BIOTECHNOLOGICAL INNOVATIONS IN ASIA: POLICY AND GOVERNANCE CHALLENGES

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EXECUTIVE SUMMARY

Biotechnological innovations, or bio-innovations, which include both conventional techniques as well as new approaches based on recombinant DNA techniques, offer potential benefits to the developing countries and to the poor of Asia. These potentials can only be realized when proper policies and governance mechanisms are in place so that countries and citizens are persuaded that a balanced approach to the technology benefits all while avoiding or mitigating risks that may accompany such innovations. Research activities that result in such effective mechanisms are therefore a priority. Indeed, while some countries in the region have the scientific and technological expertise, they are not likely to benefit from new biological technologies unless they establish the necessary policies and institutions. These include developing and implementing policies that:

- Establish a clear and definite national strategy that lays down priorities and goals of the country with respect to bio-innovations in general and modern biotechnology in particular;
- Promote a supportive environment for scientific innovations, including providing the right set of incentives and subsidies for domestic scientists;
- Provide a coherent and up to date legal framework, consistent with international standards, including an appropriate intellectual property rights (IPR) regime;
- Establish an effective, cost-efficient, credible, and transparent and biosafety, and more broadly, biosecurity regime that allows societies to have confidence on regulatory bodies;
- Take into account and incorporate into decision-making processes the socio-economic impacts of modern biotechnology, including the religious, cultural and ethical implications in a region as diverse as Asia; and,
- Institutionalize processes that are directed at educating the public on scientific innovations, with the intent of ensuring wide participation in the making of decisions and the sharing of benefits.

This strategy paper reviewed the state of biotechnology innovations in Asia, covering agriculture, health, environment and industry, with particular attention on policy and governance issues. It also reviewed the policy research supported by other institutions and agencies like the United Nations Environment Program-Global Environmental Facility (UNEP-GEF) Biosafety Projects, Food and Agriculture (FAO) Capacity Building Project in Asia, the United States Agency for International Development (USAID) Program for Biosafety Systems, the International Service for the Acquisition of Agri-biotech Applications (ISAAA) Technology Transfer Projects, etc.. Based on these reviews, the paper identified key and outstanding policy research questions, and recommended areas for engagement and investment by the Innovation, Policy and Science (IPS) Program of the International Development Research Centre (IDRC).

Most of the data available are on agricultural applications. Most of the current research being supported in this area in the region is focused on scientific research, both on technology development and on ecological risk assessment. Very little policy research, if at all, is being conducted and thus gaps in this area need to be addressed.

While there is an increase in Asia in the medical, industrial, and other non-agricultural applications of biotechnology, data are sparse and probably not up to date. The policy framework to support the research and the commercialization for medical, industrial and non-agricultural biotechnology applications (except in Singapore and India) is inadequate. Because most capacity-building programs, projects and activities are focused on agriculture, these sectors might be an area that IDRC might want to emphasize in its own investments in the region.

The objective of such an investment should be two fold: (a) how research can help in directing researchers to applications of the technology that benefit the region's poor; and, (b) how public interest can be incorporated into the policy and regulatory decisions that will have to be made with regards to these applications. These two questions are relevant as well to the other governance challenges and issues that the emergence of modern biotechnology are posing in Asia. Six areas are recommended as priorities for research. These include:

- *Determining national priorities on biotechnology;*
- *Encouraging private sector investment;*
- *Managing intellectual property rights (IPR);*
- *Applying precaution to trade and effects on bio-innovations;*
- *The appropriate role of local governments; and*
- *Regional cooperation and collaboration.*

I. Introduction

In recent years, technology advancement has been used as a strategy to cope with and spur development. One of the sectors in technology that has been rapidly advancing and is being used to address development is biotechnology, now widely touted as a key technology of the future.

Biotechnology has been around for many years. In fact, for many centuries, human beings have been using living organisms (plants, animals, microorganisms) to make or modify products, improve plants and animals, or develop microorganisms for specific uses. Biotechnology, however, has evolved over the years. From traditional biotechnology (e.g. use of organisms in producing wine, vinegar, bread, etc.) to conventional or selection breeding, advances in science and technology have made it possible for new technologies, such as modern biotechnology, to be developed. In particular, genetic knowledge is growing, improving and paving the way for new products, whether for agriculture, industry, health and medicine, and the environment.

Modern biotechnology and its products promise benefits to poor countries and communities. This includes the developing countries of Asia, particularly those with large populations and high incidence of poverty. The technology's potential benefits include improved crops, new medicines, enhanced environmental technologies, and better industrial products. At the same time, the application of modern biotechnology requires that environmental, health, and socio-economic risks be addressed through best practices in policy and governance that address the challenge of the technology[1].

This challenge to take a balanced approach to modern biotechnology is particularly acute in Asia where governments and societies are grappling with decisions on how to apply and proceed with the technology[2]. Should it be "full speed ahead" given the potential benefits or should decisions be more precautionary? What kind of policy and governance mechanisms must be put into place to maximize benefits and reduce risks? Countries like China, India, Philippines, Malaysia, Vietnam and Indonesia have the human resources as well as the scientific knowledge and infrastructure to utilize the technology, positioning many of them to take leading roles in its development and commercialization. But to succeed in becoming technology leaders, adequate policy and governance systems must be in place, including on intellectual property and biosafety. These systems must likewise be diverse enough to include measures that translate scientific knowledge into goods and services.

Technological innovations, particularly biotechnology innovations or bio-innovations, are associated with translating this scientific knowledge into processes and products under a complex market and regulatory regime. Commercializing a bio-innovation requires an understanding of the end uses of the technology that begins with identifying the

[1] Lindsey Fransen et. al., *Integrating Socio-economic Considerations into Biosafety Decisions: The role of public participation*, Washington DC: World Resources Institute (2005).
[2] Sachin Chaturvedi, *Biotechnology and Development: Opportunities for Asia,* New Delhi: Academic, Academic Foundation (2004)

innovation, defining the market potential, evaluating the intellectual property position, assessing commercialization, and finally, selling the product[3]. In turning scientific knowledge into commercially viable technologies, the transfer of intellectual property can be formalized through mechanisms such as license agreements, joint ventures and formation of start-up companies.

Bio-innovation requires a lot of resources and involves high levels of risk such that not one single innovator can effectively generate and commercialize it. An innovation systems approach is advisable considering that it can harness the resources needed. A systems approach involves the interactive participation of key players such as public research institutes, universities, industry and government that can provide the environment supportive of technological innovation. However, such a system cannot be implemented without the essential infrastructures to support and facilitate the interactions. These infrastructures can range from local and international partnerships and networks between and among key players; participation of other stakeholders; policy instruments that provide incentive measures and enable business incubation and development; regulatory frameworks that ensure an adequate level of protection while recognizing the benefits of current and emerging biotechnologies; domestic and international public and private investments and financing mechanisms that support priority research and technological innovation, human resources development, physical infrastructure, and business development[4].

While some countries in Asia have adequate innovation systems, many others are still faced with inadequate systems characterized by limited human resources, funds, physical infrastructure, and appropriate policy instruments. These same constraints face developing countries of Africa. In the draft report of the High-Level African Panel on Modern Biotechnology of the African Union (AU) and the New Partnership for Africa's Development (NEPAD), the use of regional networks to enable countries to pool resources and thereby facilitate the promotion of technological innovation was recommended. The same report likewise contends that the emergence of regional innovation communities coupled with the development of local innovation areas or clusters can be critical drivers for development. Local innovation areas or clusters can serve as centers of technological activity characterized by a concentration of research institutions, universities, private sector firms and associated industries and entrepreneurs. This concentration of technology activity can have spillover effects in terms of linkages, complementarities and synergies and further result to increased capacity, productivity and accelerated growth[5].

The focus of this strategy paper is the link between bioinnovations and policy and governance. It takes the systems approach to bio-innovations and refers to bio-innovation not only in terms of generation of scientific knowledge but more importantly, stresses its application in the production of goods and services.

[3] McGahon, B. and G. Willliams. 2001. New I.D.E.A.S. for biobusiness. The Irish Scientist Year Book. Available online at http://www.irishscientist.ie/2001/contents.asp?contentxml. Retrieved 13 August 2006.
[4] Mugabe, J. et al. 2006. Freedom to innovate: biotechnology in Africa's development. Draft Report of the High-Level African Panel on Modern Biotechnology of the African Union (AU) and the New Partnership for Africa's Development (NEPAD).
[5] Ibid., p.16.

Most of the current work being done, and the research being supported, emphasizes the scientific and the technological aspects of biotechnology and its application to the production of goods and services. There is very little work being done that focuses on the policy and governance implications of the innovations and to not address these is short-sighted.

Asian countries that have the scientific and technological expertise are not likely to advance in the responsible use of biotechnology, for example through wide spread commercialization or adoption by the poor, unless there are adequate policy and governance systems in place that assure the public in these countries that the benefits of the technology outweigh the risks – and that the latter can be reduced and mitigated. Such policy and governance systems should also address the needs of public and private sector technology developers. Research that emphasizes the policy and governance aspects is therefore clearly needed. These include developing and implementing policies that:

- Establish a clear and definite national strategy that lays down priorities and goals of the country with respect to modern biotechnology;
- Promote a supportive environment for scientific innovation, including providing the right set of incentives and subsidies for domestic scientists;
- Provide a coherent and up to date legal framework, consistent with international standards, including an appropriate intellectual property rights (IPR) regime;
- Establish an effective, cost-efficient, credible, and transparent and biosafety, and more broadly, biosecurity regime that allows societies to have confidence on regulatory bodies;
- Take into account and incorporate into decision-making processes the socio-economic impacts of modern biotechnology, including the religious, cultural and ethical implications in a region as diverse as Asia; and,
- Institutionalize processes that are directed at educating the public on scientific innovations, with the intent of ensuring wide participation in the making of decisions and the sharing of benefits.

II. State of Biotechnology Innovation in Asia

According to the Ernst & Young Global Biotech Report 2006, the biotechnology sector in the Asia Pacific, particularly in India and China, has been growing faster than ever before. In fact, performance of the sector in this region outpaces the rest of the world, with a scorching 46% increase in revenues and significant progress toward profitability. Government emphasis on bio-innovation as a strategic priority and a focus on strategic niches are helping countries' competitiveness and foreign companies are increasingly drawn to the region with growing drug markets, economic liberalization, and stronger intellectual property protections. Indeed, the region is poised to become the major hub in producing generic biopharmaceutical drugs, stem cell research, and bioinformatics and clinical data management. Just recently, India announced plans to build 10 new biotech parks by 2010. Malaysia is also hoping to clinch a $600m deal with three international biotechnology companies, to carry-out contract manufacturing and research on diagnostic kit and vaccine production. It offers tax breaks and other incentives to potential investors.

On the other hand, Singapore's strategy is to attract scientists to head the country's research activities on molecular biology and biomedical research. According to analysts, Singapore's biotech pipeline shows promise, which includes lead compounds for antibiotics, vaccines, and drugs for cancer, infectious and metabolic diseases. [6]

Given the prominence of agriculture in many Asian countries, there continues to be a major focus however on agricultural biotechnology. Some Asian countries have adopted the technology and are now growing transgenic or genetically modified (GM) crops commercially. Worldwide, 14 countries are considered biotech mega-countries or countries which grow 50,000 ha or more of transgenic crops. Eleven of these are developing countries while 10 are industrial. Of these biotech-mega countries, 4 are in Asia: China, India, Philippines and Iran. India shows the largest annual increase, with almost a three-fold increase from 500,000 ha in 2004 to 1.3m ha in 2005. About 7.7m poor farmers from developing countries have benefited from transgenic crops, with countries in Asia benefiting the most (China, 6.4m; India, 1m; Philippines, around 50,000)[7].

Four principal crops dominate the GM market, namely: soybean (60% of the global biotech area), maize (24%), cotton (11%), and canola (5%). GM soybean is grown commercially in Argentina, Australia, Brazil, Canada, *China*, Czech Republic, European Union (EU), *Japan*, *Korea*, Mexico, *Philippines*, Russia, South Africa, Switzerland, Uruguay, and the United States of America (USA). GM maize is commercially grown in the USA, Argentina, Canada, South Africa, Spain, *Philippines*, Uruguay, Honduras and Germany. GM cotton is grown in *China*, *India*, Australia, USA, Mexico, Argentina, South Africa and Colombia. GM canola is approved for food use in the USA, Australia, Canada, *China*, EU, *Japan*, and the *Philippines*.[8] *Iran* and *China* are the most advanced countries in the commercialization of transgenic rice, with Iran commercially growing it for the first time in 2005 (~4,000 ha) and China having already field-tested in pre-production trials and expecting approval shortly [9].

James (2005) further reports that in terms of genetic traits, herbicide tolerance (in soybean, maize, canola and cotton) has consistently been the dominant trait since 1996, followed by insect resistance (in maize and cotton), and stacked or combined genes for herbicide tolerance and insect resistance (in maize and cotton). Other traits that are in various stages of development are for fungal resistance, virus resistance, bacterial resistance, and improved agronomic properties and improved quality. In terms of global market value (based on the sale of GM seed plus technology fees), transgenic crops posted an estimated US $5.25b profit representing 15% of the US $34.02b global crop protection market in 2005 and 18% of the US $30 billion global commercial market.

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6 Ernst & Young, *Beyond Borders: Global Biotechnology Report 2006*, Available online at http://www.ey.com/global/download.nsf/International/Beyond_Borders_2006_20th_Anniversary_Report_Summary/$file/BeyondBorders2006Teaser05110689191FINAL.pdf

[7] James, C. 2005. Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34. ISAAA: Ithaca, NY.

[8] ISAAA Pocket K No. 2, 2005

[9] James, C. 2005. Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34. ISAAA: Ithaca, NY.

At present, most biotechnological research is focused on agriculture and food and is undertaken by private corporations such as Monsanto, Syngenta and Novartis. Public sector investments, particularly in developing countries, are very limited due to high costs and uncertain return on research investment. Moreover, many countries in Asia either lack or have weak legal, institutional and administrative mechanisms, and scientific and technical capacity to address concerns about transgenic organisms, or are just in the initial stage of understanding the technology and the potential benefits and risks associated with it.

Aside from agriculture, the primary focus of bio-innovation development in Asia is health. Progress in genomics coupled with Asia's high capability in medical sciences provides a significant opportunity for the region to become a major player in medical biotechnology and biopharmaceuticals. In the context of developing Asian countries, bionnovation can be a primary tool, among others, for molecular diagnosis of diseases, development of recombinant vaccines and production of recombinant therapeutic proteins.

In 2000, the Cartagena Protocol on Biosafety (the Protocol) was adopted by more than 130 countries as a means to ensure adequate safety measures for the transfer, handling, and use of living modified organisms (LMOs) derived from modern biotechnology. It entered into force in September 2003 and as of April 2006, a total of 132 countries have ratified or acceded, including 33 countries in the Asia-Pacific region[10]. As discussed later in this paper, several multilateral, bilateral and private donors have provided the necessary assistance to developing countries in building their capacity to manage modern biotechnology and fulfill their obligations to the Protocol.

East Asia

In the whole of Asia, *China* has taken the lead in biotechnological innovations. The government of China is fully supportive of research and development (R&D) and commercialization of biotech crops as a means to improve food security, increase productivity, and improve its position in international agricultural markets as well as in the field of biotechnology development. It has a National Program on High Technology Development and a National Program on the Development of Basic Research that reflect the government's interest to invest in biotechnology. China is regarded as having one of the largest trained workforce on biotechnology research in the world. They have many institutions and scientists engaged in R&D and has world class infrastructure for biotechnology research, including development of genetically modified organisms (GMOs). Given these advantages, scientific and technical collaboration between and among institutions in China and in the region would be beneficial.

China is the 5th largest commercial grower of GM crops in the world and the largest in Asia (James, 2005). At present, there are more than 100 GM plants with various traits

[10] See Cartagena Protocol on Biosafety Status of Ratification and Entry into Force. Available online at http://www.biodiv.org/biosafety/signinglist. Retrieved 15 May 2006

such as insect/ disease resistance and quality-improvement. Many of these plants (cotton, bean, potato, tobacco, maize, etc.) are under field trials while others (insect-resistant cotton and anti-virus tomato) have been commercialized. Progress has also been made in research on biotech animals (mouse, rabbit, goat, chicken, cattle and pig), fish and microorganisms.

From 1997 up to the present, China continues to develop, improve and harmonize its regulations on biotechnology. It received support from the UNEP-GEF Pilot Biosafety Enabling Activity and Implementation Project to develop a national biosafety framework (NBF) and to implement it in support of its obligations under the Cartagena Protocol on Biosafety to which it is a party. However, the capacity for biosafety in China needs to be improved, including those for handling requests, risk assessment and management of living modified organisms (LMOs), and mechanisms for public participation. It also has to improve its public awareness and education campaigns in order to increase public understanding of biotech products and biosafety issues. The administrative structure for biosafety regulation which involves interdisciplinary and intersectoral coordination and cooperation needs to be strengthened or streamlined. Efforts are underway to ensure that policies reflect a balance between and among biotechnology development, trade and industry, and environmental considerations in meeting the requirements of the Protocol and China's needs. [11]

Mongolia, the Democratic People's Republic of Korea (DPR of Korea) and the Republic of Korea (South Korea) all recognize the benefits and risks associated with biotechnology and have recently drafted their biosafety frameworks to address biosafety concerns. DPR of Korea also has a draft Law on the Management of GMOs. However, much needs to be done to strengthen the legal, institutional, administrative and technical systems currently in place in these countries. For example, after the infamous falsification case involving Korean stem-cell and cloning expert, Woo Suk Hwang, South Korea is trying to rebuild its position and reputation as a leader in stem cell research. The South Korean government is still committed to making the country one of the top three leading countries in stem cell research by 2015, and recently announced its intention to allocate US $846m in 2006 alone for biotech research and development, with more than half of those funds allotted for stem-cell research. The figure marks an 18.9% year-on-year increase in investment in this field[12].

Taiwan, through the Taikong Corporation has launched several glow-in the-dark genetically modified (GM) fish (purple glow with gene from a coral, green glow with gene from a jellyfish) and has recently developed a GM fish that glows two separate colors. The fish are on sale in Taiwan and are waiting for approval for sale in Singapore. Opposition, however, continues to mount against the use of GM fish as pet fads and

11 See UNEP-GEF Project on the support for the implementation of the NBF of China. Available online at http://www.unep.ch/biosafety/Implementation/Countries/China-State-of-developments.pdf. Retrieved 15 April 2006

12 South Korea Allocates $846 Million For Biotech R&D, The Biotech Weblog (1 June 2006). Available online at http://www.biotech-weblog.com/50226711/south_korea_allocates_846_million_for_biotech_rd.php

concern has also been raised about the potential effects into the environment should these escape or are released into the wild[13].

Southeast Asia

Many countries in Southeast Asia recognize the importance of biotechnological innovation and biosafety issues. Most countries, with the exception of Singapore (discussed in a later section on non-agricultural applications), have focused on bio-innovations in agriculture that are in various stages of development. On the issue of biosafety, Cambodia, Indonesia, Lao PDR, Malaysia, Thailand, and Vietnam have ratified or acceded to the Protocol. Others are in the process of ratifying. Most countries in the region have a biosafety regulation in place largely due to the support provided by the UNEP-GEF Projects on Development of NBFs which aim to prepare countries fulfill their obligations under the Protocol.

Indonesia

Indonesia has accorded biotechnology a high priority since 1985 with the establishment of a National Committee on Biotechnology by the State Ministry of Research and Technology. The Committee formulated policies and programs on biotechnology, including activities related to IPR and release of GMOs. In 1993, Indonesia started R&D on agricultural biotechnology. Most of the institutions involved in biotechnology are government institutions and attached agencies, research centers of the Ministry of Agriculture and public universities. They have adequate infrastructure and trained technical staff who are mostly engaged in conventional biotechnology but with a few who have advanced to work on modern biotechnology[14].

In 1997, Indonesia passed the Decree of the Minister of Agriculture on the Provision of Biosafety of Genetically Engineered Agricultural Biotechnology Products. This was amended in 1999 by the Joint Decree of Four Ministers (Agriculture, Forestry and Estate Crops, Health, and Food and Horticulture) on Biosafety and Food Safety of Genetically Engineered Agricultural Products. A National Biosafety Committee was created to assist the regulatory offices in assessing biosafety and/or food safety of GMOs, regulation of import/export, and field evaluation and monitoring of GMOs. The Joint Decree, however, lacks a provision or mechanism for compulsory public information, timeframe, and has a stringent procedure for R&D, among others. Indonesia has recognized the need to amend the Joint Decree to address these weaknesses and to include the Ministry of Environment as part of the regulating ministries.

Indonesia is a party to the Convention on Biological Diversity (CBD) and the Protocol. In 2002, it received support from the UNEP-GEF Projects on Development of NBFs to develop a biosafety framework in collaboration with the Ministry of Environment, the

[13] Clarke, M. 2003. Purple GM fish launched at biotech show, Independent Online. Available online at http://www.practicalfishkeeping.co.uk/pfk/pages/item.php?news=55

[14] FAO. 2004. Benchmark document on the needs and present status of the capacity building in biosafety of GM crops in Asia.

Indonesia Agency for Agricultural Research and Development, the Department of Agriculture, the Indonesia Institute of Sciences, and other stakeholders. The Project also resulted in the drafting of a regulation for biosafety and food safety of genetically engineered products, guidelines for risk assessment and risk management of LMOs, and established the Biosafety Clearing House (BCH) for data exchange and public participation issues [15].

Indonesia has required the labeling of packaged products containing LMOs with a threshold limit of 5%. It is now proposing that R&D activities go through a special or less stringent procedure, that issues on liability and redress be addressed, and that biosafety requirements do not hamper technological development. Indonesia has also formulated a patent law and legislation on IPR. Mechanisms for plant variety protection are also available.

Compared to other countries in the region, Indonesia's capacity to address the demands of modern biotechnology is quite high but it still needs to further improve its infrastructure, develop expertise on risk analysis, and strengthen its biosafety-related regulatory measures. Public awareness and education, and public-private partnerships also need strengthening.

Malaysia

Malaysia fully supports the development and promotion of biotechnology. In 1995, it created a National Biotechnology Directorate (BIOTEK) under the Ministry of Science, Technology and the Environment (MoSTE) responsible for strengthening and developing the biotechnology industry. BIOTEK established Biotechnology Cooperating Centers responsible for coordinating research on plants, animals, food, molecular biology, medical, environment, industry and biopharmacy.

In 1997, Malaysia passed the National Guidelines for the Release of GMOs into the Environment which was prepared by the Genetic Management Advisory Committee (GMAC), a national advisory body which provides technical advice to MoSTE on matters related to biotechnology and biosafety. The guidelines are administrative in nature and needs legislation to ensure compliance. Malaysia has ratified the Protocol and has formulated a Biosafety Bill to enable it to meet its obligations under the Protocol. The Bill will provide the legal and institutional base for the implementation of a national biosafety framework and the creation of a National Biosafety Board.

Malaysia needs to develop its capacity, particularly that of MoSTE and other key government agencies, to enable it to fully implement the proposed law on biosafety. At present, there is much reliance on the expertise of the GMAC which is comprised mostly of volunteer scientists. In 2005, it received a United Nations Development Program (UNDP)-GEF support to build capacity in implementing the Protocol. In particular, it has

[15] Ministry of the Environment-Republic of Indonesia. 2004. National Biosafety Framework of the Republic of Indonesia. Available online at www.unep.ch/biosafety/development/countryreports/IDNBFrep.pdf. Retrieved 10 April 2006

identified the need to look at IPR issues and public participation in decision-making. It is expected that by the end of the project, Malaysia will have established a national biosafety framework, an information dissemination system as well as broad public participation on this issue.

Malaysia's 9th Malaysian Plan (2006 - 2010) identified biotechnology as one of the areas for advancement, emphasizing research, development and commercialization, strategic technology acquisition, business and entrepreneurship development, and infrastructure for the development of its biotechnology industry. About US $ 545m has been allocated for biotechnology, 45% of which goes to physical infrastructure development [16]. FAO (2004) reports that Malaysia has recently developed the Biovalley Initiative which consists of 3 new institutions for research on genomics and molecular biology, neutraceuticals and pharmaceuticals, and agricultural biotechnology. The Initiative was recently renewed and renamed BioNexus and is projected to help Malaysia compete in the pharmaceutical and biotechnology sector when it is launched in August 2006. Bionexus is essentially a hub or a network of centers of excellence of companies and institutions which focus on bio-innovations[17].

Philippines

The Philippine government has been supportive of biotechnology since the 1970s. Biotechnology research and development started in 1979 with the establishment of the National Institute of Molecular Biology and Biotechnology at the University of Philippines in Los Banos (BIOTECH-UPLB) followed by three other biotechnology research institutes in Manila, Diliman, and Iloilo. These institutes moved forward R&D agenda in agriculture, medicine, fisheries and the industry.

There are currently several public sector R&D projects on biotech crops at experimental levels. Most of the genetically engineered products, particularly GM food, feed and plants, currently in the country are imported. Some research institutions and universities are equipped with the appropriate infrastructure to conduct work on modern biotechnology, including access to facilities at International Rice Research Institute (IRRI) located in Los Banos, Laguna. However, support is needed to improve infrastructure in national and local institutions. There are many trained scientists but these are mostly based in universities. There is a need to develop and improve the legal, scientific and technical capacity of more staff within the government departments and institutions, and other stakeholder groups.

The Philippines is a party to the CBD and a signatory to the Protocol. Even prior to its becoming a full party to the CBD, the Philippines has recognized the importance of biotechnology and biosafety issues. In 1990, Executive Order (EO) No. 430 was issued establishing the National Committee on Biosafety of the Philippines (NCBP). The NCBP

[16] Biotechnology for wealth creation, 9th Malaysian Plan 2006-2010. Available online at http://www.biotechcorp.com.my/biotechinmalaysia/chapter6.pdf. Retrieved 15 June 2006.
[17] Ismail, Z.I. 2006. Malaysian PM to launch biotech hub, New Strait Times, 24 July 2006. Available online at http://www.bic.org.my/?action=news. Retrieved 31 July 2006.

developed guidelines for contained use of GMOs and subsequent guidelines on planned release of GMOs and potentially harmful exotic species. In 2002, The Department of Agriculture (DA) issued Administrative Order (AO) No. 8 providing the rules and regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology. In 2006, EO No. 514 was issued establishing the NBF for the Philippines[18]. The NBF applies to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making biosafety decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles. The NCBP Guidelines and DA-AO 8 continue to be in force and effect unless amended by the issuing departments or agencies. With the issuance of EO No. 514, the Philippines will need to improve and strengthen the existing legal, institutional, and technical capacity of key stakeholders, both at the national and local levels, to address the requirements of the Order. It will also need to harmonize and streamline its regulatory mechanisms and administrative systems to avoid duplication and overlapping of functions and to ensure a transparent and efficient decision-making process. Other laws that impact on biotechnology and biosafety regulation in the Philippines include the Agriculture and Fisheries Modernization Act (AFMA) which supports technology-based agriculture, the Wildlife Resources Conservation and Protection Act which has explicit provisions on biosafety and bioprospecting[19], and the Intellectual Property Code which provides for patent protection, copyrights, industrial designs and trademarks but does not allow patenting of plants or animals, except microorganisms.

Capacity building efforts are currently being conducted by interest groups. The ISAAA, in collaboration with the League of Municipalities of the Philippines, is developing modules for a training course on biotechnology for local chief executives and concerned local government officials as part of its Capability Building of Local Government Units (LGUs) for Biotechnology Program. The Program intends to build the capabilities of LGUs applying biotechnology for local development. A similar Program should be developed for other stakeholders.

The DA recently announced its intention to embark on a Php1-Billion Integrated Biotechnology Program that will use indigenous plant species for value-added processing into food, pharmaceuticals and cosmetics. An incubation facility will be created and capital venture fund will be infused to help leapfrog the biotechnology industry (Aguiba, 2006). Incubators can be a single facility shared by many small, entrepreneurial start-up ventures. There are, however, existing science and technology or research parks in the

[18] Executive Order No. 514 "Establishing the NBF, prescribing guidelines for its implementation, strengthening the NCBP and for other purposes" was signed by Philippines President Arroyo on March 17, 2006 to better respond to the challenges presented by further advances in modern biotechnology. It was formulated through a multistakeholder consultation process with funds provided by the UNEP-GEF Project on the Development of NBFs.

[19] Section 14 of the Act allows prospecting of biological and genetic resources subject to certain conditions. In 1995, EO No. 247 was issued prescribing guidelines and establishing a regulatory framework for the prospecting of biological and genetic resources, their by-products and derivatives, for scientific and commercial purposes, and for other purposes". This was subsequently amended in 2005 by a Joint Department of Environment and Natural Resources (DENR) - Department of Agriculture (DA) - Palawan Council for Sustainable Development (PCSD) Administrative Order pursuant to the Wildlife Resources Conservation and Protection Act. Section 16 of the Act also provides for biosafety consideration of all activities on genetic engineering.

Philippines that already include business incubators and technology transfer services and these could be tapped by the biotechnology industry. Regional technology innovation centers could also be developed from existing facilities. Simultaneous with this initiative, the Department of Science and Technology (DOST) also launched its Biotechnology R&D Agenda for 2006-2010 classified into food, industrial, environmental, medicine and health, agriculture and forest, marine and aquatic biotechnology. Under the same agenda, the technologies will be separated into GM and non-GM. The Philippines is aiming to establish its niche in the booming global bio-enterprise using biotechnology as a potential export-revenue generator. In fact, the Export Development Council has recently included biotechnology as a new sector in its Cluster Strategy for export development.

Thailand

Thailand has major biotechnology programs based at the National Centre for Genetic Engineering and Biotechnology (BIOTEC) and the Department of Agriculture. It has several laboratories, trained professionals and universities which can be tapped to form a network but the current infrastructure, human and financial resources need to be further improved. It also spearheaded, through BIOTEC, a collaborative effort to establish the Southeast Asian Regional Training Center in Biotechnology composed of select research institutes in the Asia region and international organizations engaged in capacity building. The Training Center runs as an independent program under BIOTEC and organizes its own training program or form partnerships with various organizations to co-organize capacity building activities.[20]

Thailand's advancement in environmental biotechnology and related areas is largely fueled by the collaboration between and among its Biochemical Engineering and Pilot Plant Research and Development Unit, BIOTEC and King Mongkut's University of Technology Thonburi. This approach to shared resources (e.g. researchers, facilities and funds) has provided a successful solution for implementing research programs in Thailand. Researches and technology transfer services to the industry are focused on 4 major areas: algal biotechnology, sensor technology, microbial bioprocess development, and waste utilization and management.

Thailand is also considered to be one of the countries in Asia to pioneer the drafting of biosafety guidelines. It is developing GM crops (e.g. insect-resistant, virus-resistant, etc.) and has field-tested GM potato and cotton until protests mounted over GM cotton seeds in 1999. In the early 2000s, controversy over GM papaya erupted. Heavy protests led the Thai government to ban all field tests of GM crops.

Thailand is a party to the CBD and the Protocol. In 1992, it passed the Biosafety Guidelines on Genetic Engineering and Biotechnology for laboratory work, field-work and planned release of GMOs. It also created National Biosafety Committee and a

[20] Mugabe, J. et al. 2006. Freedom to innovate: biotechnology in Africa's development. Draft Report of the High-Level African Panel on Modern Biotechnology of the African Union (AU) and the New Partnership for Africa's Development (NEPAD).

number of Institutional Biosafety Committees. There is no law directly addressing GMOs but there are laws that are complementary such as the Plant Quarantine Act, Plant Act, and Plant Variety Protection Act. Specific Departments are responsible for specific sectoral concerns. The Department of Agriculture is responsible for plants, the Department of Livestock Development for animals and animal feed, the Department of Fisheries for fish and aquatic animals, and the Royal Forest Department for wild animals.

Vietnam

The Government of *Vietnam* puts importance to the development of science and technology, including biotechnology. In 1994, the Government issued Resolution 18/CP which laid the development of biotechnology in Vietnam. At present, however, the biotechnology capacity of Vietnam is more oriented towards conventional rather than modern biotechnology but it is moving towards this direction. The Institute of Biotechnology and some institutes of the Ministry of Agriculture and Rural Development (MARD) conduct research work on the development of GMOs but the status of these developments is not known.

Vietnam is a party to CBD and the Protocol. With the assistance of the UNEP-GEF Project on Development of NBFs, Vietnam drafted a decree on Biosafety Management and Regulation of GMOs and their Products which is now under consideration by the government. It also recognized the need to formulate a Law on Biodiversity which includes state management of biosafety and biotechnology products. Several ministries have also formulated their own biosafety regulations pending the issuance of the Decree.

There are currently no legal instruments directly addressing modern biotechnology but support legislations are in place such as the Law on Science and Technology, Biodiversity and Community Knowledge Protection Act, Law on Environment Protection, Law on Protection of Animals, Plants, and Environment etc. Although there is still no Biosafety Decree in place, the Ministry of Natural Resources and Environment (MONRE) has been given the responsibility of managing the biosafety aspects of GMOs. Six other ministries (Agriculture, Aquaculture, Science and Technology, Health, Finance and Trade) are also involved. Vietnam recognizes that biosafety cuts across sectors and involves many stakeholders and that it is important to have clearly defined responsibilities, integrated planning and coordination among concerned ministries and other sectors. Moreover, it also recognizes the need to develop and strengthen mechanisms for public deliberations on biosafety- related issues. At present, Vietnam is not a signatory to the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO). It does not have patent laws that address biotechnological interventions and use of biotechnology-derived products nor does it have any IPR legislation[21].

[21] Ministry of Natural Resources and Environment- Vietnam. 2004. The National Action Plan 2010 for the implementation of the Cartagena Protocol on Biosafety. Available online at http://www.unep.ch/biosafety/development/Countryreports/VNNBFrep.pdf. Retrieved 15 April 2006.

Vietnam recently announced its plan to build a 23-hectare biotechnology center in Ho Chi Minh City as a center for research and application of genetic technology in production, particularly of vaccines and pharma-biological products. The center will serve as a local innovation center that will receive, transfer and provide consulting services on biotechnology, train human resources and commercialize biotechnology products. It is expected to be completed by 2010. Vietnam needs to strengthen its human resources in R&D, commercialization and in developing regulatory measures and has started staff training in anticipation of its development needs.[22]

Cambodia, Lao PDR, Myanmar

In Cambodia, Lao PDR and Myanmar, biosafety and biotechnology are relatively new issues and capacity at the individual and institutional levels is low.

Cambodia has a National Biodiversity Strategy and Action Plan (NBSAP) which identifies the development and implementation of a biosafety framework as one of the priority actions. Its NBSAP also provides for a hierarchy of measures - regulation, management or other means of control- to address biotechnology and biosafety issues. However, Cambodia is more oriented towards conventional biotechnology and is aware that it is not capable of developing any LMOs and is likely to be a user rather than a producer of LMOs.

Cambodia is a party to the Protocol. It recognizes the need to develop its national strategy and framework on biosafety and build national capacity on modern biotechnology to enable it to meet the challenges of the technology as well as address gaps in technical, infrastructure, and institutional capacities. With funds from the UNEP-GEF, Cambodia drafted a national law on biosafety to deal with transboundary movement of LMOs and risk assessment and management mechanisms for the release of LMOs into the environment. It has also drafted a Sub-decree on biosafety to complement the draft law.[23]

In *Lao PDR*, policies on biodiversity and human health are incorporated in the National Socio-Economic Priority Program which serves as a major reference for the national planning system and for defining the national investment priorities. Of these priority programs (food production, commercial production, stabilization and reduction of shifting cultivation, rural development, infrastructure development, improved socio-economic and foreign economic relations, human resources development and services development) achieving permanent food security, preserving the country's natural resources, and developing the national human resource potential, are given the highest importance. Lao PDR has also approved a National Policy on Science and Technology, a National Biodiversity Strategy, a National Strategy on Environment Education and Awareness, a National Strategy on Environment, and a National Policy on Education, Agriculture and Forestry, Public health, and Processing Industry. A National Policy on

[22] HCM City to build regional biotechnology centre, VNA, 22 December 2005. Available online at http://www.agbiotech.com.vn/en/?mnu=preview&key=388. Retrieved 13 August 2006.

[23] Ministry of Environment. 2004. National Biosafety Framework of the Kingdom of Cambodia. Available online at http://www.unep.ch/biosafety/development/countryreports/KHNBFrep.pdf. Retrieved 15 April 2006.

Biotechnology and Biosafety has been drafted with support from the UNEP-GEF Project on Development of NBFs. The objective of the policy is to promote biotechnology R&D for the conservation, sustainable use and the fair and equitable sharing of the benefits from the use of genetic resources and contribute to the objectives of the Protocol. Research and policy priorities have been identified, including those on genetic identification and database, in situ and ex-situ conservation, genetic resources access and benefit sharing, traditional knowledge, IPR, and biosafety regulation. Lao PDR intends to translate the National Policy on biotechnology and biosafety into a national framework, regulations, technical guidelines, plans and projects for the management, and monitoring of biotechnology and LMOs[24].

Myanmar recognizes that biotechnology is an important tool for economic development of the country and that biosafety is an important issue. The development of biotechnology in the country is in its early stages and utilization of GMOs is comparatively low. Research on the impacts of LMOs to the environment is non-existent and information, knowledge and skills on the application of biosafety measures is low.

South Asia

South Asia, particularly India, Pakistan, and Bangladesh, is home to more than a billion people. Agriculture plays a major role in alleviating poverty and providing food security to a majority of the population in these countries, and biotechnological innovations are considered a key component in fulfilling this role.

Bangladesh

Bangladesh recognizes the importance of biotechnology but it has currently no national policy or strategy or structured program on biotechnology development. A comprehensive biotechnology program composed of 6 program areas has been proposed. These program areas include: (1) formulation of a national policy on biotechnology and establishment of a National Authority for Biosecurity; (2) formulation of regulatory measures to generate, develop, acquire and use biotechnology; (3) strengthening of institutions and fostering inter-institutional collaboration, public-private sector cooperation and research-extension-farmer -market linkage; (4) development of human resources development, especially in upstream research areas of modern biotechnology and in enabling regulatory measures; (5) public awareness and education; and, (6) priority project areas based on country needs and prospects. To boost biotechnology, a National Institute of Biotechnology has been established under the Ministry of Science and Information and Communication Technology (SICT). The Ministries of Agriculture, Fisheries and Livestock, and Environment and Forest, are also keen to strengthen their capacities in biotechnology but coordination between and among these ministries need to be addressed to avoid duplication and overlapping of functions.

[24] Science Technology and Environment Agency. 2004. National Biosafety Framework of Lao PDR. Available online at http://www.unep.ch/biosafety/development/Countryreports/LAnbfFinal.pdf. Retrieved 15 April 2006.

Bangladesh has a biosafety guideline prepared under the auspices of the SICT which was officially adopted in May 2000. The guideline aims to ensure safe transfer, handling, use and transboundary movement of LMOs to safeguard human and animal health, environment, biodiversity and the socio-economic welfare of the society. A National Committee on Biosafety of Bangladesh, composed of representatives from government, farmer's sector, business chambers, NGOs and the general public, was constituted in October 2002 to oversee compliance with policies.

Drafts of a Biosafety Act and Consumer Protection Act (with no reference to biosafety) have been prepared. The draft Biosafety Act provides for the formation of an authority called the Bangladesh Biosafety Monitoring and Control Authority and public participation in decision-making, among others. However, the legal implications of such participation remain unclear. A draft Biodiversity Act has also been prepared to address access to genetic resources, IPR, and the creation of a National Biodiversity Authority that would study and recommend policies and regulations on the use of biological and genetic of resources and monitor the importation and introduction of GMOs. A draft Plant Varieties Act also seeks to regulate the commercial transaction of plant varieties including new plant varieties. The draft Act does not recognize any claim of new variety for private IPR protection. Further, a Biodiversity and Community Knowledge Protection Act and Plant Diversity Act are also under review. Bangladesh is a party to the CBD and the Protocol, the Patent Cooperation Treaty, the International Treaty on Plant Genetic Resources (ITPGR), Gene Treaty and the Trade Related Aspects of Intellectual Property Right[25].

Bangladesh has very low capacity for addressing modern biotechnology applications. The current infrastructure, legal, institutional, administrative, technical and financial systems are weak. Some institutions and NGOs are engaged in biotechnology research but majority of the scientists are trained in conventional biotechnology. There is a need to build the legal, institutional and human capacity so it can cope with the demands and rapid development of modern biotechnology.

India

Next to China, *India* also gives high priority to biotechnology and has a high rate of adoption of biotech crops. It is the second of the 4 biotech mega-countries in Asia, having commercially grown about 1.3m hectares of biotech crops. India showed the highest annual increase in area planted, from 500,000 ha in 2004 to 1.3m in 2005[26]. A recent survey by the Indian Market Research Bureau (IMRB) International also indicates that Bt cotton farmers earned high revenues in 2005, about 118% net increase in profit over those who planted conventional cotton[27].

[25] Bangladesh National Progress Report submitted to the third series of sub-regional workshops (2003/2004). Available online at http://www.unep.ch/biosafety/development/countryreports/BDprogressrep.pdf. Retrieved 15 April 2006.
[26] James, C. 2005. Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34.
[27] India Bt cotton revenues, high, survey finds, CropBiotech Update, 07 April 2006. Available online at http://www.isaaa.org/kc/CBTNews/2006_Issues/April/CBT_April_7.htm#9. Retrieved 30 April 2006.

In the 1980s, India established its Department of Biotechnology to deal with biotechnology research and applications. It also passed its Environmental Protection Act in 1986 to balance conservation and development. In 1989, it issued a rule governing the manufacture, use, import, export and storage of hazardous microorganisms/genetically engineered organisms and cells. The rule covered areas of research and application of GMOs and defined the administrative structure for the supervision of research activities and approvals for release and commercialization. In 2003, it ratified the Cartagena Protocol of Biosafety.

India has a strong legal and institutional system to meet the demands of biotechnology. It has a well-established regulatory system, many research institutions and trained scientists engaged in research, and an active private sector developing biotech crops. There is, however, an urgent need to establish an efficient and transparent system for testing and evaluating GMOs, a mechanism to overcome IPR-related barriers for GM commercialization, and a mechanism for public awareness, education and participation. It also needs to address issues on biosafety, labeling, liability and redress, and intra-regional collaboration[28].

While India has many research institutions and trained scientists, there is a shortage of those working on molecular biology and biotechnology. India needs advanced training in these areas for its technical personnel, legal experts, administrators and professionals responsible for implementing regulatory mechanisms. This is an enormous undertaking considering the large number of district and state level committees. Public-private sector partnership and collaboration is also encouraged and needs to be strengthened. Networks of research institutions also need to be established.

Iran

Iran is a party to the CBD and the Protocol. It has a National Biotechnology Strategy which supports the development of biotechnology in environment, botany, medicine, livestock and marine life, industry and mining. The strategy emphasizes the need to balance development and environment, and recognizes that the development of biotechnology should be in accordance with biosafety regulations. In 2005, it joined the ranks of biotech-mega countries in Asia, with its commercial planting of ~4,000 ha of transgenic rice[29].

Iran has several laws that complement biotechnology and biosafety concerns but there is no specific law that directly addresses these concerns. Existing laws and regulations related to biosafety include the Environmental Protection and Enhancement Act (1974), Third Economical, Social and Cultural Development Plan (2000), Game and Fish Law (1967), Plant Protection Act (1967), Medical and Pharmaceutical Affairs and Food and Beverages Act (1965, 1988), Rule for the Production and Import of Medicine, Civil Code and Civil Liability Act, and Executive By -Law on Sanitary Supervision and Control of

[28] FAO. 2004. Benchmark document on the needs and present status of the capacity building in biosafety of GM crops in Asia.
[29] James, C. 2005. Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34.

Poisonous and Chemical Materials (1999). A national biosafety framework has been prepared. A law on liability and redress, National Biosafety Law, and Biosafety Regulations and Criteria are being proposed.

Several ministries and departments share responsibilities for biotechnology and biosafety issues, namely: the Department of Environment, Ministry of Agricultural Jihad, Ministry of Science, Research and Technology, Ministry of Heath and Medical Education, and Ministry of Industry and Mining[30].

Pakistan

Pakistan has a national policy on biotechnology and biotechnology programs which include activities on modern biotechnology. It has launched a major program to develop biotech chickpea, insect-resistant cotton and rice, fungal and bacterial-resistant rice, salt-tolerant rice, all of which are at the developmental stage. There are institutes focusing on biotechnology research such as the Institute of Biotechnology and Genetic Engineering (NIBGE) and the Centre of Excellence in Molecular Biology. Expertise is available but needs to be augmented.

In 1994, NIBGE prepared a Voluntary Code of Conduct for the release of GMOs. Beginning in 1998, draft biosafety guidelines were formulated through multi-stakeholder consultation. [31] The guidelines are yet to be adopted.

Several ministries and departments are responsible for biotechnology research, policy and regulation. These include the Ministry of Food, Agriculture & Livestock, the Ministry of Science & Technology Research, Higher Education Commission, National Commission on Biotechnology, Pakistan Council of Science and Technology, and the Pakistan Atomic Energy. Biosafety aspects are the responsibility of the Ministry of Environment, Local Bodies and Rural Affairs.

Pakistan is a party to CBD, a signatory to the Protocol and the SPS Agreement of the WTO, and a party to the ITPGR. Plant variety protection is regulated by the Plant Breeders Rights Ordinance (2000) which still needs enactment. Amendments to the Patent and Designs Act (1911) and Patent Ordinance (2000) to cover biotechnological innovations are also pending enactment. The IPR Law does not cover live material and the Environment Protection Act does not cover GMOs[32].

Overall, Pakistan needs to strengthen its legal, institutional, scientific and technical capacity. These can be achieved through training, study or exchange visits, workshops, public awareness and education and public-private partnerships.

[30] Islamic Republic of Iran- Department of Environment. 2004. Draft National Biosafety Framework. Avilable online at http://www.unep.ch/biosafety/development/Countryreports/IRNBFrep.pdf. Retrieved 15 April 2006.
[31] Shaheen Aftab. 2004. Status of Biotechnology/Biosafety Regulations/Public Participation and Awareness in Pakistan. National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad.
[32] FAO. 2004. Benchmark document on the needs and present status of the capacity building in biosafety of GM crops in Asia

Sri Lanka

In *Sri Lanka*, biotechnology is accorded high priority, with a National Biotechnology Policy already in place and a draft biosafety framework formulated through the UNEP-GEF Project on Development of NBFs. There are also legislations on IPR and Biodiversity and Community Knowledge Protection. There is, however, a limited application of modern biotechnology which is at present confined to genetic transformation of plants and development of recombinant vaccines. Field-testing has not been initiated. Despite the high priority given to biotechnology, there are meager funds allocated to it and the infrastructure for biotechnology research is inadequate. The capacity of key players, such as government, research institutions, scientists and the public, needs to be strengthened, and basic infrastructure needs to be improved.

Non-agricultural biotechnology applications in Asia

There is limited data available on non-agricultural applications of modern biotechnology in Asia. Most data available are general in nature and refer to biotech microorganisms, animals, and fish that are in various stages of development for various applications. Data on health and industrial applications are sparse although reports indicate that significant strides have been made by some developing countries in the health sector. Applications of biotechnology in the health and industrial sectors have elicited less controversy than agricultural biotechnology.

Genetically modified fish (e.g. salmon with growth hormone) are nearing approval for human consumption. GM cows with allergen-free milk and GM pigs with cow protein that protects piglets from gastroenteritis exist. Other GM farm animals include a scrapie-resistant sheep and sleeping sickness-resistant cattle[33]. China has reported progress on research made on biotech animals (e.g. mouse, rabbit, goat, chicken, cattle and pig), fish and microorganisms.

Genetically modified ornamental fishes that glow in the dark (e.g. GM zebra fish with a purple glow from a coral gene, GM zebra fish with a green glow from a jellyfish gene) are on sale in Taiwan and awaiting approval for sale in Singapore. A GM zebra fish that glows bright red has been produced by the Yorktown Technologies LP in the United States. Scientists from the National University of Singapore-Department of Biological Sciences are also developing GM zebra fish that can detect water pollutants by changing color. Ornamental marine fish such as carp and goldfish can also be engineered to display different flourescent colors that indicate changes in water temperature[34].

Six years ago, Singapore identified the biomedical sector as an area that it was going to prioritize as a growth engine. Its biomedical sciences sector covers a whole range of products and services, including pharmaceuticals, biotechnology, medical technology and healthcare services, and is already a substantial part of the economy. In 2004,

[33] Marchant, J. 2001. Future farm. New Scientist print edition. Available online at http://www.newscientist.com. Retrieved 15 April 2006.
[34] Zebra fish as pollution indicators. Available online at http://www.nus.edu.sg/corporate/research/gallery/research12.htm.

manufacturing output for the biotechnology sector was $9.6b or 8.8% of Singapore's total manufacturing output and the sector's manufacturing value-add was $6.1b or 21% of Singapore's total manufacturing value-add. In 2005, it employed some 9,500 people — including over 4,000 in the pharmaceutical industry and 5,400 in the medical technology industry. Value-add per worker in biomedical manufacturing is an impressive $700,000. In its push to be a biomedical player, Singapore has successfully attracted big names, including companies like GlaxoSmithKline and Merck & Co. which have huge plants and research operations in Singapore and internationally prominent researchers such as Alan Colman, the British scientist who produced Dolly the sheep — the world's first cloned mammal — who for ES Cell International, a local biotech company studying the potential uses of stem cells, could one day revolutionize human transplants.[35]

In Japan, the Government invested in 2000, ¥347b in the Millennium Project covering the areas of the rice genome, human genome and regenerative medicine (e.g. genetic study of diseases such as cancer, dementia, diabetes and hypertension). Japan's Science and Technology Agency and Keio University Medical Department are actively contributing to the sequencing of the human genome while its Ministry of International Trade and Industry, through the Centre for Analysis of Information Relating to Biological Resources, is analyzing the genome of micro-organisms for use in the industrial sector. Private sector interest and participation in medical biotechnology is also noteworthy, with pharmaceutical and industrial companies and universities forming alliances. Hitachi Ltd, Takeda Chemical Industries and Jutendo Medical Faculty did genetic polymorphism studies on allergic diseases. A similar study was done in 2000 under the aegis of Tokyo University and the Japanese Foundation for Science. In 2000, Daiichi Pharmaceutical and Fujitsu embarked on a genomics project to study genes involved in cancer, ageing, infectious diseases and hypertension (Sasson, 2005).

A survey by the Japan Bioindustry Association in 2002 showed that the number of bioventures (defined as firms that employ or develop for biotechnology applications) in Japan reached 334 with operations in pharmaceuticals and diagnostic product development, production of DNA, proteins, etc., bioinformatics, and reagents and consumables development. These bioventures had combined sales of ¥105b and R&D costs estimated at ¥51b[36].

Most developed countries are interested in developing products for geriatric diseases such as cancer, heart attack and strokes while developing countries go for prevention or treatment of tropical diseases. Zilberman (undated) recognizes the gap between product development in the North and the needs of the South. Multinational companies invest more in drugs that generate more immediate returns leaving the public sector to develop and manufacture vaccines. Some reports suggest that the cost of developing new medical products in the US or Europe is very costly compared to developing a similar product in countries like India. While most of the knowledge and intellectual property in medicine

[35] Assif Shameen, Brave new biotech world (2005), Available online at http://www.asia-inc.com/September05/Fea_Bravenew_sep.htm
[36] Sasson, A. 2005. Medical biotechnology: Achievements, prospects and perspectives. UNU Press.

are in developed countries, this could shift with the increasing intellectual growth in developing countries. This shift could include production patents and gains from trade.

Some countries in the region also use indigenous knowledge in health biotechnology R&D and have put in place policy instruments to govern access and sharing of benefits derived from the use of this knowledge.

A major challenge, however, is providing the right incentives to universities and individuals in countries of origin where they can serve the purpose of producing products for the poor and improving the competitiveness of countries in this area. Even more challenging is designing the optimal IPR arrangements and addressing fair and equitable distribution of benefits between and among concerned parties.

In terms of industrial applications, biotechnology has been known to provide significant environmental benefits- reduce water pollution, reduce greenhouse gases, and produce clean fuel. Many industries now use biotechnology applications such as the use of microorganisms in bioprocessing or biomining, the use of microorganisms in biotreatment or bioremediation- in landfills and solid wastes sites, in oil spills, in wastewater treatments, in eliminating toxic and hazardous pollutants at source, etc.[37] Although there is no data yet on how they are being applied in Asia, other industrial applications of biotechnology include[38]:

- Industrial biotechnology now enables the production of ethanol transportation fuel from corn and cellulosic biomass such as crop residues (e.g. corn stover, wheat straw, rice straw, etc.). It is estimated that bioethanol from cellulose generates eight to 10 times as much net energy as is required for its production, and one gallon of cellulosic ethanol can replace 30 gallons of imported oil equivalents.

- Biotechnology process changes in the textile finishing sector can reduce water usage by about 17 to 18% and textile mills may potentially reduce water consumption by as much as 30 to 50% through the use of biotechnology.

- Bioplastics, which may be used to make products ranging from clothes to eating utensils to car parts, are biodegradable. If widely used, bioplastics may reduce plastics in the waste stream by up to 80%. If all plastics were made from bio-based polylactic acid, oil consumption used in the manufacturing process would decrease by 90 to 145m barrels per year.

- Biotechnology process changes in the neutraceutical and pharmaceutical sector during production of riboflavin (vitamin B2) can reduce associated carbon dioxide emissions by 80% and water emissions by 67%. Changes in the production of the

[37] Industrial biotechnology gaining speed, has many applications. 2005. NAWG Newsletter 7.29.05
[38] Biotechnology Industry Organization (BIO), *New Biotech Tools for a Cleaner Environment:*
Industrial Biotechnology for Pollution Prevention, Resource Conservation, and Cost Reduction (2004), Available online at http://www.bio.org/ind/pubs/cleaner2004/CleanerReport.pdf

antibiotic cephalexin reduce carbon dioxide emissions by 50%, energy demand by 20%, and water usage by 75%.

In the textile and paper industry, Thailand has recently allowed the commercialization of biotech cassava which can be a source of starch for making paper while India is producing enzymes for the industry. China hosts one of the bioreactors of Genencor (others are USA, United Kingdom, Belgium, and Finland) which produces massive quantities of biotech enzymes for the stone-wash color in jeans and for use in detergents.

In the area of bioplastics, a research consortium comprised of Malaysian scientists and scientists of the Massachusetts Institute of Technology is working on the development of biotech oil-palms that produce bioplastics in their leaves.

In the area of biomining and biobleaching, a Japanese corporation- Nippon Mining & Metals Co. Ltd. has joined BioSigma S.A. (Chile) in a copper biomining and bioleaching venture. It has invested in a $150 m pilot plant to test the applicability of the bioleaching process named BioCop developed in South Africa. This has opened the door for advanced technology and industry transfers among key players in these countries. The partnership has contributed to the biomining program, a component of Chile's national genomic program which also involves the participation of government, an academic and scientific research institution, and the private sector[39].

Although there is an increase in Asia in the medical, industrial, and other non-agricultural biotechnology innovations, the policy framework (except probably in Singapore and India) to support the research and the commercialization is generally weak and in some countries, non-existent. This could be an area that IDRC might want to emphasize in its research and capacity-building initiatives.

III. Review of Policy Research Support

There are several programs, projects and activities on biotechnology and biosafety in Asia currently being funded by multilateral, bilateral and private donor organizations. A list of these initiatives is annexed to this paper, based among others on a recent study by the United Nations University – Institute of Advanced Studies (UNU-IAS). In their study, UNU-IAS identified $157m in capacity-building projects for biosafety alone. The study found that the geographical distribution of projects for biosafety capacity building is relatively uneven (see figure below), with most of the projects located in Africa and Asia while the Central and Eastern Europe region has the lowest number of projects[40].

Asia ranks second in terms of total percentage of funding, with 22.1% of total funds for capacity building. It has a broad array of projects and donors working in the region with a total of US $ 39m available for national and regional projects, a third of which comes from the Global Environment Facility (GEF)[41].

[39] Sasson, A. 2005. Industrial and environmental biotechnology: achievements, prospects and perceptions. UNU Press. Available online at http://www.ias.unu.edu/binaries2/Ind_Envbiotech.pdf. Retrieved 31 July 2006.
[40] UNU-IAS, 2006.
[41] UNU-IAS, 2006.

The majority of the biosafety capacity building projects focus primarily on creating the legal and regulatory environments for compliance with the Cartagena Protocol. As such, they emphasize risk assessment and risk management procedures. Among the gaps, according to the UNU-IAS study[42]:

- There is a need for closer examination of socio-economic impacts of biosafety regulation and capacity building activities, particularly since activities appear to be science driven.
- Many of the projects have sidestepped more contentious issues that underlie regulatory challenges, assuming that risk is the appropriate framing of the issue.
- Coordination between the training program appears *ad hoc* at best, and non-existent in some cases.
- There appears to be a role for regional coordination of regulation, though more research is needed to ascertain whether this is a priority at the national level. Regional institutions may also help overcome national level biases for or against biotechnology.
- Support for consideration of the more basic issues such as goals, roles and country-specific priorities for biotechnology does not appear to be adequate.

While there are over fifty biosafety and biotechnology capacity building programs and projects that are currently being implemented in Asia, there are five that are the most significant because, to some extent, they do address the gaps identified by the UNU-IAS study. These are:

- The UNEP-GEF Biosafety Projects;
- The FAO Capacity Building in Biosafety of GM Crops in Asia;
- The USAID Program for Biosafety Systems;
- The ISAAA Technology transfer Projects; and
- IFPRI-Oxfam Collaboration on Socio-economic Impacts of Transgenic Crops

The UNEP-GEF Biosafety Projects

The UNEP-GEF Biosafety Projects (*Development* of NBFs and add-on capacity-building support for the Biosafety Clearing House and *Implementation* of NBFs) stem from the GEF initial strategy on biosafety to: (a) assist countries with their NBFs; (2) promote information sharing and collaboration, particularly at the regional and sub-regional levels; and, (c) promote collaboration with other organizations to assist capacity building for the Cartagena Protocol[43]. The total cost of the UNEP-GEF Biosafety Projects is US $38.4m, US $26.1m from the GEF and US $12.3m from UNEP and participating countries who contribute one third of the costs of their national projects, in cash and/or in kind.

[42] UNU-IAS, 2006.
[43] UNEP-GEF Biosafety Projects. Available online at http://www.unep.ch/biosafety/about.htm. Retrieved 15 July 2006.

These projects support Article 22 of the Protocol which calls for Parties to cooperate in the development and/or strengthening of human resources and institutions in biosafety, including biotechnology to the extent that it is required for biosafety. Such cooperation in capacity building also includes scientific and technical training in the proper and safe management of biotechnology and the use of risk assessment and management.

Began in 1991, the Development Project has assisted more than 123 countries develop their NBFs to enable them to meet the requirements of the Protocol. This effort has succeeded in promoting collaboration and exchange of experiences and lessons learned between and among countries. As of June 2006, 68 countries have completed their NBFs[44]. Also in 1991, 12 countries received support ranging from US $500,000 to US $1m from the Implementation Project to implement their NBFs: *India* and Colombia (through World Bank), *Malaysia* and Mexico (through UNDP) and Bulgaria, Cameroon, *China*, Cuba, Kenya, Namibia, Poland and Uganda (through UNEP). The countries in Asia- India, China and Malaysia- are some of the top leaders in the application of biotechnology in the region.

The FAO Capacity Building in Biosafety of GM crops in Asia

This project was designed to establish and strengthen technical cooperation among countries in the region and build capacity in the safe introduction and use of GM crops. Its main objective is to enhance food and livelihood security in Asia by increasing yield and quality produce using sustainable and environment-friendly methods, including, where appropriate, the safe and judicious use of modern biotechnology. A noteworthy result of this Project is the publication of a benchmark reference document that lists the relative strengths, weaknesses and gaps in human resources, research, technology, infrastructure, regulations and policies in the participating countries. This document is a useful tool for exchange of information on biotechnology and GM-related biosafety standards in the region. Another significant output of this Project is the establishment of the Asian Network of Biotechnology (Asian BioNet) which provides a forum for sustained regulatory collaboration among Asian countries for the safe and judicious use of modern biotechnology. Participating countries in the region include: Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand, Viet Nam and other selected countries in Asia and the Pacific [45].

The USAID Program for Biosafety Systems (PBS)

Began in 2003, the PBS is a 5-year US $15 m consortium-led program that provides assistance to developing countries to enhance policy, research, and capacity on biosafety systems, including how to best create such a system and make decisions based on science while also addressing socioeconomic considerations.

The Program covers two geographic areas: Asia (Philippines and Indonesia) and Africa (East, West and South). The principal collaborators in the Philippines are the University

[44] UNEP-GEF Biosafety Projects. Available online at http://www.unep.ch/biosafety/news.htm. Retrieved 31 July 2006.
[45] Asian BioNet. Available online at http://asiabionet.org/about.htm. Retrieved 15 July 2006.

of the Philippines at Los Baños-National Institute of Molecular Biology and Biotechnology (UPLB-BIOTECH), Department of Agriculture- Bureau of Plant Industry and the Department of Science and Technology-National Committee on Biosafety of the Philippines; in Indonesia, the Agency for Agricultural Research and Development and the R&D Center for Biotechnology-Indonesia Institute of Sciences. Among others, the Program aims to build a firm foundation for policy development and biosafety decision-making in these countries, improve regional cooperation on transgenic issues and biosafety management skills, and build collaboration between agricultural research and environmental conservation communities in the United States and developing countries. The Program encompasses a wide-range of country-driven activities that include participatory policy development and implementation, education and technical training on biosafety and food safety, communications strategy and outreach, regulatory approval strategies, and scientific research on environmental risk issues through the Biotechnology-Biodiversity Interface (BBI) competitive grants[46].

The ISAAA Technology Transfer Projects

The ISAAA is a non-profit organization whose primary mission is to contribute to poverty alleviation in developing countries through improved and sustainable agricultural production. This is served through the transfer of biotechnology applications and through building capacity to evaluate, regulate and deploy these applications. In the recent decade, ISAAA's Technology Transfer Projects have helped facilitate the transfer of proprietary technologies from the private sector in industrialized countries to benefit resource poor and small-scale farmers, national agricultural research programs, and private-sector companies and entrepreneurs in developing countries.

In January 1998, ISAAA's Southeast (SEAsia) Center was established with 5 partner countries- Indonesia, Malaysia, Philippines, Thailand, and Vietnam. Consistent with its global mission, ISAAA's program on crop biotechnology in Asia aims to help reduce rural poverty and ensure food security. Its technology transfer projects are country-driven, aimed at building capacity and facilitating the acquisition, transfer, and adoption of biotechnology applications for crops that are important to these countries. Since its establishment, it has led initiatives that contribute to providing an enabling environment for the introduction and use of important biotechnology applications. These include adoption of biosafety regulatory systems, management of IPRs, and building public awareness. ISAAA also provides fellowship grants to build capacity of national scientists in biotechnology. It also sponsors national and regional trainings that facilitate exchange of information and harmonization of biotechnology and biosafety guidelines.

ISAAA's current Asian project portfolio focus on 4 major areas: (a) addressing challenges in papaya production- papaya ring spot virus and spoilage- in partnership with ISAAA SEAsia member countries and private sector companies (Monsanto and Syngenta); (2) supporting research to develop transgenic sweet potato resistant to weevil and virus diseases; (3) estimating the economic, social, and environmental impacts of

[46] Consortium to support biosafety in developing countries group awarded US$ 15 Million for work on strategies and policies. Available online at http://www.ifpri.org/themes/pbs/pbsintro.asp. Retrieved 15 July 2006.

crop biotechnology as compared to conventional technologies; and, (4) contributing to the development of Intellectual Property (IP)/Technology Transfer (TT) management in SEAsia aimed at South-South sharing of appropriate knowledge and experience on IP/TT management and developing capacity to deal with these matters[47].

IFPRI-Oxfam Collaboration on Socio-economic Impacts of Transgenic Crops

Article 26 of the Cartagena Protocol states that countries may take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, particularly with regard to the value of biological diversity to indigenous and local communities when making decisions under its domestic measures or under the Protocol. It further states that Parties are encouraged to cooperate on research and information exchange on this aspect. Decisions from the second meeting of the Conference of the Parties serving as a Meeting of the Parties to the Protocol (COP-MOP/2) held on 30 May – 4 June, 2005 called for cooperation on research and information exchange dealing with social and economic impacts of LMOs among Parties, other governments and organizations.

The International Food Policy Research Institute (IFPRI) and Oxfam America are currently engaged in research projects exploring the socio-economic impacts of transgenic crop varieties on small-scale farmers. These projects will contribute to the need expressed by Parties during the COP-MOP/2 for a methodology to assess the social and economic impacts of transgenic crops. In addition, both projects will contribute to enabling national and local decision-makers to assess the benefits of transgenic crop varieties, make policy choices, and develop regulatory processes, as well as guide development organizations and small-scale farmers in deciding whether or not to plant transgenic crops.

IFPRI (with funding support from IDRC), in collaboration with national partners, will be doing case studies in the Philippines and Latin America. Oxfam America is undertaking case studies in India and China to provide information and guide decision-making in several West African countries who are considering the adoption of *Bt* cotton. IFPRI and Oxfam America are coordinating the implementation of these projects to ensure complementarity and synergy, and not duplication, in efforts.

The overall outcomes of this collaboration will be a comprehensive methodology to assess the social and economic impacts of transgenic crops; updated information about the impacts of key transgenic crops on small-scale farmers in a number of developing countries where the methodology is piloted; and policy tools to better integrate social and economic considerations into decision-making. There is also a potential for greater impact and wider reach of the results of this collaboration. For example, the UNEP-GEF Project on Development of NBFs is pushing through with its proposal to develop a toolkit on socio-economic considerations to guide Parties on how to implement Article 26 of the Protocol. The findings from these studies can provide significant inputs to such a toolkit.

[47] ISAAA Programs and Regional Centers. Available online at http://www.isaaa.org. Retrieved 15 July 2006.

IV. GOVERNANCE CHALLENGES AND ISSUES: TOWARDS A RESEARCH AGENDA AND MECHANISM

In a previous section, the lack of a policy framework for medical, industrial and non-agricultural biotechnology innovations was identified as a potential area for IDRC investment in research and capacity-building. The objective of such an investment should be two fold: (a) how can research help in directing researchers to applications of the technology that benefit the region's poor; and, (b) how can the public interest be incorporated into the policy and regulatory decisions that will have to be made with regards to these applications.

These two questions are relevant as well to the other governance challenges and issues that the emergence of bio-innovations are posing in Asia. These include:

- *Determining national priorities on biotechnology;*
- *Encouraging private sector investment;*
- *Managing intellectual property rights (IPR);*
- *Applying precaution to trade and effects on bio-innovations;*
- *The appropriate role of local governments; and*
- *Regional cooperation and collaboration.*

Determining national priorities on biotechnology. How should countries determine their biotechnological needs and priorities in relation to overall national objectives? In agriculture, do national and regional capacities to acquire, develop, and commercialize biotechnology applications and products respond to the high-priority needs of the region's countries and focus on delivering benefits to resource-poor and small-scale farmers? Or do they principally serve the interests of technology developers, the agro-industry and donor countries? How about medical, industrial and other non-agricultural applications? Are the trends in these sectors being incorporated into national priority setting processes?

Cohen (1994) suggests a 4-phase framework for decision-making in biotechnology priorities, planning and policies involving the participation of key stakeholders from several sectors. The framework basically involves elements of a planning process: choosing the right people, defining objectives and options, choosing and evaluating, and preparing for implementation [48]. It would be interesting to examine if countries in Asia follow the same process and the extent to which the process is influenced by capacity, politics, industry and consideration for the needs of resource-poor and small-scale farmers. Research on how countries are currently determining their priorities would be useful if conducted with a view of identifying best practices in priority-setting processes.

48 The 4-phase framework basically involves elements of a planning process: In Cohen, J.I. 1994. Biotechnology priorities, planning and policies: a framework for decision-making (ISNAR Research Report 6), The Hague: International Service for National Agricultural Research. Intermediary Biotechnology Service.

An essential element of examining how countries determine national priorities is an understanding of how socio-economic impacts and priorities are integrated into decision-making. In addition, research on determining national priorities should include looking at mechanisms for public participation in policy development and decision-making. Indeed, best practices on public participation in Asia would be helpful to countries that are at an early stage of designing their regulatory regimes.

Some countries in Asia are now proactively pursuing biotechnology innovations as part of a broader national S&T policy in an effort to carve their own niches in the global bio-enterprise market. Among others, China, India, Malaysia, Singapore and the Philippines are scrambling to jump-start their own biotech industries.

In the Philippines, for example, biotechnology has been part of the S&T agenda for many years now but government support has not been matched with the appropriate funds to move it forward. The Philippines Department of Science and Technology (DOST) and Department of Agriculture (DA) recently announced that they are institutionalizing biotech R&D funding. DOST unveiled its R&D Agenda for 2006-2010 and identified biotechnology as one of 5 key priority areas for R&D funding. The biotechnology roadmap was developed with the participation of leaders and representatives of various biotechnology stakeholder groups from across the country. The DA also launched its Philippine Agriculture and Fisheries Biotech Road-map for 2006-2016, and has mapped out an integrated biotechnology program that will use indigenous materials for value-added processing into pharmaceuticals, cosmetics and food products. The Philippines may need to prioritize many biotechnology R&D programs to make gains in these areas. This is supported by the National Academy of Science and Technology (NAST), the highest advisory body to the government which recommends continuing support and investment to be provided to biotechnology mega projects[49]. Other government policy support services, such as those of the Intellectual Property Office and the Build-Operate-Transfer Center of the Department of Trade and Industry are being tapped for Philippine biotechnology development.

China plans to become a major world power in agricultural science and technology by 2020, focusing its efforts on five areas: i) maintaining an edge in super rice, GM anti-worm cotton, and development of new breeds: (ii) developing core technologies in the production of safe farm products and improving the ecological environment; iii) manufacturing critical agricultural equipment; iv) strengthening research in agricultural high technologies and their industrial application; and, v) building capacity in agricultural research institutions and colleges, and corporate research centers[50]. In Bangladesh, the National Taskforce on Biotechnology of Bangladesh chaired by Prime Minister Khaleda Zia recently approved Bangladesh's National Biotechnology Policy, considered a milestone in the country's effort to promote the highest level of science and technology. An international biotechnology advisory committee will be formed with internationally recognized experts in different areas of biotechnology to advise the government on

[49] See Melody Aguiba "Government urged to modify regulations on Bt crops", in The Philippine Star, 16 July 2006; "RP's premier S&T body bats for more support to biotech", in SEARCA Biotechnology Information Center (BIC), 18-July-2006.
[50] See Xinhua "Science and technology to play bigger role in china's agriculture" in AgbioView. 07 July 2006.

priority areas of research and development[51]. It is unclear, however, what the roles of national stakeholders are and what participatory processes were used to arrive at such national priorities. Research in this area will help other countries in the Region develop their own processes for determining national priorities that truly address their urgent needs and concerns.

Encouraging private sector investment. In many developing countries, including in Asia, there is limited public support for bio-innovations, including the use of public funds to support R&D, biotechnology development and commercialization. Encouraging private sector investment, including through public-private partnerships is therefore critical to promote innovations. Many countries in the region are recommending and supporting public-private partnerships. They have identified biotechnology in their national planning and budgeting process as a potential priority investment area. In this regard, research that identifies best practices and models of partnerships would be valuable. Comparative studies of successful public-private partnerships in biotechnology in East Africa, India and the United States could be made. A study of science and technology related laws and policies in Asia, similar to the US Federal Technology Transfer Act of 1986 which paved the way for government researchers and private enterprise to work together, can also be undertaken. The goal of such research would be to identify the policy elements that must be put into place to foster an enabling environment for public-private partnerships.

Innovative funding mechanisms for bio-innovations, such as joint ventures with government, or consortium of private-sector agencies or academic and research institutions with government, should be examined. In terms of transfer of suitable proprietary technology, the proposal to form a consortium of users to negotiate transfer of proprietary technology to developing countries should also be explored. The role of regional networks and organizations to serve as intermediary organizations should also be explored. Investments in bio-innovations can be achieved by working to promote IPR protection, integrity and transparency in technology transfer and commercialization, and providing economic incentives to stimulate innovations. There is a need to examine how markets work in developing countries- e.g. controlled prices or information, weak or non-existent credit markets, land tenure, IPR restrictions, and high costs of transactions.

Some countries in Asia are now developing incentive packages that attract private sector investments in pro-poor technologies beyond the so-called corporate social responsibilities. In the Philippines, for example, pioneering industries registered with the Board of Investments are accorded a 6-year tax holiday, duty free importation of capital goods and other fiscal and non-fiscal incentives[52]. DA's biotechnology program proposes the use of a government corporation such as the National Agribusiness Corp. (NABCOR) or Philippine Genetics Inc. to run biotechnology operations. However, the long-term goal is to attract private sector investment, set up an incubation facility and venture capitals

[51] See Rafig Hasan "Biotech policy declared", in The Daily Star, 19 July 2006.
[52] See Ronnel Domingo "BOI grants perks to ethanol project", in Philippine Daily Inquirer, 31 July 2006.

where the private sector can be convinced to finance technologies that have high profitability and high marketability potentials[53].

In Malaysia, the government is preparing to launch in mid-August 2007 the Bio-Nexus, a cluster of biotechnology firms that will bring together the best of local and foreign universities, R&D organizations, government agencies, and private firms, to boost Malaysia's biotechnology sector. A package of tax incentives, R&D grants, and loan financing schemes to local and foreign biotech firms will accompany the said launch[54].

Researches on the biotech entrepreneurial climate being advanced by countries in the Region, including incentive packages offered by them and how these are actually implemented could help others that are contemplating on carving their own niches in this enterprise.

Managing intellectual property rights (IPR). As hinted above, related to research that could provide guidance on how to put into place an enabling environment for investments in bio-innovations by the private sector is putting into place an effective intellectual property rights framework. Many countries in the region are faced with the complexities of regulating biotechnology and in particular, in designing IPR policies that are appropriate to the situation of developing countries. Governments should consider the existing level of technology in their country and expectations as to its future development, the need to promote endogenous innovations, encourage technology transfer, and the need for foreign investments. A strong IPR system may promote or stifle innovations, technology transfer and foreign investment. In the North, strong IPR systems can stimulate innovation as firm-innovators are able recover their investments and therefore invest more in research. In the South, strong IPR systems can prevent small companies such as those in India, from manufacturing generic drugs. A strong IPR system can also increase the rate at which firms shift production to the South, where uneducated labor is cheap. It can increase the innovation rate, regardless of whether technology is transferred by foreign direct investment or through imitation (Nicholson, 2000).

Some countries in Asia have adequate number of highly trained scientists and researchers in biotechnology and related fields. Alexander (2003) determined the combined impact of the influence of IPRs and level of education on the rate of economic growth and analyzed that a weak IPR reduces demand for educated labor force by firm-innovators, which in turn implies a reduced rate of economic growth. The lack of IPR implies a decrease in incentives to invest in the development of new innovations, which in turn affects the rate of economic growth. Under insufficient IPR, one of the ways government can stimulate economic growth is by subsidizing firm-innovators and introducing taxes on firm-imitators.

In 2001, the British Government set up a Commission to determine how IPRs can work better for poor people and developing countries. The UK Commission on IPR and

[53] See Melody Aguiba "DA maps out biotechnology program", in Manila Bulletin, 25June 2006.
[54] See "Malaysia: PM to launch Biotech hub", in CropBiotech Update, 28 July 2006.

Development Policy (2002) reported that internationally-mandated expansion of IPRs is more likely to impose costs, such as higher medicines or seeds, and will not benefit developing countries significantly. It enjoined the WTO, World Intellectual Property Organization (WIPO), and other developed nations to consider the circumstances and needs of poor and developing countries when seeking to develop international IPR systems.

The objective for the research on IPR should be practical: how can benefits from bio-innovations be distributed fairly? From a private sector perspective there are concerns that the regulations for biotechnology R&D and commercialization remain unclear to key players, including government, and that confidentiality of information may not be observed. From the perspective of communities, there is concern for the need to develop IPR systems that recognize the contributions made by farming communities and support the conservation of genetic resources, especially at community level. Overall, the benefits from bio-innovations should be fairly shared among various interest groups; how can IPR laws be designed to ensure this policy goal? The establishment of international mechanisms for acquisition and exchange of proprietary techniques can also be examined through such IPR research.

Precaution, Trade and Bio-innovation. The precautionary principle is used in several multilateral environmental agreements (MEAs) and national policies as a core approach and guiding principle for decision-making on matters that affect the environment and human health. Precaution has economic and social implications on trade such that it can also be seen as a trade restriction or a protectionist barrier to free trade of goods, including biotech products.

There are only a small number of MEAs that contain trade measures, hence, there is hardly any conflict with WTO. This is, however, changing with the case of the biotech approval issue lodged under the WTO Dispute Settlement System. The complainants (US, Canada and Argentina) contended that the moratorium applied by the European Communities (EC) on the approval of biotech products has restricted imports of agricultural and food products from their countries. In February 2006, a WTO Panel issued interim reports on this dispute. The WTO Panel agreed with the complainants that the EC had indeed applied a “de facto” moratorium on the approval of biotech products between June 1999 and August 2003. It also noted that this moratorium did not constitute a Sanitary and Phytosanitary (SPS) measure but resulted in a failure to complete individual procedures without undue delay, thereby violating Article 8 and Annex C of the SPS Agreement which set out rules for such approval procedures. The panel likewise concluded that the completion of the approval process had been duly delayed for 24 out of 27 biotech products (WTO GMOs, 2006). In the same ruling, the Panel also observed that the legal debate over whether the precautionary principle constitutes a recognized principle of general or customary international law is still ongoing and that there continues to remain questions regarding the precise definition and content of the precautionary principle. It, therefore, refrained from expressing a view on the issue.

The application of the principle, particularly highly restrictive and protectionist approaches, can be problematic for reasons of both pragmatism and equity. La Vina (2006) suggests several norms in applying precaution to trade decisions that can guide decision makers in reducing uncertainty and advancing equity. These are: (1) the principle of good science; (2) the principle of proportionality; (3) the principle of equitable implementation; and, (4) the principle of stakeholder participation. The first two reduces uncertainty while the last two advances equity.

The practical implication of the principle of good science is that there must be a recognition that risks exist along different dimensions and along different perspectives not only within societies but also between countries, and particularly between rich and poor countries. In the context of national regulatory decisions, identification of risks can be based on purely domestic perceptions of what are acceptable risks. With regard to decisions of international and extraterritorial reach, the identification of risks can be made through a consensus-based process, in the WTO or in the appropriate environmental or health forum.

In applying the principle of proportionality (already adopted by the EC in 2000), highly restrictive measures should be avoided as much as possible and the burden of proof should be on those who would pursue such measures. As a general rule, cost-benefit analyses should precede the imposition of precautionary measures. Such analyses should include examining the costs of the measures on exporters, particularly when poor countries, communities and sectors are affected. The direct and indirect socio-economic and environmental impacts of the precautionary measures should also be looked at. Appropriate mitigation and compensation measures and mechanism should be developed and implemented to help poor countries, communities and sectors adapt.

Applying the precautionary principle to trade also raises important equity issues. Highly restrictive or protectionist approaches can have negative socio-economic and environmental impacts on poor countries, communities and sectors. For this reason, attention should be paid to which groups bear the burdens of precautionary restrictions, including who bears the burden of proof, and who participates in and influences decision-making. Cooney (2004) suggests that the burden of the precautionary principle must be borne by those most able to afford it, for precaution to contribute to, rather than conflict with sustainable development. The Trade Knowledge Network (TKN) has documented case studies where environmental measures in developed countries inadvertently resulted to development implications in developing countries, not so much in terms of protectionism but because they favor larger, more intensive or more integrated producers. For example, EU's relatively strict Hazard Analysis and Critical Control Points (HACCP) has affected the shrimp aquaculture industry in Bangladesh such that small scale producers are being pushed out of the system in favor of larger producers. While large producers are better equipped to comply with the HACCP requirements, they could actually also increase environmental degradation since they tend to create larger environmental problems than small-scale producers. The lesson from the TKN research is that higher environmental and health standards can have serious impacts beyond their intended goals. Higher standards can be more difficult for small and medium-sized

enterprises than they are for larger enterprises because of the costs of changing the production process, as well as costs to information, certification, monitoring and management. This can result to consolidation in larger firms but could also mean closure of many small enterprises in favor of a large one built in their place. If this happens, what does this mean for sustainable development especially for poor communities and sectors (Cosbey, 2004)?

The allocation of burden of proof also bears major consequences for equity and the distribution of costs. In the WTO context, the burden of proof rests with those attempting to demonstrate environmental harm in the absence of adequate scientific evidence. However, this could impose substantial burdens on developing countries or local resource-using communities seeking to protect their biodiversity and natural resources with scarce technical and financial resources. For example, requirements under the SPS Agreement for extensive scientific assessments to support precautionary action against threats may impose major regulatory burdens (Cooney 2004).

Applying precaution requires the involvement and representation of the affected stakeholders in the decision-making process. In developing and implementing such an approach to precaution, the establishment of multi-stakeholder decision- making processes supported by appropriate political and legal authority and adequate budgets, is critical for ensuring ownership by stakeholders of decisions that affect them. An essential component of authentic stakeholder participation is transparency and access to relevant information so that stakeholders can meaningfully participate in the process.

It may be necessary to establish a common understanding of precaution to avoid confusing it with protectionism. It is important that this confusion does not arise particularly in developing countries with high biodiversity who may benefit from the application of precaution in the Biosafety Protocol, yet whose exports may also be affected by protectionist measures. Applying precaution that addresses the environment and health, and at the same time encourages technological innovations and facilitate international trade are important considerations for economic development, particularly for developing countries (UNU-IAS, 2005).

In the end, applying precaution to trade is all about good governance. Developing a practical, predictable and effective regulatory framework for applying precaution to trade is not in the realm of science alone or trade law and policy. It is about governance in societies- how do societies, with the diversity of interests within them, make decisions on risks, who benefits from and bears the cost for them (La Vina, 2006.)

Many trade-related issues are also seen in Free Trade Agreements (FTAs) that many countries are signing with the US and other countries. It is important to look into how such trade agreements affect bio-innovations, including exporters' and firm-innovators' views of Asia. For example, some countries in Asia are proactively soliciting trade and investment in biotechnology. Thailand has outlined opportunities for US companies to invest in its growing biotechnology sector and has identified FTAs with other countries as one of its comparative advantages. Along with FTAs, its pro-business government

policies, commitment to IPR protection (including new incentives for participants in investment, joint research, clinical trials, etc.), geographic location, well-developed transport, service and support sectors, including the improvement of economies in the region, are making Thailand attractive to investors that are expanding operations to Asia. Opportunities in FTAs with other countries in Asia such as India, ASEAN, China and Japan and Korea also abound.

The appropriate role of local governments. The principle of subsidiarity provides that decisions should be made at the lowest level where competence exists. This rests on the theory that decentralized management is more responsive, and for as long as the lower level of government has competence and jurisdiction, then it should be left to decide on its own. In the case of GMOs, the impact of field release, for example, may have a very limited geographical extent. While it may not be reasonable to expect that local institutions have the technical capacity to evaluate risk assessments in order to grant permits, the local institutions should have a substantial influence on the final decision because they have a better knowledge of the local situation, including socio-economic conditions.

Most countries in the region lack a unified regulatory system. Several ministries and departments are involved in regulation and this presents a problem in terms of efficiency. A single window system has not been developed in most of the countries. A decentralized system has not also been developed in most countries. A coherent mechanism for coordination between the Ministries and Departments, and between national and local governments, including what decisions should be devolved to the latter, need to be designed based not only on current practices in Asia but also comparing how countries in other regions (e.g. North America and Europe) are addressing the same challenge.

Regional cooperation and collaboration. The regulatory frameworks of countries in the region have basically the same common features despite the disparity in the level of technology development and applications, and legal, institutional, administrative and scientific and technical capacity. Since resources for capacity building are scarce, it would be beneficial to the countries in the region if there is regional or sub-regional cooperation, collaboration and harmonization of regulations and systems (without impinging on sovereign rights of individual nations). This will facilitate mutual exchange and sharing of information, encourage research collaborations, and arrive at well-informed decisions. This will further develop mutual understanding and maximum use of available resources (e.g. human, financial, etc.).

It is important to examine existing networks such as the Asian BioNet established through the FAO RAP Capacity Building in Biosafety of GM Crops in Asia and regional organizations such as the Association of Southeast Asian Nations (ASEAN) and determine how they can further help build capacity in policy and governance matters.

The gains associated with the establishment of the Asian BioNet should be sustained, e.g. provide a mechanism for continuous collaboration between and among public and private sector institutions and other stakeholders, and expand to cover other countries in the

Region. FAO's aim to provide a neutral forum to develop international instruments of governance and to provide policy advice on biotechnology and biosafety capacity building can be met through this network.

ASEAN, as a well-functioning organization in the region, has charted a new direction through its ASEAN Vision 2020 of Partnership in Dynamic Development. Among others, it envisions a technologically competitive ASEAN with technologically equipped manpower, a strong network of S&T institutions, and a harmonized system that facilitates free flow of ASEAN trade while meeting health, safety and environmental needs. In 1999, it adopted a non-legally binding ASEAN Guidelines on Risk Assessment of Agriculture-related GMOs which served as a common framework for member-countries on science-based risk assessment of GMOs. Other issues such as compensation, liability, labeling, socio-economic and religious factors are not covered by the Guidelines. Many developments have occurred since then within member-countries and within ASEAN such that an assessment of how ASEAN can further its assistance in biotechnology-related policy and governance matters is overdue[55].

V. CONCLUSION AND RECOMMENDATIONS:

Biological technological innovations, or bio-innovations, which include genetic engineering, can benefit the developing countries and the poor of Asia. But this can only be realized when policy and governance mechanisms are in place so that countries and citizens are that the benefits of the new technologies outweigh the risks. Research that results in such effective mechanisms is therefore a priority if scientific innovation, in this case biotechnology, is to benefit the region.

In the preceding section, six areas are recommended as priorities for research. Some examples of researches that could be done under these priorities are:

a) *Determining national priorities on biotechnology*

- Research on best practices in decision-making on biotechnology priorities, planning and policies and the extent to which the process is influenced by capacity, politics, industry and consideration for the needs of resource-poor and small-scale farmers. In addition, research on determining national priorities should include looking at mechanisms for public participation in policy development and decision-making.

- Research on how countries in Asia are pursuing biotechnology innovations as part of a broader national S&T policy in an effort to carve their own niches in the global bio-enterprise market, the roles of national stakeholders, and participatory processes to arrive at such national priorities.

[55] See ASEAN Vision 2020. Available online at http://www.aseansec.org/1814.htm. Retrieved 31 July 2006.

b) *Encouraging private sector investment*

- Research that identifies best practices and models of partnerships, including comparative studies of successful public-private partnerships in biotechnology in East Africa, India and the United States or a study of S&T-related laws and policies in Asia, similar to the US Federal Technology Transfer Act of 1986. The goal of such research would be to identify the policy elements that must be put into place to foster an enabling environment for public-private partnerships.

- Research on innovative funding mechanisms for bio-innovations, such as joint ventures with government, or consortium of private-sector agencies or academic and research institutions with government.

- Research on the biotechnology entrepreneurial climate being advanced by countries in the Region, including incentive packages offered by them and how these are actually implemented could help others that are contemplating on carving their own niches in this enterprise.

c) *Managing intellectual property rights (IPR)*

- Research on IPR and endogenous innovations and on how IPR laws can be designed to ensure that the benefits of biotechnology are fairly shared among various interest groups, including the establishment of international mechanisms for acquisition and exchange of proprietary techniques.

d) *Applying precaution to trade and effects on bio-innovations*

- Research on approaches to the application of precaution to trade in a manner that is consistent with sustainable development can guide decision makers in reducing uncertainly and advancing equity. The direct and indirect socio-economic and environmental impacts of the precautionary measures should also be looked at. Appropriate mitigation and compensation measures and mechanisms should be developed and implemented to help poor countries, communities and sectors adapt.

- Research on how Free Trade Agreements (FTAs) affect bio-innovations, including exporters' and firm-innovators' views of Asia.

e) *The appropriate role of local governments*

- Research on decentralized management and the roles of local governments in decision-making, such as in field releases and commercialization, considering that they have a better knowledge of the local situation, including socio-economic conditions.

- Research on mechanisms for coordination between Ministries and Departments, and between national and local governments, including what decisions should be devolved to the latter based not only on current practices in Asia but also comparing countries in other regions (e.g. North America and Europe), and development of a unified regulatory system or single window system for efficient decision making.

f) *Regional cooperation and collaboration*

- Research on how regional or sub-regional cooperation, collaboration and harmonization of regulations and systems (without impinging on sovereign rights of individual nations), including the use of existing networks such as Asian BioNet and regional organizations such as ASEAN, can facilitate mutual exchange and sharing of information, encourage research collaborations, arrive at well-informed decisions, and maximize use of available resources (e.g. human, financial, etc.).

In addition, as a cross-cutting theme, it is important to take note that the medical, industrial, and other non-agricultural biotechnology innovations are important for Asia, and that the policy framework (except in Singapore and India) to support research and commercialization in these areas is inadequate. Because most capacity-building programs, projects and activities are focused on agriculture, these sectors might be an area that IDRC might want to emphasize in its own investments in the region.

ANNEX

Select List of Biotechnology and Biosafety Programs, Projects/ and Activities in Asia funded by multilateral, bilateral and other organizations.

Donor	Programs/Projects/ Activities	Objectives	Time Frame	Country	Reference
MULTILATERAL					
UNEP-GEF	Pilot Biosafety Enabling Activity Project	• To prepare a National Biosafety Framework (NBF)	1997-1999	China Pakistan	www.unep.ch/biosafety
UNEP-GEF	Development of National Biosafety Frameworks	• To prepare NBFs to meet the requirements of the Cartagena Protocol using a country-driven process; • To promote regional and sub-regional collaboration and exchange of experience on issues of relevance to the NBFs, to make efficient use of financial and human resources, establish regional and sub-regional networks, and promote harmonization of risk assessment procedures and regulatory instruments. • To provide advice and support throughout the development of NBFs.	2001-	17 countries in Asia	www.unep.ch/biosafety
UNEP-GEF	Capacity for Effective Participation in the Biosafety Clearing House (BCH) of the Cartagena Protocol	• To strengthen capacity through training of key stakeholders in data entry and management; identification and access to information required for decision- making under the Protocol; access to, and registration of information in the BCH; • To create an enabling environment through provision of computer hardware and software for data storage and exchange (with the BCH) over the Internet and by other means; • To support further capacity building through the development and dissemination of an interactive computer-based training package	2001-	15 countries in Asia	www.unep.ch/biosafety
UNDP-GEF Government of Malaysia	Support to Capacity-Building Activities on Implementing the Cartagena Protocol on Biosafety	• To support implementation of the future law on biosafety and develop capacity-building; • To establish a NBF, an information dissemination system, and broad public participation.	2006-	Malaysia	http://www.undp. org.my
UNEP-GEF Government of China	Support to the Implementation of the National Biosafety Framework of China	• To implement the NBF of China • To provide legal and administrative basis to meet the obligations under the Cartagena Protocol.	2002-2005 $1.27M	China	www.unep.ch/biosafety/partcountries/ImpChina.htm

		• To produce and promulgate technical Guidelines and develop techniques to improve the ability to monitor environmental release of LMOs and provide guidance for assessing and managing the related risk • To develop proper monitoring parameters/indicators and methods to improve the capacity to monitor environmental release of LMOs • To develop and set up a Biosafety Database system to serve the purpose of the BCH and to facilitate information sharing among decision-makers, managers, scientists and the public • To organize training courses and workshops for decision-makers, custom officials, inspectors, scientists and technicians.			
World Bank-GEF Government of India	Capacity Building for the Implementation of the Cartagena Protocol in India	• Strengthen the legislative framework and operational mechanisms for biosafety management • Enhance capacity for risk assessment and monitoring • Establish the biosafety database system and Biosafety Clearing House Mechanism • Support centers of excellence and a network for research, risk assessment and monitoring • Establish the Project Coordination and Monitoring Unit (PCMU)	2003-06 $1.20 M	India	http://www.indbch.nic.in/cb_projects.asp
FAO	Capacity Building in Biosafety of GM Crops in Asia	• The assist countries in the region in safe harnessing of the benefits of biotechnology in accordance with relevant global agreements on the subject • To establish and strengthen technical cooperation among and capacity building of Asian countries to ensure safety in the introduction and use of GM crops, based on transparent and science–based approaches-development and harmonization of appropriate regulatory framework to deal with biosafety concerns relating to GM crops; and the collection, analysis, dissemination and exchange of information on biotechnology and GM-related biosafety standards through inventories, databases and decision-	2003-05	Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand, Vietnam	www.asiabionet.org/

		support systems.			
FAO	Capacity Building on Regulation of Import, Contained Use and Release of Genetically Modified Plants and Plant Material in Malaysia	• To strengthen the national capacity on regulation of import, contained use and release into the environment of GM plants or plant materials.	2002-2003 US$156,000	Malaysia	http://www.fao.or.th/Field_Operations/Countries/TCP_projects/MAL_TCP2801.htm
BMZ	Biosafety Capacity Building in China: Data Management, Promoting Expertise and Awareness Raising	• to support the Nanjing Institute for Environmental Sciences (NIES) in its efforts to inform decision-makers on biosafety and to develop mechanisms for PR work, so that the relevant political actors can incorporate national and international expertise and interested members of the general public in decisions pertaining to the management of GMOs	2003-05	China	www2.gtz.de/biodiv/download/biosafety-special/Biosafety_China_en.pdf
Ministry of Health and Care, Environment, Agriculture and Food, Foreign Affairs, Research Council of Norway, and NORAD.	Genok/ GE/GMO Biosafety Capacity Building Program	• To conduct an International biosafety course "Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms".			www.genok.org/english/default.asp
Swiss Development Agency; Department of Biotechnology, New Delhi, India	Indo-Swiss Collaboration in Biotechnology	• To promote research partnerships between Swiss and Indian institutions in various areas of biotechnology and foster technology transfer to the private industry.	1999-2007 $11.9M	India	http://iscb.epfl.ch/
Swiss Agency for Development	GMO-ERA Project	• To develop tools to support environmental risk assessment (ERA) of GMOs • To provide decision makers with tools and training to help decide what information and data are most important and appropriate for an ERA that is tailored to the GM crop and agricultural system in country.	2002-05	Vietnam	www.gmo-guidelines.info/
USAID	Program for Biosafety Systems	• To empower partner countries for science-based biosafety decision-making while strengthening capacity to implement biosafety through innovative system design. • To address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade and environment objectives; • To implement activities on:	2003-08	Philippines Indonesia	www.ifpri.org/themes/pbs/pbs.htm

		Policy development/new models ;Risk assessment and the Biotechnology and Biodiversity Interface (BBI) grants; Facilitating regulatory approval; and, Communication, public and food safety outreach and capacity building.			
USAID	South Asian Biosafety Program	• To conduct national workshops and trainings on review and evaluation of experimental field trials of GM crops, biosafety awareness building, GM food safety assessment	2004-07	India Bangladesh	www.agbios.com/sabp_main.php
USAID	Rural and Agricultural Incomes with a Sustainable Environment (RAISE) - Sanitary and Phytosanitary Measures (SPS)	• To conduct workshops on trade/biosafety interface		Global (trainees from all over)	www.raise.org
UNIDO	Diploma in Biosafety •	• To conduct diploma course by distance learning biosafety, including: risk assessment and regulatory structures, and national and international regulatory systems		Global (trainees from all over)	http://binas.unido.org/udec/
ISAAA SEAsia Center	Technology transfer Projects	• Papaya Biotechnology Network of Southeast Asia • Socioeconomic Impact Assessment Studies of Insect Resistant Corn Cultivation in the Philippines • Intellectual Property/Technology Transfer (IP/TT) Management Network of Southeast Asia • Development and Transfer of Insect Resistant Sweet Potatoes in Vietnam • Development of Virus Resistant Sweet Potatoes in the Philippines		Indonesia Malaysia Philippines Thailand Vietnam	www.isaaa.org/Regional_centers/SEAsiacenter/SEAsia_main.htm
OTHERS					
IUCN	Regional Biodiversity Program in Asia: Biosafety Program			Cambodia Bangladesh Bhutan, China Indonesia, Lao PDR, Malaysia Philippines Vietnam	www.biodiversityasia.org/biosafety
Rockefeller Foundation	Assorted biosafety projects • Various meetings		1993-	India Vietnam	www.rockfound.org
International Centre for Genetic Engineering and Biotech (ICGEB)	Biosafety Program	• Biosafety Bibliographic database • Risk Assessment Searching Mechanism • Workshops for scientists and regulatory officers on biosafety and risk assessment • ICGEB Biosafety Outstation for training and research on biosafety	Ongoing	Global (trainees drawn from all over)	www.icgeb.org/~bsafesrv/.

Source: Adapted from UNU-IAS. 2006. An assessment of ongoing efforts to build capacity for biotechnology and biosafety.

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