciences</td>
<td>Hunan Medical University</td>
</tr>
<tr>
<td>7. National Key Lab of Medical Genetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. National Key Lab of Medical Molecular Biology</td>
<td>Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences</td>
<td></td>
</tr>
<tr>
<td>9. National Key Lab of Medical Neuro-biology</td>
<td>Shanghai Medical University</td>
<td></td>
</tr>
<tr>
<td>10. National Key Lab of Nucleic Medical Sciences</td>
<td>Jiangsu Medical Institute of Atomic Energy</td>
<td></td>
</tr>
</tbody>
</table>

*Source: Huang, Wang, Zhang and Zepeda, 2004*