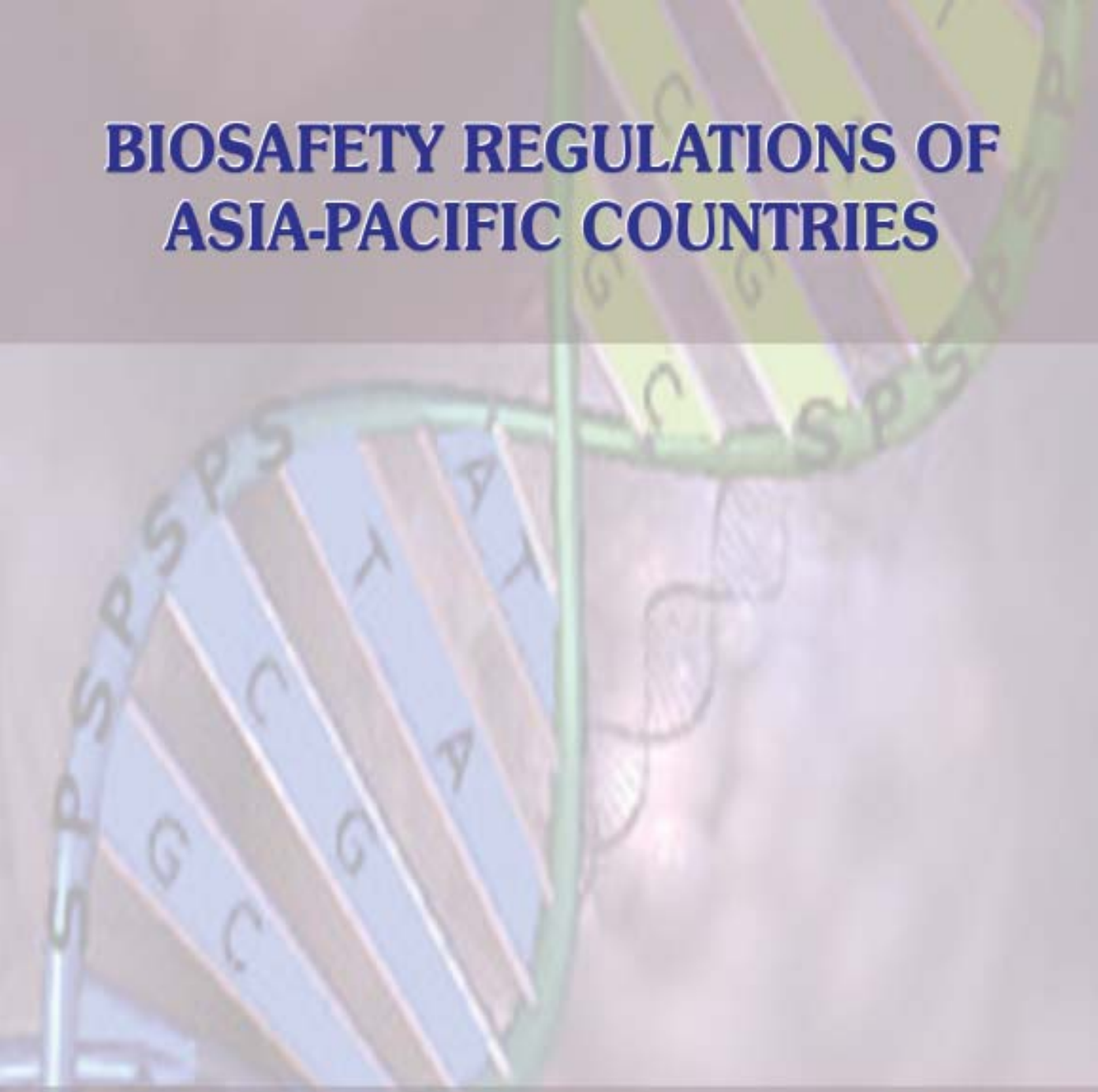
BIOSAFETY REGULATIONS OF ASIA-PACIFIC COUNTRIES



Asia-Pacific Association of Agricultural Research Institutions
Asia-Pacific Consortium on Agricultural Biotechnology
Food and Agricultural Organization of the United Nations

BIOSAFETY REGULATIONS OF ASIA-PACIFIC COUNTRIES

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FOREWORD

For achieving the common goals of food security and poverty alleviation, countries of Asia and the Pacific have accorded high priority to agricultural biotechnology. Recent experiences concerning adoption of genetically modified (GM) cotton in China and India, and maize in the Philippines, indicate that the farmers, irrespective of the size of their holdings, have harvested greater quantities of produce and gained higher incomes. Accordingly, there has been a substantial increase in the area sown to GM crops in the developing countries over the last few years. While these reports are very encouraging, the farmer-level cultivation of GM crops is still limited to a few crops and a few countries. Therefore, the expected impact in addressing poverty and hunger in the region has remained limited so far.

In spite of the obvious benefits of GM crops, there have been concerns about the likely risks to environment and human/animal health associated with their wide scale cultivation and use. Possible adverse effects on non-target species and other components of biodiversity, and rapid evolution of resistant pests and pathogens are some of these. Therefore, biosafety related issues have been accorded priority in many countries and specific measures have been taken to assess and manage the risks associated with it. As most of the countries of Asia-Pacific are members of the Cartagena Protocol on Biosafety, they have biosafety regulations in place or are in the process of developing and adopting national biosafety frameworks.

The Asia-Pacific Association of Agricultural Research Institutions (APAARI) has been promoting agricultural research and development in the region through strengthening cross-linkages among national and international organizations. The Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), one of the programs of APAARI, has been working to facilitate exchange of information and promote informed opinion across the region on issues of common interest related to agricultural biotechnology. Biosafety, intellectual property rights (IPR), germplasm exchange, and public-private partnership (PPP) are some such issues that APAARI and APCoAB have been addressing through expert consultations, workshops and brainstorming sessions. Accordingly, APCoAB had organized a workshop on Biosafety Regulations for Transgenic Crops and the Need for Harmonizing them in the Asia-Pacific Region at ICRISAT, India in July-August 2006.

The current compilation "Biosafety Regulations of Asia-Pacific Countries" is an outcome of the need expressed by the biotechnology and biosafety experts of the region. It was recommended to compile the existing biosafety regulations into a single document for clear understanding and comparison. It is our hope that this publication will serve a useful purpose and become a source book of basic information on biosafety regulatory systems of the region. We are especially pleased to receive the support of Plant Production and Protection Division of FAO in bringing out this publication.

Efforts of Dr. J.L. Karihaloo, Coordinator, APCoAB, and Drs. Kavita Gupta and R.K. Khetarpal, scientists at the National Bureau of Plant Genetic Resources (NBPGR), Indian Council

of Agricultural Research (ICAR), New Delhi are also acknowledged. APAARI and APCoAB will continue to promote agriculture research for development through organizing policy dialogues, increasing public understanding and promoting the necessary legal and regulatory framework, thus contributing to the much required human resource development.

(Raj Paroda)
Executive Secretary, APAARI

PREFACE

"Biosafety Regulations of Asia-Pacific Countries" has its genesis in the workshop entitled "Biosafety Regulations for Transgenic Crops and the need for Harmonizing them in the Asia-Pacific Region" organized by APCoAB in 2006. The workshop, attended by Convention on Biological Diversity (CBD) National Focal Points (NFPs)/NFP representatives, and agricultural biotechnology experts from 13 countries of Asia and the Pacific (Annexure I), had the objective to familiarize the national stakeholders with developments on agricultural biotechnology in the region, and to jointly identify areas of regulatory harmonization to facilitate exchange and trade in GM crops, food and feed. A unanimous recommendation made by the workshop was for APCoAB to collate information on biosafety regulations of all countries of the region, which would help in taking informed decisions regarding specific areas and modalities of harmonization.

This publication lists and briefly details the regulatory instruments comprising laws/acts/decrees/regulations/rules related to biosafety of products of biotechnology for agriculture and food existing in 39 countries of Asia and the Pacific. Besides, additional chapters have been included to introduce the readers to recent developments in agricultural biotechnology in the region, issues on biosafety, and international regulatory instruments on biosafety. A brief analysis of the present status of national biosafety regulations with respect to the Cartagena Protocol on Biosafety has also been included.

Information for compiling the national biosafety regulations has been obtained from different sources. Besides official documents published by the respective countries, unofficial documents and translations were also consulted for the purpose. Main websites consulted were those of CBD, National Biosafety Clearing House, United Nations Environment Programme – Global Environment Fund, Food and Agricultural Organization (FAO) and USDA-GAIN Reports. The national information thus obtained was sent to the respective CBD NFPs of 37 countries for verification, several of who responded with their comments and suggestions. We are especially grateful to Peter Thygesen, Australia; Mohammed Solaiman Haider, Bangladesh; Ugen Tenzin, Bhutan; Pisey Oum, Cambodia; Manoranjan Hota, India; Inez H.S. Loedin, Indonesia; Nasrin S. Esmailzadeh, Iran; Ryoko Sakuramata, Japan; Kangayatkarasu Nagulendran, Malaysia; Ananta V. Parajuli, Nepal; Yu Wenxuan, China; and Julieta Fe Estacio, the Philippines who not only provided updated information about country regulations but also helped in defining their salient features.

We are grateful to the FAO for providing funding support for this publication. FAO recognizes the potential of biotechnology in fighting hunger and malnutrition in developing countries and has contributed in several ways towards harnessing the benefits of biotechnology while minimizing its potential adverse effects. It has produced numerous publications on biotechnology and biosafety, and including through its website on biotechnology provides science-based information and analysis regarding biotechnology and biosafety applications in agriculture. The FAO-BioDec serves as a database on developments in biotechnology, including biosafety regulations, in developing countries.

Kavita Gupta and R.K. Khetarpal are also grateful to the Director, NBPGR, ICAR for his kind support and encouragement to undertake this collaborative work.

Kavita Gupta
JL Karihaloo
RK Khetarpal

ACRONYMS AND ABBREVIATIONS

APCoAB	Asia-Pacific Consortium on Agricultural Biotechnology
ABSP II	Agricultural Biotechnology Support Program II
AIA	Advanced Informed Agreement
APAARI	Asia-Pacific Association of Agricultural Research Institutions
BCH	Biosafety Clearing House
Bt	*Bacillus thuringiensis*
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CFIA	Canadian Food Inspection Agency
Codex	Codex Alimentarius Commission
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic acid
EC	European Commission
EPA	Environment Protection Act
EU	European Union
FAO	Food and Agricultural Organization
FDA	Food and Drug Administration
FFP	Food, feed and processing
GE	Genetic Engineering
GM	Genetically modified, genetic modification
GMOs	Genetically Modified Organisms
GT	Gene Technology
GURT	Genetic use restriction technology
HIV	Human Immunodeficiency Virus
HSNO	Hazardous Substances and New Organisms
HT	Herbicide tolerance
IBSC/IBC	Institutional Biosafety Committee
IPPC	International Plant Protection Convention
IPR	Intellectual Property Rights
ISPM	International Standard for Phytosanitary Measures
LMOs	Living Modified Organisms
mha	Million hectares
mRNA	Messenger RNA
NBF	National Biosafety Framework
NIH	National Institute of Health
OECD	Organization of Economic Cooperation and Development
OIE	World Organization for Animal Health
PCR	Polymerase chain reaction
PHES	Potentially harmful exotic species

PPP	Public Private Partnership
PRA	Pest Risk Analysis
RAC	Recombinant Advisory Committee
rDNA	Recombinant DNA
SPS	Sanitary and Phytosanitary
TRIPs	Trade Related Intellectual Property Rights
UNCED	UN Conference on Environment and Development
UNEP-GEF	United Nations Environment Programme – Global Environment Fund
US	United States
WHO	World Health Organization
WTO	World Trade Organization

1. STATUS OF AGRICULTURAL BIOTECHNOLOGY IN ASIA-PACIFIC

World population is expected to increase from the current 6.3 to 7.5 billion by 2020 (IDB, 2007). Asia-Pacific region, being home to nearly 60% of the world's population, is expected to contribute significantly to this increase. While spectacular rise in food production was made especially in Asia during 1970s and 1980s, the recent years have seen a slow down or even stagnation, raising concerns about food and livelihood security in the developing countries. Several countries are increasingly resorting to imports either because domestic production is too low or because there are growing demands for food and feed grain. It is predicted that developing countries in Asia will account for half of the increase in global demand for the cereals by the year 2020 (Rosegrant *et al.*, 2001). It is also being felt that under the prevailing conditions, most of the developing countries in Asia and the Pacific will be unable to meet the Millennium Development Goals of halving poverty and hunger by 2015 (UNESCAP, 2005).

Biotechnology[1] is globally recognized as a powerful tool of plant and animal genetic modification (GM) that holds promise of improving productivity, profitability and sustainability of farm production systems, including those existing in small and poor farming situations (Cohen, 2005; Delmer, 2005; Brookes and Barfoot, 2006). *Ex ante* studies by the International Agriculture Biotechnology Support Program II (ABSP II) on the economic impacts of GM crops reveal that drought and salt tolerant rice, would provide roughly three billion US dollars for India over a period of 15 years (*http://www.gmo-compass.org/eng/news/348.docu.html*; Ramasamy *et al.*, 2007). The present chapter details the status of Asia-Pacific countries on adoption and research in genetically modified (GM) crops.

1.1 FARM LEVEL ADOPTION AND APPROVAL OF GM CROPS

The world's first GM crops were sown in farmers' fields in 1996 when Bt soybean and Bt maize with traits for herbicide tolerance and insect resistance, respectively, were grown in the USA on an area of 1.7 million hectares (mha). Eleven years later, the global area under GM crops has increased sixty-seven fold reaching 114.3 mha with 12 million farmers in 23 countries growing them (James, 2007). During 2004-2007, there has been an annual worldwide growth of about 13% area under GM crops while in developing countries the growth in area ranged between 30% and 40%. India and the Philippines were among the developing countries that showed exceptionally high increase in area sown to GM crops.

Among the GM crops and traits under cultivation, the highest area is occupied by soybean genetically engineered for herbicide tolerance (HT) followed by insect resistant Bt maize (Gómez-

[1] The term "biotechnology" in its broad sense is applied to the use of biological processes or organisms for the production of materials and services of benefit to humankind (Zaid *et al.*, 1999). For the present report, however, we use the term in a more restricted sense referring to the use of recombinant DNA technology to transfer genes from one organism to another. The terms "genetic engineering" (GE) and "genetic modification" (GM) are used interchangeably with "biotechnology".

Barbero and Rodríguez-Cerezo, 2006; James, 2007, Fig. 1.1). More recently, cotton and maize with "stacked" genes combining insect resistance with herbicide tolerance have been released and are becoming popular.

In the Asia-Pacific region, four countries have GM crops under commercial cultivation. Approximately, 0.1 mha are under insect resistant and HT cotton in Australia (James, 2007). GM canola and GM carnation have also been approved for environmental release in Australia although state governments have banned GM canola. China has been cultivating Bt cotton since several years, the area under the crop reached 3.8 mha in 2007. In India, Bt cotton occupied an area of 6.2 mha in 2007, showing an enormous increase of 4.9 mha between 2005 and 2007. Sixty-two Bt cotton hybrids were released by the end of 2006 while their number increased to 156 by May 2008 (IGMORIS, 2008a). Bt maize in the Philippines grown for the first time in 2003, covered an area of 0.3 mha in 2007. By early 2006, maize with stacked Bt and HT traits was also under cultivation.

Besides the above crops under commercial cultivation, several others are approved for environmental release, food/feed or food (Table 1.1). Approval of GM crops for food has been granted to more events and in more countries than approvals for environmental release.

1.2 RESEARCH IN GM CROPS

In their global survey on the status of plant biotechnology, Runge and Ryan (2004) recorded 64 countries, including 12 countries of the Asia-Pacific, as being involved in plant biotechnology

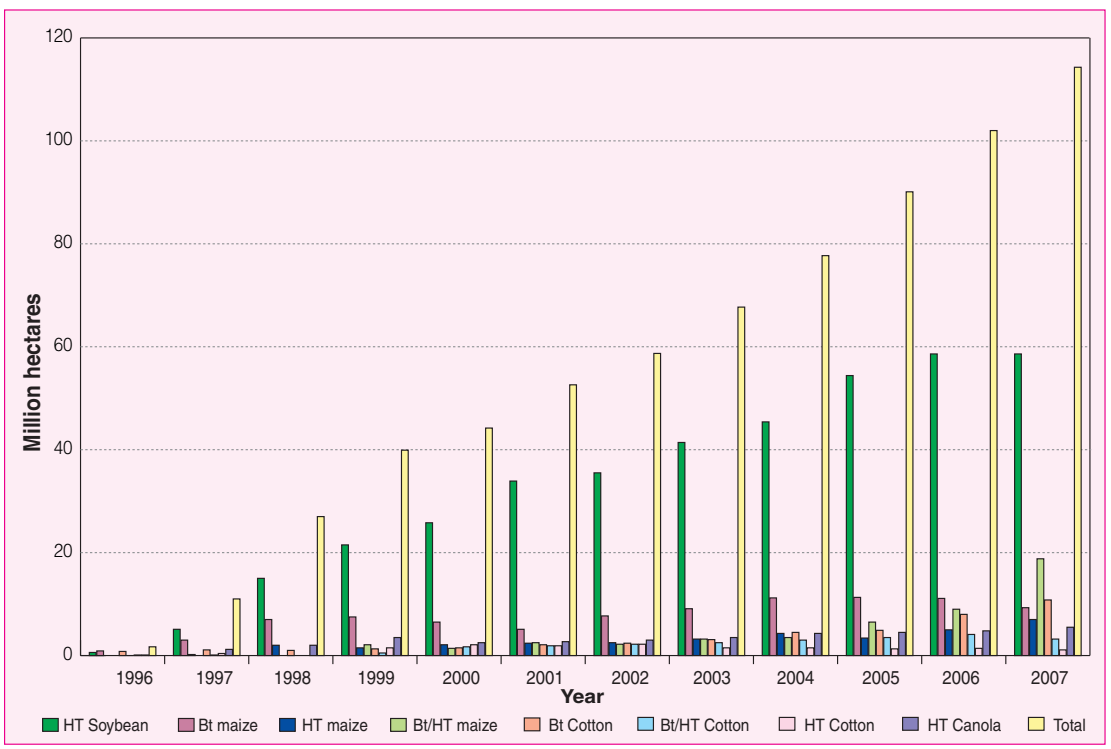

Fig. 1.1: *Global area under commercial cultivation of GM crops and traits*
(Source of original data: Gómez-Barbero and Rodríguez-Cerezo, 2006; James, 2007)

research and development. The 52 listed crops on which GM research was being undertaken included almost an equal proportion of field crops, vegetables, fruits and other crops. The FAO database on biotechnology in developing countries (FAO-BioDec, 2007) lists eight developing countries of Asia operating research programs on GM crops development (Table 1.2). Practically,

Table 1.1 Crop genetic modification events approved for various uses in some Asia-Pacific countries

Country	Environmental release		Food/ livestock feed		Food	
	Crop/traits	No. of events	Crop/traits	No. of events	Crop/traits	No. of events
Australia	Argentine canola (HT, PC), carnation (HT, MC), cotton (HT, IR)	16	Argentine canola (PC), cotton (HT), maize (HT, IR), potato (PLRVR, CPBR, PVYR), sugarbeet (HT)	12	Alfalfa (HT), Argentine canola (PC), cotton (HT), maize (HT, IR), soybean (HT, MO), sugarbeet (HT)	24
China	Cotton (HT, IR), papaya (VR), petunia (MC), poplar (IR), sweet pepper (VR), tomato (AFR, VR)	8	Argentine canola (HT), cotton (HT), maize (HT, IR)	17	Cotton (HT IR), sweet pepper (VR), tomato (AFR, VR)	5
Japan	Alfalfa (HT), Argentine canola (HT, PC), cotton (HT), maize (HT, IR), soybean (HT, MO), sugarbeet (HT), tomato (AFR)	44	Cotton (HT), maize (HT, IR)	10	Alfalfa (HT), Argentine canola (HT, PC), cotton (HT, IR), maize (HT, IR), potato (IR, VR), soybean (HT, MO), sugarbeet (HT), tomato (AFR)	53
India	Cotton (IR)	4	–	–	–	–
Indonesia	Cotton (IR)	1	–	–	–	–
Korea	–	–	–	–	Argentine canola (HT, PC), cotton (HT, IR), maize (HT IR), potato (PLRVR, CPBR, PVYR), soybean (HT), sugarbeet (HT)	42
Malaysia	Soybean (HT)	6	–	–		–
Philippines	Maize (HT, IR)	4	Cotton (HT), maize (HT, IR)	5	Alfalfa (HT), Argentine canola (HT), cotton (IR, HT), potato (CPBR, PLRVR), soybean (HT), sugarbeet (HT)	33
Singapore	–	–	–	–	Maize (HT, IR)	2
Chinese Taipei	–	–	–	–	Maize (HT, IR), soybean (HT)	13
Thailand	–	–	–	–	Maize (HT, IR), soybean (HT)	2

AFR: Altered fruit ripening; CPBR: Colorado potato beetle resistance; HT: Herbicide tolerance; IR: Insect resistance; MC: Modified colour; MO: Modified oil composition; PC: Pollination control; PLRVR: Potato leaf roll virus resistance; PVYR: Potato virus Y resistance; VR: Virus resistance.
(Source: AGBIOS, 2007; James, 2007).

all the important crops comprising cereals, vegetables, fruits, pulses, oilseeds and commercial crops, are being targeted for improvement for several traits, most prominent among which are resistance to diseases and pests, and abiotic stress tolerance. Most of these researches are in laboratory or greenhouse phase while some are in advanced field trial phase. Virus resistant papaya and Bt eggplant are in advanced stages of development in the Philippines (Fernandez, 2008). In India, Bt rice, Bt maize, Bt okra, Bt eggplant, Bt cabbage, Bt cauliflower, HT cotton and virus resistant tomato are under advanced field trials (Warrier, 2006; IGMORIS, 2008b).

Table 1.2 Status of crop GM research in developing countries of Asia-Pacific

Country	Experimental phase	Field trial phase
Bangladesh	Eggplant (IR), jute (BR, FR, IR), kenaf, lentil, mesta, mungbean, oilpalm (IP), papaya (VR), rice (AST), tobacco, potato (FR)	–
China	Barley, cotton (FQ, VR), maize, papaya (AFR), potato (IR), rapeseed (FR), rice (AST, CQ, IR), sorghum (AST), soybean, sugarbeet (AST), wheat (AST, BR, IR, VR)	Cotton (HT, IR), maize (HT, IR), soybean (HT)
India	Banana (AFR), black gram (FR, HT, IR, VR), bell pepper (MR), brassica (AST, FR, IR), cabbage (IR), cauliflower (FR, IR, PC), chick pea (FR, IR), chilli (FR, IR), cassava (NQ), citrus (VR), coffee (FR), cotton (HT, IR), cucurbits (VR), cucumber (VR), eggplant (AST, FR, IR), ground nut (VR), maize (IR), melon (VR), muskmelon (EV), mustard (AST, HT, NQ, PC), mustard green (AST), papaya (VR), pigeon pea (FR, IR), potato (AST, IR, NQ, VR), rice (AST, BR, EV, FR, HT, IR), tobacco (AST, FR, IR, VR), tomato (AFR, FR, IR, VR), wheat (AST, IR)	Brassica (MT), brinjal (IR), cabbage (IR), cauliflower (IR), chickpea (IR), cotton (IR), maize (HT), mustard (AST, HT), mustard/rapeseed (PC), okra (IR), pigeonpea (IR), potato (AST, IR, MT, NQ, VR), rice (BR, FR, IR,), sorghum (IR), tomato (EV, FR, IR), tobacco (IR)
Indonesia	Cabbage (FR), cacao (IR, VR), cassava (SC), chilli (VR), citrus (VR), coffee (FR), maize (IR), oil palm (IR, MO), papaya (AFR), peanut (VR), potato (BR, IR, VR), rice (AST, FR, IR, VR), shallot, soybean (IR, MO, NQ), sugarcane (AST, IR, VR), sweet potato (VR)	Cotton (HT, IR), maize (HT, IR), soybean (HT)
Malaysia	Banana (AFR), chilli (VR), maize (HT, IR), eggplant (IR), melon (FR), muskmelon, oil palm (MO, PI, Y), orchid (AFR), papaya (AFR, VR), pepper (VR), rice (FR), rubber (Y), teak (WQ), tobacco, winged bean (FR)	Rubber (DR)
Pakistan	Brassica (PC), chickpea (AST, IR), chilli (VR), cotton (IR, VR), cucurbits (VR), potato (VR), rice (AST, BR, FR, IR), sugarcane (IR), tobacco (AST, IR), tomato (IR, PC, VR)	Cotton (IR, VR)
Philippines	Banana (VR), coconut (MO), eggplant (IR), mango (AFR), papaya (AFR, VR), rice (AST, BR, FR, NQ, VR), squash (VR), sweet potato (IR, VR), tobacco (GC), tomato (AFR, VR), yellow ginger (MO)	Banana (VR), maize (IR), rice (BR)
Thailand	Cassava, cucurbits (VR), mango, orchids (VR), papaya (IR, VR), pineapple, rice (BR, FR, VR), tobacco, tomato (BR), yard long bean (VR)	Cotton (IR), rice (AST), tomato (AFR, VR), pepper (VR)

AFR: Altered fruit ripening; AST: Abiotic stress tolerance; BR: Bacterial resistance; CQ: Cooking quality; DR: Disease resistance; EV: Edible vaccine; FR: Fungal resistance; FQ: Fibre quality; HT: Herbicide tolerance; GC: Growth control; IP Industrial Product; IR: Insect resistance; MO: Modified oil composition; MR: Multiple resistance; NQ: Nutrition quality; PC: Pollination control ; SC: Starch composition; VR: Virus resistance; WQ: Wood quality: Y: Yield.
(Source: FAO-BioDec, 2007)

According to ISAAA Briefs (James, 2007), about a dozen GM crops including cereals, vegetables, oilseeds, fruits and commercial crops are under field testing in China.

1.3 ECONOMIC AND ENVIRONMENTAL IMPACT OF GM CROPS

Studies on the impact of GM crops under field cultivation in the Asia-Pacific countries have been made on Bt cotton in China and India, and Bt corn in the Philippines.

In China, Bt cotton varieties comprising those released by both public and private sector companies are under cultivation. Impact analysis made by Huang *et al.* (2002a, 2002b) revealed that on an average Bt cotton yielded 8%-15% higher than non-Bt cotton. There was a cost saving in pesticide sprays which reduced cost of production up to 33%. Further, small farmers benefited more through larger increases in net incomes than the larger farmers by the adoption of Bt varieties. Dong *et al.* (2004) reported that true breeding Bt cotton varieties brought incremental benefits by decreasing pesticide usage, reducing environmental pollution and saving labour, thus significantly increasing the net revenue of farmers. However, the increased revenue resulted from cost savings and not increases in yield. Hybrid Bt cotton, on the other hand, resulted in approximately 20% yield increase over Bt cotton varieties.

A number of studies have been made on the farm-level impact of Bt cotton in India. Qaim and Zilberman (2003) reported the results of data collected from 157 farms in 25 cotton-growing districts. On an average, Bt hybrids received three times less sprays against bollworm than non-Bt hybrids and local checks (Bt, 0.62; non-Bt, 3.68; local check, 3.63). Amounts of insecticide sprayed were reduced by about 70% on Bt cotton both in terms of commercial products and active ingredients. More interestingly, the article reported higher average yield of Bt hybrids exceeding those of non-Bt counterparts and popular checks by 80% and 87%, respectively. Analysis of the results showed that the general germplasm effect was negligible and the yield gain was largely due to Bt gene itself.

Bennett *et al.* (2004) presented an assessment of the performance of Bt cotton under typical farmer-managed conditions in India. The study met the recommendations of FAO (2004) for market-based studies that would accurately reflect the agronomic and economic environments faced by growers. The number of sprays required for bollworm control was much lower for Bt plots (1.44 for Bt versus 3.84 for non-Bt during 2002 and 0.71 for Bt versus 3.11 for non-Bt during 2003). There was a corresponding reduction of up to 83% in expenditure. However, when balanced with higher cost of Bt cotton-seed, the results showed higher average costs for Bt cultivation compared to non-Bt cultivation. The real benefit came from the higher yield of cotton in Bt plots, ranging between 45% and 63%. Taking into account the seed cost and variable cotton prices, the results showed a much higher gross margin for Bt growers (US$ 1,156.9/ha) than for non-Bt growers (US$ 665.4/ha).

Bambawale *et al.* (2004) reported performance of Bt cotton hybrid along with its non-Bt counterparts and a conventional hybrid under integrated pest management (IPM) in farmers' participatory field trials. Under IPM, 11.5% of the fruiting bodies were damaged in Bt hybrid compared to 29.4% in conventional cotton and 32.9% in non-Bt hybrid. Seed cotton yield in Bt (12.4 q/ha) was much higher than that of non-Bt counterpart (9.8 q/ha) and conventional cotton (7.1 q/ha). Net returns after taking into account cost of production and protection were US$ 368.9/ha in Bt hybrid, US$ 282.6/ha in non-Bt counterpart and US$ 238.8/ha in conventional cotton.

In the Philippines, survey of 107 Bt and non-Bt maize growing farmers was conducted (Ebora *et al.,* 2005). Bt maize gave a 34% higher yield than non-Bt maize and there was saving

of US$ 3.1/ha on insecticide sprays. On average, Bt maize gave a net income of US$ 393/ha while from non-Bt maize the average net income was US$ 208/ha.

Brookes and Barfoot (2006) analyzed the environmental impact of GM crop cultivation that resulted from changes in insecticide and herbicide use. The authors concluded that GM crops have contributed significantly to reduction in global environmental impact of production agriculture by reducing the use of pesticide active ingredients by 6.9% and the overall environmental impact associated with pesticide use by 15.3%. The impact reduction due to cultivation of insect resistant cotton was largest for any crop on a per hectare basis.

Not all the studies, however, have reported positive impact of GM crops (Arunachalam and Bala Ravi, 2003; Sahai, 2005). Some of the surveys on Bt cotton in India have reported lower yields than conventional cotton, particularly under rainfed conditions and, lower net returns to farmers (Sahai and Rahman, 2003; Qayum and Sakkhari, 2005). Part of the problem has been attributed to the widespread use of low cost but inferior quality spurious Bt cotton seed by farmers.

1.4 CONCLUSION

Countries of the Asia-Pacific region have in general adopted a cautious approach to open field cultivation of GM crops. Those that have approved such cultivation have mostly experienced benefits through improved yields, fewer applications of pesticides and higher farmers' income. Public sector research involving GM technology for crop improvement is, however, more widely pursued. The crops being modified encompass cereals, pulses, oilseeds, vegetables, fruits and others while the traits being introduced include biotic and abiotic resistance, herbicide tolerance, and improved yield and harvested product quality. Majority of the research results are still at the laboratory or greenhouse stage while some have reached field testing stage.

References

1. AGBIOS. 2007. (available at: *http://www.agbios.com/dbase.php;* accessed on 23 September 2007).
2. Arunachalam, V. and S. Bala Ravi. 2003. Conceived conclusions in favour of GM cotton? A riposte to a paper in Science. *Current Science* **85:** 1117-1119.
3. Bambawale, O.M., A. Singh, O.P. Sharma, B.B. Bhosle, R.C. Lavekar, A. Dhandapani, V. Kanwar, R.K. Tanwar, K.S. Rathod, N.R. Patange and V.M. Pawar. 2004. Performance of *Bt* cotton (MECH-162) under integrated pest management in farmers' participatory field trail in Nanded district, Central India. *Current Science* **86:** 1628-1623.
4. Bennett, R.M., Y. Ismael, V. Kambhampati and S. Morse. 2004. Economic impact of genetically modified cotton in India. *AgBioForum* **7:** 96-100.
5. Brookes, G. and P. Barfoot. 2006. Global impact of biotech crops: Socio-economic and environmental effects in the first ten years of commercial use. *AgBioForum* **9:** 139-151.
6. Cohen, J.I. 2005. Poorer nations turn to publicly developed GM crops. *Nature Biotechnology* **23:** 27-33.
7. Delmer, D.P. 2005. Agriculture in the developing world: Connecting innovations in plant research to downstream applications. *Proceedings of the National Academy of Sciences* **102:** 15739-15746.
8. Dong, H., W. Li, W. Tang and D. Zhang. 2004. Development of hybrid *Bt* cotton in China – A successful integration of transgenic technology and conventional techniques. *Current Science.* **86:** 778-782.
9. Ebora, R.V., A.C. Ampil, M.B. Palacpac and C.G. Custodio. 2005.Commerialization of Bt Corn in the Philippines-A status report. Asia-Pacific Consortium on Agricultural Biotechnology, New Delhi, India. P. 32.
10. FAO. 2004. The state of food and agriculture 2003-2004. Agricultural biotechnology: Meeting the needs of poor? Food and Agricultural Organisation, Rome. P. 208.

11. FAO-BioDec. 2007. Biotechnologies in developing countries. (available at: *http://www.fao.org/biotech/inventory_admin/dep/default.asp*; accessed on 29 June 2007).
12. Fernandez, R.A. 2008. Comm'l production of GM eggplant, papaya, seen in 2 yrs. Philstar Global Corporation. (available at *http://www.philstar.com/scripts/article_print.php?PhilStar&id=2008030154&type=2* ; accessed on 7 March 2008).
13. Gómez-Barbero, M. and E. Rodríguez-Cerezo. 2006. Economic impact of dominant GM crops worldwide: a review. European Commission. Directorate General, Joint Research Centre. EUR 22547 EN. P. 43.
14. *http://www.gmo-compass.org/eng/news/348.docu.html*: accessed on May 6 2008
15. Huang, J., R. Hu, C. Fan, C.E. Pray and S. Rozelle. 2002b. Bt cotton benefits, costs, and impacts in China. *AgBioForum* **5:** 153-166.
16. Huang, J., S. Rozelle, C.E. Pray and Q. Wang. 2002a. Plant biotechnology in the developing world: the case of China. *Science* **295:** 674-677.
17. IDB. 2007. International Data Base. U.S. Census Bureau. (available at: *http://www.census.gov./ipc/www/idb/worldpopinfo.html*; accessed on 11 December 2007).
18. IGMORIS. 2008a. Year-wise list of commercially released varieties of Bt cotton hybrids by GEAC. Indian GMO Research Information System. (available at: *http://igmoris.nic.in/files/List_of_approved_hybrids200807.pdf*) (Accessed on 11 January 2008).
19. IGMORIS 2008b. Transgenic crops under development and field trials in 2006.*(http://igmoris.nic.in/field_trials.asp*; accessed on 10 March, 2008).
20. James, C. 2007. Global status of commercialized biotech/GM crops: 2007. ISAAA Brief No. 37. ISAAA, Ithaca, NY., P. 125.
21. Qaim, M. and D. Zilberman. 2003. Yield effects of genetically modified crops in developing countries. *Science* **299:** 900-902.
22. Qayum, A. and K. Sakkhari. 2005. Bt cotton in Andhra Pradesh – A three-year assessment. Deccan Development Society, A.P., P. 49.
23. Ramasamy, C., K.N. Selvaraj, G.W. Norton and K. Vijayaraghavan (eds). 2007. Economic and Environmental Benefits and Costs of Transgenic Crops: Ex- ante Assessment. Tamil Nadu Agricultural University, Coimbatore, India. P 142.
24. Rosegrant, M.W., M.S. Paisner, S. Meijer and J. Witcover. 2001. 2020 Global Food Outlook – Trends, Alternatives, and Choices. International Food Policy Research Institute, Washington, D.C., P. 24.
25. Runge, F.C. and B. Ryan. 2004. The global diffusion of plant biotechnology: International adoption and research in 2004. University of Minnesota, USA. P. 117.
26. Sahai, S. 2005. The science of Bt cotton failure in India. *The Hindu*, 29 July 2005.
27. Sahai, S. and S. Rahman. 2003. Study reveals that Bt cotton performing poorly in India. (available at: *http://www.genecampaign.org/Publication/Article/BT%20Cotton/BtCotton-is-failure.pdf;* accessed on 20 March 2008).
28. UNESCAP. 2005. A future within reach: reshaping institutions in a region of disparities to meet the Millennium Development Goals in Asia and the Pacific. United Nations Economic and Social Commission for Asia and the Pacific, Asian Development Bank, and United Nations Development Programme. P. 78.
29. Warrier, R. 2006. Regulatory framework and biosafety assessment of GM crops in India. In. Verma, D.D. and M. Hota (eds.). *Biosafety: Issues and Challenges*. Ministry of Environment and Forests, Govt. of India. P. 62-82.
30. Zaid, A., H.G. Hughes, E. Porceddu and F. Nicholas. 1999. Glossary of biotechnology and genetic engineering. FAO Research and Technology Paper 7. FAO, Rome. P. 250.

2. BIOSAFETY ISSUES IN AGRICULTURAL BIOTECHNOLOGY

Application of GM technology for commercial crop production is faced with a number of issues and challenges the most important being safety of environment, and human and animal health (Grumet and Gifford, 1998; Khetarpal, 2002; Philippe, 2007). These concerns are based on the argument that recombinant DNA-based GM technology differs from traditional breeding in that totally new genes using potentially risky technology are transferred between widely unrelated organisms, and the location of these genes on the recipient genome is random, unlike when gene transfer takes place through conventional breeding. These differences demand that adequate laboratory safeguards are used and plants developed by GM technology are rigorously assessed for their performance as also for the likely risks they pose. The present chapter deals with potential risks to the environment and human health and a few other concerns related to the application of biotechnology in agriculture.

2.1 POTENTIAL RISK TO THE ENVIRONMENT AND HUMAN HEALTH

2.1.1 Gene Flow

Gene flow is the movement of genes between genomes or between environments (Heinemann, 2007). Gene flow is a normal biological phenomenon taking place through either cross pollination within and between sexually compatible species (vertical gene flow), transfer of genes between unrelated organisms through nonsexual means (horizontal gene flow) or by movement of seeds or vegetative propagules into new environment. Crop varieties and their wild relatives often share genes through cross pollination when they occur close together (Ellstrand *et al.*, 1999; Ellstrand 2003; Stewart *et al.*, 2003; Duputi *et al.*, 2007). Studies with transgenic herbicide-tolerant rapeseed (*Brassica napus*) in the UK, showed that the gene flow rates through cross pollination ranged between 0.0156% and 0.0038% at 200 m and 400 m, respectively (Scheffler *et al.*, 1995). However, when male-sterile lines were used as pollen recipients, the outcrossing was as high as 88.4%, 13%–58% and 5% at distances of 1m, 400 m and 4 km, respectively (Thompson *et al.*, 1999). Pollen mediated transgene flow has been detected in maize landrace samples from Oaxaca in Mexico (Quist and Chapela, 2001). In Asia, Chen *et al.* (2004) from their studies in Korea and China reported gene flow from cultivated rice to weedy rice and wild rice in the range of 0.011%–0.046% and 1.21%–2.19%, respectively. Wang *et al.* (2004) demonstrated flow of transgenes from transgenic adzuki bean cultivars to its landraces grown in the Tochigi Prefecture area of Japan. Armstrong *et al.* (2005) assessed the potential of transgene escape via hybridization for 123 widely grown temperate crops and their indigenous and naturalized relatives present in the New Zealand flora. Fifty four per cent were found to be reproductively compatible with at least one other indigenous or naturalized species in the flora.

Seeds left behind in soil after harvesting of the crop can become important vectors of transgenes. In rapeseed, scattering of seeds consistently maintains a seed bank in the soil in

the rapeseed production areas; the seeds may germinate under favourable conditions becoming a source of pollen contamination (Chang-Ming *et al*., 2005).

Gene flow in transgenic crops is a serious concern since it reverses efforts to contain transgenes and poses challenges in assessment and management of risks associated with GMOs (Conners *et al*., 2003; Nap *et al*., 2003). Some specific concerns associated with transgene flow include development of new weeds, erosion of genetic diversity in wild and weedy relatives of crop plants and development of antibiotic resistance in pathogenic microorganisms.

2.1.1.1 *Development of New Weeds*

Weeds often cause serious crop yield losses and eradicating them is expensive and time consuming. While herbicide tolerance to facilitate weed control has been a major success of GM technology in agriculture, gene flow can aggravate the problem by giving rise to new weeds (Alvarez-Buylla, 2003). Gene flow due to cross pollination or presence of volunteers and involving traits like herbicide tolerance or insect resistance can result in development of tolerant/ resistant weeds that are difficult to eradicate. In rapeseed, development of multiple herbicide resistance by stacking of glufosinate, glyphosate and imidazolinone tolerance genes present in different GM varieties cultivated in the same field at different times has been reported (Hall *et al*., 2000). While it is known that weeds often evolve resistance by natural evolutionary processes (Holt *et al.*, 1993), gene transfer from crops through cross pollination could speed up this process considerably.

2.1.1.2 *Erosion of Genetic Diversity in Crop Landraces and Wild Relatives*

A plant acquiring insect or disease resistance genes through gene flow would have enhanced fitness resulting in its preferential selection and consequent shift in the natural population structure (Ellstrand, 2003; Soleri *et al*., 2006). The selection would affect not only the concerned locus in which the wild-type alleles would be lost but also other loci that are closely linked to the fixed new allele. Erosion of genetic diversity in landraces and wild relative of crop plants is an issue of concern since these have been donors of many useful genes, including resistance to biotic and abiotic stresses. Several regions in the Asia-Pacific are rich in genetic diversity of important crops like rice, sugarcane, coconut, jute, cotton, cucumber, eggplant, mango and banana, and their related species being their primary or secondary centers of diversity.

Besides genetic erosion, commercialization of transgenic crops in centers of diversity could lead to pollution of gene pools, an area of concern for genebank managers (Engels *et al.*, 2006; APCoAB, 2006). Since the objective of *ex situ* conservation is to retain the genetic identity of collection in its native form, the adventitious presence of transgenes is seen as contamination which could lead to genetic erosion and spread of the transgene during regeneration and breeding.

2.1.1.3 Development of antibiotic resistant microorganisms

The possibility that transgene DNA of GM plants could get transferred to unrelated organisms via horizontal gene transfer has raised concerns about its consequences on environment and human health (Netherwood *et al*., 2004). Antibiotic resistance genes, used as markers for selection of transformants during development of GMOs, have been of particular concern since their transfer to plant or human pathogenic bacteria could lead to development of antibiotic resistant strains. Such a transfer could take place by uptake of DNA released in GM plant debris by soil microorganisms, and in humans and animals by horizontal transfer of antibiotic resistance marker genes present in GM foods to gut bacteria.

Horizontal gene transfer is quite rare (Deni *et al*., 2005), though its occurrence over evolutionary timescale is well documented (Syvanen, 1994; Bergthorsson *et al*., 2003). However, it is argued that over a period of time even rare events may have significant ecological and health impacts and thus possible consequences of horizontal gene transfer should be a focus of attention for biosafety consideration (Thomson, 2001; Celis *et al*., 2004).

2.1.2 Toxicity and Allergenicity

The introduction of new proteins in transgenic crops from the organisms that have not been consumed as foods may pose the risk of these proteins becoming toxic or allergenic (Cockburn, 2002; Goodman *et al*., 2005). Therefore, the expression of the recombinant protein needs to be carefully assessed based on protein structure comparisons, animal models and *in vitro* tests (Ruibal Mendieta, *et al*., 1997). Transgenic soybean containing allergenic seed storage protein from Brazil nut was found to retain the allergenic property and was subsequently withdrawn from release (Nordlee *et al.*, 1996). Similarly, development of a transgenic pea expressing the α-amylase inhibitor-1 protein from beans was stopped when it was found that the protein could invoke an immune response (Prescott *et al.*, 2005). Concerns have been raised particularly about the safety of food products derived from GM crops with Bt protein as also with new toxins still under development and testing (Heinemann, 2007). Some experimental studies suggest that Bt protein is not harmful to mammals, and it degrades within 20 seconds in the presence of mammalian digestive enzymes (Krattiger and Raman, 1996). However, there have been contradictory reports as well.

The use of food crops for production of GMOs having non-food product use like feed, plant-made pharmaceuticals and plant-made industrial products has raised the need for developing effective containment and segregation systems to prevent such products from entering the human food supply chain. Past experiences when non-food GM maize varieties were detected to have got mixed with human food indicate the difficulty in maintaining containment particularly at the global level (Lee and Natesan, 2006).

2.1.3 Emergence of New Viruses

Developing virus resistant crop varieties using genes derived from plant viruses themselves has been a major objective of crop biotechnology research. Viral coat protein genes inhibit replication of the virus when engineered into recipient plants. Virus resistant varieties having coat protein genes have been developed in sweet pepper, tomato and potato and some of these have even received approval for commercial release (Table 1.1). It is feared that the transfer of viral sequences to plant genomes will increase the likelihood of creating novel viruses through recombination with other viruses present in the plant. On the other hand, it is argued that, while multiple infection of plants by different viruses is of common occurrence, there are few cases of new viruses arising from genetic recombination among these and that the probability of occurrence of this recombination in transgenic plants in no greater than in typical situations of virus infection (Hammond *et al.*, 2000).

2.1.4 Effect on Non-target Species

It is feared that the toxins produced by genetically engineered insect resistant plants may have adverse impact on non-target insect species which either forage on the toxin carrying plants or which prey on insects that forage on such plants (Hilbeck *et al.,* 1998). Experimental studies have, however, shown that Bt proteins are highly specific in their toxic effects with one group affecting only certain species of caterpillars (Lepidoptera), while other Bt proteins affect only

a restricted set of beetle species (Coleoptera). Studies indicate that the populations of predators of pest species also do not show any significant reduction due to consumption of Bt toxin affected prey (Callaghan *et al.,* 2005; Sharma *et al*., 2007) though there have been some reports of reduced fecundity of ladybird insects when fed with aphids that were reared on GM potatoes expressing snowdrop lectin for aphid resistance (Birch *et al*., 1999).

Toxins produced by GM crops could also have a direct impact on soil flora and fauna since they also introduce toxins into organisms living in the rhizosphere and in the debris. Initial experimental results indicate that Bt plants in some instances reduce the population or functioning of some soil organisms while having no effect or even stimulating other organisms. Further, the proteins degrade rapidly in crop residues as well as in the soil thus posing limited long-term risk (Head *et al*., 2002).

Other effects on flora and fauna present in GM crop fields have also been reported. During 1999-2005, Field Scale Evaluation experiments were conducted to compare the ecological impact of GM, HT and non-HT crops in oilseed rape, sugar beet and maize (Firbank *et al*., 2003; Burke, 2005; Squire *et al.,* 2005). In winter rape, it was found that the cultivation of HT varieties in conjunction with the application of complementary broad-spectrum herbicide affected dicot weeds. The results indicated that a decline in weed flora could be harmful to bees and butterflies and also to birds that feed on dicot seeds.

2.1.5 Erosion of Crop Diversity due to Monoculture

Apprehensions have been expressed that dominance of one or a few GM varieties/hybrids may lead to disappearance of traditional varieties as is perceived to have happened with the large-scale adoption of high yielding crop varieties during the Green Revolution. However, based on the experience of Bt cotton in India and HT soybean in the US, such fears appear to be unfounded. In India, since 2002 when the first Bt cotton hybrids were released for open field cultivation, 156 Bt hybrids have been developed by several private and public sector organizations (IGMORIS, 2008). The Bt genes have been transferred into several backgrounds to suit different cotton-growing regions. Similarly, though all herbicide tolerant GM soybean varieties grown in the US have been derived from a few transformation events, hundreds of different varieties have been developed from these by conventional breeding to suit different soil and climatic conditions.

2.2 EFFECTS ON FITNESS OF THE GM PLANT *PER SE*

2.2.1 Gene Silencing and other Effects

Gene silencing, referring to partial or complete inactivation of a transgene or its homologous gene in the recipient plant, has been reported in several GM experiments (Cherdeshewasart *et al.,* 1993; Dunwell, 1999). Transgenes that get inserted into non-coding methylated regions of the genome are prone to become effectively silenced. Other mechanisms of gene silencing involve specific degradation of the mRNA transcribed by the transgene in the cytoplasm and interaction between different transgene events in the same plant (Mello and Conte, 2004).

Transgenes may also cause unexpected side effects making the plant unacceptable for commercial cultivation. An interesting example of such effect has been reported from Bt lines in maize which were found to have significantly higher (33%-97%) lignin content, compared to corresponding isogenic non-GM plants (Saxena and Stotsky, 2001). Some of the negative consequences of the higher lignin content could be the prolonged accumulation of Bt toxin in the soil and the difficulty in digesting high lignin bearing maize when fed to cattle.

2.2.2 Breakdown of Resistance

Disease or pest resistance conferred by a transgene can become ineffective due to evolution of new pest strains. Many plant disease resistance genes are specific to a particular strain of pathogen and growing such crops becomes, effectively, an ideal environment for the rare mutant pathogen or pest population that could overcome the resistance. Similarly, resistance to specific insects conferred by Bt gene could be overcome in due course of time by insects developing resistance to Bt toxin. In fact, there has been a recent report of insects developing resistance to Bt toxin (Tabashnik, 2008), though this report has been refuted (Lutteral, personal communication). However, breakdown of resistance is a general phenomenon and conventionally bred resistant crops also are liable to such breakdown. GM sources of resistance are, therefore, likely to be no different from conventional resistance genes.

2.3 ADDRESSING BIOSAFETY ISSUES

Attempts to prevent or mitigate the perceived or actual undesirable effects associated with development, cultivation and use of GM as food or feed have been made through a range of strategies comprising testing for the risks, and physical and biological containment and management. Some of these have been adopted at the level of regulatory management.

As a part of regulatory requirements of many countries, GM research and crop development is conducted under contained conditions, for which appropriate guidelines are issued from time to time. Similarly, guidelines are provided for toxicity and allergenicity testing and for testing the performance and stability of GM crops under field conditions. For open field cultivation, appropriate isolation distances, depending upon potential pollen movement, are followed to restrict gene flow within acceptable threshold levels. Extensive field trials are often required to ensure efficiency and stability of the GM trait as also the overall performance of the plant under different environments. Strategies to avoid, or at least delay, development of resistance in pests include the use of multiple resistance genes and cultivation of small areas of susceptible varieties along with resistant GM varieties to provide refuges in which the non-resistant pests may persist (Glould, 1998; Bates *et al.*, 2005). Some countries require labeling of GM food and food products for information of consumers. International instruments have been developed to regulate transboundary movement of GMO.

A number of biological strategies for prevention or containment of biosafety risks are at experimental or conceptual stage. The approaches being adopted for containment of gene flow include insertion of transgenes on plastid genome, male sterility, Genetic Use Restriction Technology (GURT), self-pollination, apomixis and gene excision systems. Plastids (chloroplasts) are known to be maternally inherited in most crops which excludes plastid-based transgenes from pollen transmission (Scott and Wilkinson, 1999; Ruf *et al.*, 2007). GURT technology is of two types: varietal restrictive GURT (v-GURT) which renders the subsequent generation sterile, and trait restrictive GURT (t-GURT) which ensure that the modified trait can be turned "on" and "off" by certain conditions such as chemical application and environmental factors (Jefferson, 1999; Guanming Shi, 2006). Use of GURT technology has, however, been widely opposed since it restricts the choice of farmer to save seed. Further, failure of control due to mutation could cause crop losses in the GM field or in the neighboring fields due to gene flow. Apomixis or production of seed without sexual fusion ensures that pollen does not take part in seed production. Gene excision systems might be used to remove genes in GM plants in a tissue specific manner. For example, it has been shown that use of 'GM gene deletor'

sequences greatly enhances the efficiency of FLP or CRE recombinase in removing transgenes from tobacco pollen, seed or both and provides a bioconfinement tool for transgenics (Luo *et al*., 2007). Lin *et al.* (2008) reported a method for creating a selectively terminable transgenic rice in which the gene is tagged with RNA interference sequence which suppresses the expression of an enzyme that renders the plant sensitive to bentazon, a rice herbicide.

Use of antibiotic resistance imparting marker genes in development of GM crops is being phased out, and marker disarming methods and safe alternative markers are being developed. Some of the suitable alternatives are positive selectable marker genes that are conditional on non-toxic agents (Miki and McHugh, 2004). Several methods have been developed to eliminate marker genes after achieving successful transformation, such as site-specific recombination, homologous recombination and co-transformation (Cuellar *et al*., 2006; Natarajan and Turna, 2007).

Brenz Verca *et al.* (2007) demonstrated induction of RNA interference using RNA polymerase I, which is ubiquitous and stable in different cell types besides being highly species specific. The system provides a means of silencing genes with unknown functions.

2.4 CONCLUSION

The need for adopting adequate safety measures for development, environmental release and use of transgenic crops and their products is well appreciated. Accordingly, most Asia-Pacific countries have developed or are in the process of developing regulatory systems to manage biosafety. However, since basic information on several biosafety issues is still limited, the regulatory norms are going to evolve over a period of time. Researchable issues, like the extent of gene flow and influence of local environment and management practices on it, need to be addressed particularly in developing countries, wherefrom only fragmentary information is available so far. In this regard, due attention needs to be given to capacity building. The FAO and the Global Environment Facility of the UN Environmental Programme (UNEP-GEF) have provided significant support to capacity building on biosafety in developing countries. These programs need to be carried forward through bilateral and regional initiatives.

With biosafety regulations in place, attention also needs to be paid to post-release monitoring of GM crops to ensure that there is no unforeseen damage to the environment. In an Expert Consultation hosted by the FAO on post-release monitoring (FAO, 2005), it was emphasized that GM crop deployment must comprise the whole technology development process, from pre-release risk assessment to biosafety considerations and post-release monitoring. The latter should take into account the existing variations in location and context within and among farming systems.

References

1. Alvarez-Buylla, E.R. 2003. Ecological and biological aspects of the impact of transgenic maize, including agro-biodiversity. Secretariat of the Commission for Environmental Cooperation, Canada, Mexico and United States. P. 24.
2. APCoAB. 2006. Bt cotton in India- A status report. Asia-Pacific Consortium on Agricultural Biotechnology, New Delhi, India. P. 34.
3. Armstrong T.T., R.G. Fitzjohn, L.E. Nesstrom, A.D. Wilton, W.G. Lee. 2005. Transgene escape: what potential for crop-wild hybridization? *Molecular Ecology*, **14:** 2111–32.
4. Bates, S.L., J.Z. Zhao, R.T. Roush and A.M. Shelton 2005. Insect resistance management in GM crops: past, present and future. *Nature Biotechnology*. **23:** 57-62.

5. Birch, A.N.E., I.E. Geoghegan, M.E.N. Majerus, J.W. McNicol, C.A. Hackett, A.M.R. Gatehouse, and J.A. Gatehouse. 1999. Tritrophic interactions involving pest aphids, predatory 2-spot ladybirds and transgenic potatoes expressing snowdrop lectin for aphid resistance. *Molecular Breeding* **5:** 75-83.
6. Bergthorsson, U., K.L. Adams, B. Thomason and J.D. Palmer. 2003. Widespread horizontal transfer of mitochondrial genes in flowering plants. *Nature* **424:** 197-201.
7. Brenz Verca M.S., P. Weber, C. Mayer, C. Graf, D. Refojo, R. Kühn, I. Grummt and B. Lutz. 2007. Development of a species-specific RNA polymerase I-based shRNA expression vector. *Nucleic Acids Research*. **35:** 10.
8. Burke, M. 2005. Managing GM crops with herbicides – Effects on farmland wildlife. Department of Environment, Food and Rural Affairs, UK. P. 9. (*available at: http://www.defra.gov.uk/environment/gm/fse/results/fse-summary-05.pdf ; accessed on 20 February 2008*).
9. Callaghan M.O., T.R. Glare, E.P.J. Burgess and L.A. Malone. 2005. Effects of plants genetically modified for insect resistance on non-target organisms. *Annual Review of Entomology* **50:**1- 27.
10. Celis C, M. Scurrah, S. Cowgill, S. Chumbiauca, J. Green, J. Franco, G. Main, D. Kiezebrink, R.G.F. Visser, H.J. Atkinson. 2004. Environmental biosafety and transgenic potato in a centre of diversity for this crop. *Nature* **432:** 222-225.
11. Chang-Ming L., X. Ling and W. Yu-Hua. 2005. Transgenic rapeseed: environmental release and its biosafety relevance in China. *Chinese Journal of Agricultural Biotechnology* **2(3):** 219–227.
12. Chen L.J., D.S. Lee, Z.P. Song, H.S. Suh and B.R. Lu. 2004. Gene flow from cultivated rice (*Oryza sativa*) to its weedy and wild relatives. *Annals of Botany* **93:** 67-73.
13. Cherdeshewasart, W., G.B. Gharti-Chhetri, M.W. Saul, M. Jacob and I. Negrutiu. 1993. Expression instability and genetic disorders in transgenic *Nicotiana plumbaginifolia* L. plants. *Transgenic Research* **2:** 307-320.
14. Cockburn, A. 2002. Assuring the safety of genetically modified (GM) foods: the importance of a holistic integrative approach. *Journal of Biotechnology* **28:** 79-106.
15. Conners, A.J., T.R. Glare and J. Nap. 2003. The release of genetically modified crops into the environment: Part II. Overview of ecological risk assessment. *The Plant Journal* **33:** 19-46.
16. Cuellar W., A. Gaudin, D. Solorzano, A. Casas, L. Nopo, P. Chudalayandi, G. Medrano, J. Kreuze and M. Ghislain. 2006. Self-excision of the antibiotic resistance gene nptII using a heat inducible Cre-loxP system from transgenic potato. *Plant Molecular Biology*. **62:** 71-82.
17. Deni J., B. Message, M. Chioccioli, D and Tepfer. 2005. Unsuccessful search for DNA transfer from transgenic plants to bacteria in the intestine of the tobacco horn worm, *Manduca sexta*. *Transgenic Research* **14:** 207-215.
18. Dunwell, J.M. 1999. Transgenic crops: The next generation, or an example of 2020 vision. *Annals of Botany* **84**: 269-272.
19. Duputi, Ã., P. David, C. Debain and D. Mc Key. 2007. Natural hybridization between a clonally propagated crop, cassava (*Manihot esculenta* Crantz) and a wild relative in French Guiana. *Molecular Ecology* **16:** 3025-3038.
20. Ellstrand, N.C. 2003. Current knowledge of gene flow in plants: implications for transgene flow. *Philosophical Transactions of the Royal Society London B* **358:** 1163-1170.
21. Ellstrand, N.C., H.C. Prentice and J.F. Hancock. 1999. Gene flow and introgression from domesticated plants into their wild relatives. *Annual Review of Ecological Systems* **30:** 539–563.
22. Engels, J.M.M., A.W. Ebert, I. Thormann and M.C. de Vicente. 2006. Centres of crop diversity and/or origin, genetically modified crops and implications for plant genetic resources conservation. *Genetic Resources and Crop Evolution* **53:** 675-1688.

23. FAO. 2005. Genetically Modified Organisms in Crop Production and their Effects on the Environment: Methodologies for Monitoring and the Way Ahead. Report of Expert Consultation, 18–20 January 2005, Food and Agriculture Organization Rome, Italy, pp 33.
24. Firbank, L.G, M.S. Heard, I.P. Woiwod, C. Hawes, A.J. Haughton, G.T. Champion, R.J. Scott, M.O. Hill, A.M. Dewar, G.R. Squire, M.J. May, D.R. Brooks, D.A. Bohan, R.E. Daniels, J.L. Osborne, D.B. Roy, H.I.J. Black, P. Rothery, J.N. Perry. 2003. An introduction to the farm-scale evaluations of genetically modified herbicide tolerant crops. *Journal of Applied Ecology* **40:** 2–16.
25. Goodman, R.E., S.L. Hefle, S.L. Taylor and R.V. Ree. 2005. Assessing genetically modified crops to minimise the risk of increased food allergy: a review. *International. Archives of Allergy and Immunology* **137:** 153-166.
26. Gould, F. 1998. Sustainability of transgenic insecticidal cultivars: integrating pest genetics and ecology. *Annual Review Entomology* **43:** 701-726.
27. Grumet, R. and F. Gifford. 1998. Plant biotechnology in the United States: issues and challenges en route to commercial production. *HortScience* **33(2):** 187-192.
28. Guanming Shi. 2006. *Intellectual Property Rights, Genetic Use Restriction Technologies (GURTs), and Strategic Behavior* – In: American Agricultural Economics Association 2006 Annual Meeting Long Beach, CA July 23-26, 2006 (*available at http://www.aaea.org/2006am/Program%20Part%20II.pdf accessed on 5 May 2008*).
29. Hall L., K. Topinka, J. Huffman, L. Davis, and A. Good. 2000. Pollen flow between herbicide-resistant *Brassica napus* is the cause of multiple-resistant *B. napus* volunteers. *Weed Science* **48:** 688-694.
30. Hammond, J., H. Lecoq and B. Racaah. 2000. Epidemiology risks from mixed infections and transgenic plants expressing viral genes. *Advances in Virus Research* **54:** 187-315.
31. Head, G., B. Surber, J.A. Watson, J.W. Martin and J.J. Duan. 2002. No detection of Cry1Ac protein in soil after multiple years of transgenic Bt cotton (Bollgard) use. *Enviromental Entomology* **31:** 30–36.
32. Heinemann, J. 2007. A typology of the effects of (trans)gene flow on the conservation and sustainable use of genetic resources. Background study paper No. 35. FAO, Rome. P. 100.
33. Hilbeck, A., M. Baumgartner, P.M. Fried and F. Bigler. 1998. Effect of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae). *Environmental Entomology* **27:** 1-8.
34. Holt, J.S., S.B. Powels and J.A.M. Holtum. 1993. Mechanisms and agronomic aspects of herbicide resistance. *Annual Review of Plant Physiology Plant Molecular Biology* **44:** 203-229.
35. IGMORIS. 2008. Year wise list of commercially released varieties of Bt cotton hybrids by GEAC. Indian GMO Research Information System. (*available at: http://igmoris.nic.in/files/List_of_approved_hybrids200807.pdf; accessed on 11 January 2008*).
36. Jefferson, R.A., D. Byth, C. Correa, G. Otero and C. Qualset. 1999. Genetic Use Restriction Technologies. An Expert paper presented before the Fourth Meeting of the UNEP/CBD secretariat, Montreal Canada.UNEP/CBD/SBSTTA/4/9/Rev.1.
37. Khetarpal, R.K. 2002. Biosafety of genetically modified crops and its implications. In: *Hitech Horticulture*, (eds K.L. Chadha, M.L. Choudhary and K.V. Prasad), Horticulture Society of India, New Delhi. P. 444-453.
38. Krattiger, A.F. and K.V. Raman, 1996. The Acquisition and transfer of transgenic plant technology for the Asian-Pacific region: Case Study of the Bt gene. International Service for the Acquisition of Agri-biotech Applications (ISAAA), Ithaca, New York.
39. Lee, D. and E. Natesan. 2006. Evaluating genetic containment strategies for transgenic plants. *Trends in Biotechnology* **24:** 109-114.

40. Lin, C, J. Fang, X. Xu, T. Zhao and J. Cheng. 2008. A built-in strategy for containment of transgenic plants: creation of selectively terminable transgenic rice. *PLoS ONE* **3(3):** 1818.
41. Luo, K., H. Duan, D. Zhao, X. Zheng, W. Deng, Y. Chen, C. N. Stewart, Jr., R. McAvoy, X. Jiang, Y. Wu, A. He, Y. Pei, Y. Li. 2007. 'GM-gene-deletor': fused loxP-FRT recognition sequences dramatically improve the efficiency of FLP or CRE recombinase on transgene excision from pollen and seed of tobacco plants. *Plant Biotechnology Journal*. **5:** 263-374.
42. Lutteral, R. 2008. Personal communication.
43. Miki, B and S. McHugh. 2004. Selectable marker genes in transgenic plants: applications, alternatives and biosafety. *Journal of Biotechnology* **107:** 193-232.
44. Mello, C.C. and D. Conte Jr. 2004. Revealing the world of RNA interference. *Nature* **432:** 338-342.
45. Nap J., L.J. Peter, M.E. Metz and J.C. Anthony. 2003. The release of genetically modified crops into the environment. Part I. Overview of current status and regulations. *The Plant Journal* **33:** 1–18.
46. Natarajan, S. and Jn Turna. 2007. Excision of selectable marker genes from transgenic crops as concern for environmental biosafety. *Journal of the Science of Food and Agriculture* **87:** 2547-2554.
47. Netherwood, T., S.M. Martín-Orúe, A.G. O'Donnell, S. Gockling, J. Graham, J.C. Mathers and H.J. Gilbert. 2004. Assessing the survival of transgenic plant DNA in the human gastrointestinal tract. *Nature Biotechnology* **22:** 204-209.
48. Nordlee, J.A.,S. L. Taylor, J.A. Townsend, L.A. Thomas and R.K. Bush. 1996. Identification of a Brazil-nut allergen in transgenic soybeans. *New England Journal of Medicine* **334:** 688-692.
49. Philippe, V. 2007. Trends in GM crop, food and feed safety literature. *Nature Biotechnology* **25:** 6, 624.
50. Prescott, V.E., P.M. Campbell, A. Moore, J. Mattes, M.E. Rothenberg, P.S. Foster, T.J.V. Higgins and S.P. Hogan, 2005. Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity. *Journal of Agricultural and Food Chemistry* **53:** 9023-9030.
51. Quist, D. and I. H. Chapela. 2001. Transgenic DNA introgression into traditional maize landraces in Oxaca, Mexico. *Nature* **414:** 541-543.
52. Ruf, S., D. Karcher, R. Bock. 2007. Determining the transgene containment level provided by chloroplast transformation. *Proceedings of the National Academy of Sciences of the United States of America* **104:** 6998-7002.
53. Ruibal Mendieta, N.L., A.M. Nagy, F.A. Lints. 1997. The potential allergenicity of novel foods. *Journal of the Science of Food and Agriculture* **75:** 405-411.
54. Saxena, D. and G. Stotsky. 2001. Bt corn has higher lignin content than non Bt corn. *American Journal of Botany* **88:** 1704-1706.
55. Scott, S.E. and M.J. Wilkinson. 1999. Low probability of chloroplast movement from oil seed rape into wild *Brassica rapa*. *Nature Biotechnology* **17:** 391-392.
56. Scheffler, J.A., R. Parkinson and P.J. Dale. 1995. Evaluating the effectiveness of isolation distances for field plots of oilseed rape (*Brassica napus*) using a herbicide-resistance transgene as a selectable marker. *Plant Breeding* **114:** 317–321.
57. Sharma, H.C., R. Arora and G. Pampapathy. 2007. Influence of transgenic cottons with *Bacillus thuringiensis* cyr1 Ac gene on the natural enemies of *Helicoverpa armigera*. *BioControl* **52:** 469-489.
58. Soleri, D., D.A. Cleveland, and F. Aragon Cuevas. 2006. Transgenic crops and crop varietal diversity: the case of maize in Mexico. *Bioscience* **56:** 503-513.
59. Squire, G.R., C. Hawes, D.A. Bohan, D.R. Brooks, G.T. Champion, L.G. Firbank, Haughton, A.J.M.S. Heard, M.J. May, J.N. Perry and M.W. Young. 2005. Biodiversity Effects of the Management Associated With GM Cropping Systems in the UK. Final report of Defra Project EPG 1/5/198. A review of research

into the effects of farmland biodiversity on the management associated with genetically modified cropping systems. Scottish Crop Research Institute. Invergowrie, Dundee DD2 5 DA., P. 76.

60. Stewart, C.N., M.D. Hafhill and S.I. Warwick. 2003. Transgene introgression from genetically modified crops to their wild relatives. *Nature Review of Genetics* **4:** 806–817.
61. Syvanen, M. 1994. Horizontal gene transfer: evidence and possible consequences. *Annual Review of Genetics*. 28: 237-261.
62. Tabashnik, B.E., Gassmann A.J., Crowder D.W., Carriére Y. 2008. Insect resistance to Bt crops: evidence versus theory. *Nature Biotechnology* **26(2):** 199-202.
63. Thomson, J.A. 2001. Horizontal transfer of DNA from GM crops to bacteria and to mammalian cells. *Journal of Food Science* **66:** 188-193.
64. Thompson, C.E., G. Squire, G.R. Mackay, J.E. Bradshaw, J. Crawford and G. Ramsay. 1999. Regional patterns of gene flow and its consequences for GM oilseed rape. In: Lutman, P. (ed.) Gene Flow and Agriculture: Relevance for Transgenic Crops. BCPC Symposium Proceeding No. 72. Farnham, Surrey: British Crop Protection Council. Pp. 95–100.
65. Wang, X.W., A. Kaga, N. Tomooka, D.A. Vaughan. 2004. The development of SSR markers by a new method in plants and their application to gene flow studies in adzuki bean [*Vigna angularis* (Willd.) Ohwi & Ohashi]. *Theoretical and Applied Genetics* **109:** 2-7.

3. INTERNATIONAL AGREEMENTS RELATED TO BIOSAFETY

Biosafety issues as detailed in the previous chapter are being addressed through a range of policy and procedural measures at both international and national levels. These measures aim at minimizing the potential risks that biotechnology processes and products pose to the environment and human health and are essentially based on the principles of risk assessment and management. Risk assessment is the determination of potential risk associated with a specific activity while risk management is the use or application of procedures and means to reduce the negative consequences of a risk to an acceptable level. It is assumed that risks can be limited by proper handling and use of various preventive measures.

Discussions on the hazards of recombinant DNA cloning began in the early 1970s. The set of guidelines produced by the Recombinant Advisory Committee (RAC) of the US National Institutes of Health in 1975, were among the first to ensure safety of the laboratory workers involved in biotechnology research, the public and the environment (Office of Biotechnology Activities, 2006). The biosafety guidelines were voluntary and had no legal standing. Over the years many countries have adopted them, or a derivation thereof for purposes of biosafety management. Besides, several countries, including those in the Asia-Pacific region, have entered into international agreements that address biosafety issues related to transboundary movement of GM crops and their products.

3.1 INTERNATIONAL INSTRUMENTS ON BIOSAFETY

Six organizations are directly or indirectly involved in international biosafety regulation:

(a) *The Convention on Biological Diversity (CBD)-1992:* Concerns conservation, sustainable use and fair and equitable sharing of benefits arising from the use of biological resources. The Cartagena Protocol on Biosafety regulates transboundary movement of living modified organisms (LMOs)[2].

(b) *The World Trade Organization (WTO)-1995:* Deals with trade in goods and services and dispute settlement. The WTO Agreement on Application of Sanitary and Phytosanitary (SPS) Measures is related to procedures of risk analysis of plant and animal pests and diseases, and food safety.

(c) *The International Plant Protection Convention (IPPC)-1952:* Develops International Standards on Phytosanitary Measures (ISPMs) against pests of plants and plant products including GMOs.

(d) *The Codex Alimentarius Commission (CAC)-1972:* Develops international standards including those for food safety and food labeling.

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[2] The term "living modified organisms" (LMOs) is defined by the Protocol as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology". For the present report, the term has been used interchangeably with GMOs.

(e) *The World Organization for Animal Health (OIE)-1924:* Harmonizes trade regulations for animals and animal products, and develops standards on animal health including for infectious animal diseases.

(f) *The Organization for Economic Cooperation and Development (OECD)-1961:* Undertakes harmonization of international regulations, standards and policies.

The Cartagena Protocol on Biosafety and the WTO are directly involved in regulation of trade in products of agricultural biotechnology. WTO-SPS recognizes three standard setting bodies, IPPC, CAC and OIE that address different biosafety aspects including environment, health and food safety. Under SPS rules, member countries can use other standards but they have to develop their standards on the basis of the principle of risk assessment. OECD develops documents, guidelines and recommendations on harmonized rules, policies and standards for its members.

3.1.1 Cartagena Protocol on Biosafety

The Convention on Biological Diversity of the United Nations adopted the Cartagena Protocol on Biosafety (hereinafter, the Protocol) in the year 2000 which entered into force on 11 September 2003. The Protocol has been ratified by 143 Parties (as on January 2008) including most countries from the Asia-Pacific region (Annexure II). Since these countries have either developed or are in the process of developing their biosafety regulatory systems in conformity with the Protocol, detailed information about its provisions is given here.

3.1.1.1 *Salient Features*

The Protocol comprising 40 articles is a legally binding agreement to ensure adequate levels of protection for safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on human health and conservation and sustainable use of biological diversity (CBD, 2008). It covers transboundary movement, transit, handling and use of LMOs. However, it does not cover non-food or non-feed products derived from LMOs (e.g. paper from GM trees) and LMOs that are pharmaceuticals for humans. It allows the members to take decisions on the import of LMOs intended for direct use as food or feed, or for processing, under their domestic regulatory framework. The Protocol also promotes cooperation to help developing countries acquire resources and capacity to use biotechnology safely and more efficiently and encourages training to promote safe transfer of technology. It also includes a clause clarifying that it does not alter the rights and obligations of parties under the WTO or other international agreements.

The following details on the Protocol's key articles are largely based on the reviews published by FAO (2001), Mackenzie *et al.* (2003) and CBD (2006).

3.1.1.2 *Advanced Informed Agreement (AIA) (Article 7)*

The Protocol's main mechanism is its AIA requirement. Under this procedure, the exporting party must first as specified in Article 8 provide written notification (which includes a full set of information specified in Appendix II to the Protocol) to the importing government that it is interested in exporting a new LMO into the importing country. The importing country government must then acknowledge receipt of the notification as per Article 9. A competent body within the importing country must then make a decision according to Article 10, using risk assessment procedures described in Article 15. Article 10 contains explicit support for the precautionary approach of risk assessment stating "lack of scientific certainty due to insufficient relevant scientific

information and knowledge regarding the extent of the potential adverse effects of the LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision". The exporter must provide a notification to the importing country containing detailed information about the LMO, its previous risk assessments and its regulatory status in the exporting country. The importing country must acknowledge receiving the information within 90 days and whether the notifier should proceed under a domestic regulatory system or under the Protocol procedure. In either case, the importing country must decide within 270 days whether to allow the import, with or without conditions or deny it.

The AIA is meant only for first time shipments and consecutive shipments are exempt from it. Also, LMOs not intended for release into the environment, those in transit and destined for contained use are exempt from the requirement of AIA. The Protocol also sets up a separate procedure for LMOs intended for direct use as food or feed, or for processing, in Article 11. Under its provision, any party making a final decision regarding domestic use of LMOs including placing on the market must within 15 days notify other parties of the Convention on the Biological Diversity of this fact through the Biosafety Clearing House (BCH).

3.1.1.3 *Risk Assessment (Article 15)*

The Protocol requires that decisions on proposed imports be based on risk assessments, which are undertaken in a scientific manner based on recognized risk assessment procedures, taking into account advice and guidelines developed by relevant international organizations. Lack of scientific data or consensus must not be interpreted as indicating acceptance of particular level of risk. The risks associated with LMOs or their products should be considered in the context of risks posed by the non-modified recipients or parental organisms in the potential receiving environment. Risk assessment is carried out on a case-by-case basis.

3.1.1.4 *Handling, Transport, Packaging and Identification (Article 18)*

This article concerns the measures to be taken to avoid risks during transboundary movement of LMOs for intentional introduction into the environment. The objective of this article is to make sure that the LMOs are handled and moved safely to avoid adverse effects on biodiversity and human health.

3.1.1.5 *Biosafety Clearing House (BCH) (Article 20)*

The BCH is an information sharing mechanism operated through a website (*http://bch.cbd.int*) and administered by the Secretariat to the Convention. It has been established to (a) facilitate the exchange of scientific, technical, environmental and legal information on LMOs and (b) assist members to implement the Protocol. Examples of information contained in the BCH include any existing laws, regulations, or guidelines for implementation of the Protocol, summaries of risk assessments or environmental reviews of LMOs and final decisions regarding the importation and release of LMOs.

3.1.1.6 *Capacity Building (Article 22)*

This article calls for cooperation in the development and/or strengthening of human resources among developing countries, island developing states and Parties with economies in transition for sharing resources and institutional capacities on biosafety including biotechnology for effective implementation of the Protocol. The Protocol recognizes the inability of some countries to cope

with the nature and scale of known and potential risks associated with LMOs. Hence, cooperation for capacity building is a priority.

3.1.1.7 *Public Awareness and Participation (Article 23)*

Parties are obliged to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs by, *inter alia*, providing access to information on LMOs that may be imported.

3.1.1.8 *Socio-economic Considerations (Article 26)*

In making import decisions, parties may take into account socio-economic considerations arising from the import of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biological diversity to indigenous and local communities.

3.1.1.9 *Liability and Redress (Article 27)*

This article addresses issues of liability and redress for damage resulting from the transboundary movement of LMOs. The liability procedure is under negotiation.

3.1.1.10 *Compliance (Article 34)*

The compliance regime for the Protocol which is not yet finalized will provide procedures and mechanisms to promote compliance and address non-compliance.

3.1.2 WTO-Agreement on Application of Sanitary and Phytosanitary (SPS) Measures

3.1.2.1 *Scientific Principle*

This Agreement concerns the application of food safety and animal and plant health regulations, which should be based on science, applied only to the extent necessary and not discriminate between countries with similar conditions. The guidelines for pest risk analysis (PRA) ensure that all restrictions in trade are based on the assessment of risks and are not arbitrary or discriminate against any exporting country with the same pest status (WTO, 2008).

3.1.2.2 *Risk Identification*

Risk posed by a pest is identified through a systematic PRA comprising three stages of evaluation (a) Stage 1- *Initiation* identifies pathways and pests to be analyzed; (b) Stage 2- *Pest Risk Assessment* gives estimates on risk based on the probability of entry and establishment of pest and its potential impact and (c) Stage 3- *Pest Risk Management* identifies management measures to reduce the risk to an acceptable level.

3.1.2.3 *Basis of Assessment*

PRA is based on the probability of a pest entering and establishing in the importing country and its potential impact there.

3.1.2.4 *Monitoring and Review*

WTO members need to seek comments on their country regulations and standards and provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which deviate from international standards, guidelines or recommendations. The dispute settlement framework of the WTO agreement requires that PRA is fully documented

so that when a review is undertaken or a dispute arises it should clearly state the source of information and the rationale used in reaching a particular management decision regarding SPS measures taken/being taken.

3.1.3 IPPC-ISPM 11 – Guidelines for Pest Risk Analysis for Quarantine Pests including Analysis of Environmental Risks and Living Modified Organisms

The guidelines include phytosanitary risks that might be associated with LMOs as they are included within the scope of pests and hence, should be considered for PRA to make decisions regarding their risk management (IPPC, 2008).

3.1.3.1 *Scientific Principle*

The potential of risk from LMO pests depends in part on the intended use. As for other organisms, certain intended uses (such as high security contained use) may significantly manage risk. For LMOs, as with other pests, options within the country also include the use of emergency measures related to phytosanitary risks.

3.1.3.2 *Risk Identification*

Potential phytosanitary risks posed by LMOs may also include changes in adaptive characteristics which may increase the potential for introduction or spread, adverse effects of gene flow or gene transfer, adverse effects on non-target organisms including, genotypic and phenotypic instability or any other injurious effects.

3.1.3.3 *Basis of Assessment*

Phytosanitary risks from LMOs may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences.

(a) In cases of phytosanitary risks related to gene flow, the LMO is considered more as a potential vector or pathway for introduction of a gene construct of phytosanitary concern than a pest in itself. Hence, the term "pest" is understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.

(b) The risk analysis procedures of the IPPC concern more with phenotypic characteristics than genotypic characteristics but the latter may also be considered when assessing the risks of LMOs.

3.1.3.4 *Monitoring and Review*

The IPPC-ISPM 11 is binding on all WTO-SPS members to facilitate trade in LMOs and avoid trade disputes. The principle of "modification" states: "As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary".

3.1.4 CAC – Codex Guidelines for GM Foods including the Analysis of Unintended Effects

The Codex's aim is to anticipate not only the direct risks, but also the indirect/unanticipated risks that the products of modern agriculture might pose for human health. It states that all the methods including protoplast fusion and/or recombinant DNA technology have the potential to generate unanticipated effects in plants (Haslberger, 2003).

3.1.4.1 *Scientific Principle*

Case-by-case premarket assessment includes an evaluation of both direct and unintended effects. The safety assessment of GM foods covers direct health effects (toxicity), tendency to provoke allergic reactions (allergenicity), specific components thought to have nutritional or toxic properties, the stability of the inserted gene, nutritional effects associated with genetic modification and any unintended effects that could result from the gene insertion (WHO, 2008).

3.1.4.2 *Risk Identification*

Risk identification to encompasses not only health-related effects of the food itself, but also the indirect effects of food on human health (for example, potential health risks derived from out crossing).

3.1.4.3 *Basis of Assessment*

The potential long term effect of any foods is difficult to identify. In many cases, this is further confounded by wide genetic variability in the population, such that some individuals may have a greater predisposition to food-related effects. It concludes that application of the *substantial equivalence* concept contributes to a robust safety assessment framework.

3.1.4.4 *Monitoring and Review*

Codex principles are not binding on member nations, but are referred to specifically in the SPS Agreement of the WTO, and can be used as a reference in case of trade disputes.

3.1.5 World Organization for Animal Health (OIE)

The OIE ensures *transparency* in the global animal disease situation to improve the legal framework and resources of national *veterinary services.* It establishes standards, guidelines and recommendations relevant to animal diseases and zoonoses in accordance with its statutes and as defined in the WTO-SPS Agreement (OIE, 2006; Sendashonga *et al*., 2005).

3.1.5.1 *Scientific Principle*

The standards are based on the principle of validation, control of exotic diseases and certification of diagnostic assays (test methods) for infectious animal diseases by the OIE.

3.1.5.2 *Risk Identification*

It is aimed to provide importing countries with an objective and defensible method of assessing the disease risks associated with the import of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. The risk identification criteria are case specific for the listed diseases requiring appropriate measures during import and export of animals and animal products. The exporting country is provided with clear reasons for the imposition of import conditions or refusal to import.

3.1.5.3 *Basis of Assessment*

Risk assessment is categorized into quantitative and qualitative assessments. Quantitative assessments require mathematical modeling while qualitative assessments do not require mathematical modeling and are for routine decision making. No single method of risk assessment is applicable to all situations and different methods are used in different circumstances. The requirements are elaborated case-by-case under the various standards- "Terrestrial Animal Health Code", "Aquatic Animal Health Code, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals", and "Manual of Diagnostic Tests for Aquatic Animals".

3.1.5.4 *Monitoring and Review*

The OIE has an information system for dissemination of early warning messages whenever epidemiologically significant events are officially reported. This alert system helps decision-makers to take necessary preventive measures as quickly as possible. In order to improve transparency and animal health information quality, the OIE has also set up an animal health information search and verification system for non-official information from various sources on the existence of outbreaks of diseases that have not yet been officially notified to the OIE.

3.1.6 OECD – Safety Considerations for Biotechnology, 1986 and 1992

The 1986 OECD report was the first attempt to set international safety guidelines for industrial, agricultural and environmental applications of biotechnology. It presents scientific principles that could underlie risk management for the release of GMOs into the environment. The 1992 report follows from this and defines "Good Development Principles" for the design of safe, small-scale field trials of GM plants and microorganisms (OECD, 1992).

3.1.6.1 *Scientific Principle*

Proposals to release GMOs are considered on a case-by-case basis. The development and assessment of GMOs takes place in a step-wise fashion moving from the laboratory to the greenhouse, to small-scale field trials and then large-scale field trials. Each step in the process generates information to predict the safety of the next step. Safety concerns focus on whether GMOs pose an "incremental risk" above and beyond the background risks of conventional agriculture.

3.1.6.2 *Risk Identification*

The 1986 report identifies fault trees and event trees as a means to quantify probability of risk.

3.1.6.3 *Basis of Assessment*

Fault trees, event trees and simulation can be used to quantify the probability and the magnitude of consequences in the first two stages of the assessment framework. The last stage can be analyzed by adapting/adopting conventional epidemiological or toxicological methods, although ecological consequence assessment is less well developed than its human counterpart. It suggests that qualitative risk assessment can be used to compare the propensities for survival, establishment and genetic stability under different environmental conditions, as much data are not available in these fronts. The reports do not clearly discuss uncertainty or the significance of the risk estimates.

3.1.6.4 *Monitoring and Review*

The 1992 report states that scientifically acceptable and environmentally safe field research

requires formulation of a hypothesis and statement of objectives, development of specific methodologies to introduce and monitor the organisms and mitigate the risk, a precise description of the design of experiments, including planting density and treatment pattern, and a description of specific data to be collected, and methods for analysis to test for statistical significance.

3.2 SOME REGIONAL BIOSAFETY REGULATIONS

Besides the international instruments, some region specific biosafety regulatory systems have been effected/proposed. These serve as good examples of regional approaches to biosafety management.

3.2.1 EU – Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs

This directive is aimed to provide a common European wide methodology for ecological risk assessment and objectives for monitoring GMO releases to the environment (European Commission, 2001). It has been framed in accordance to the precautionary approach of the Protocol whereby the potential effects of GMOs are to be assessed case-by-case. Releases are to be carried out in a stepwise fashion and must be field-tested in ecosystems that could be affected by their use. The procedure is permitted to be slightly relaxed for GMOs that are well known and characterized. For risk identification, the directive does not identify or recommend any hazard assessment procedure but notes that potential adverse effects would vary case-by-case and lists generic hazards such as toxicity, impacts on population dynamics, altered susceptibility to pathogens etc. The main factor considered for risk assessment is the environment into which the GMO is released and the manner of release. The directive does not refer to uncertainty or the significance of the risk estimates. The monitoring plan consists of confirmation of the assumptions made during risk assessment and identification of adverse effects that were not anticipated in the assessment. The latter are required to be continued for a sufficient period of time to identify delayed and indirect effects.

3.2.2 African Model Law on Safety in Biotechnology

The Organization of African Unity (now African Union) drafted a biosafety law to serve as a model regulation especially to protect Africa's biodiversity, environment and the health of its people from the risks posed by GMOs. The member states were urged to use the Model Law to draft their respective national legislations. The Model Law recognizes that while biotechnology holds promise for the improvement of human well-being, it could have potential adverse effects on the environment, biological diversity and human health (African Ministerial Conference on Science and Technology, 2007). The Model law:

(a) Recognizes the principle of precautionary approach for regulating import, contained use, release or marketing of GMOs and their products;

(b) Although adopts several of the provisions of the Protocol as such but in some cases goes a step further. For example, unlike the Protocol procedures, the AIA procedure is applied to all imports of GMOs, including those intended for contained use, food aid, or those in transit, products of GMOs, along with those for direct use as food, feed or for processing;

(c) Outlines the application process to be applied equally to all types of GMOs that includes an assessment report on risks that may be posed by the GMO or their products on the environment, biological diversity or human health, including unintentional release;

(d) Provides that where a risk assessment proves that risks are unavoidable, the Competent Authority shall refuse approval of any GM activity;

(e) Suggests that countries create a Competent Authority to take decisions on GM imports; establish a National Biosafety Committee to make policy recommendations and develop guidelines on biosafety issues. The public to be involved in the decision-making process by way of notice and comment procedure;

(f) The Model Law recommends labeling of all GMOs and products of GMOs for the purposes of traceability.

A revision of the Model Law was undertaken in 2007 due to the need felt by African countries to have a harmonized position in matters of biosafety.

The Third World Network Model National Biosafety Law (TWN, 2005) and the Model Act (Abramson and Van der Meer, 2006) are the other proposed model laws on biosafety regulation.

References

1. Abramson, S.H. and L. Van der Meer. 2006. Model Act: Proposed provisions for a transparent, effective and workable biosafety regulatory framework. (available at: *http://www.agbios.com/docroot/articles/07-298-001.pdf*; accessed on 8 December 2007).
2. African Ministerial Conference on Science and Technology. 2007**.** Third Ordinary Session 12-16 November 2007 Mombasa, Republic Of Kenya Au/Exp/St/17(III) African Model Law on Safety in Biotechnology. (available on at: *http://www.nepadst.org/doclibrary/pdfs/amcost3_17_nov2007.pdf;* accessed on 18 January 08).
3. CBD. 2006. About the Protocol. (available at *http://www.cbd.int/biosafety/about.shtml;* accessed on 22 February 2008).
4. CBD. 2008. Cartagena Protocol on Biosafety. (available at *http://www.cbd.int/biosafety/protocol.asp;* accessed on 6 January 2008).
5. European Commission. 2001. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. *Official Journal of the European Communities* **L106:** 1-38.
6. FAO. 2001. FAO and the Biosafety Protocol to the Convention on Biological Diversity (available at *http://www.fao.org/waicent/faoinfo/sustdev/RTdirect/RTre0034.htm;* accessed on 18 June 2007).
7. Haslberger, A. 2003. Codex guidelines for GM foods include the analysis of unintended effects. *Nature Biotechnology* **21:** 739-741.
8. IPPC. 2008. International Standards for Phytosanitary Measures ISPM No. 11. (available at: *https://www.ippc.int/servlet/BinaryDownloaderServlet/34163_ISPM_11_E.pdf?filename=1146658377367_ISPM11.pdf&refID=34163;* accessed on 16 January 2008).
9. Mackenzie, R., F. Berhenne-Guilmin, A.G.M. La Vina and J. Werksman. 2003. An Explanatory Guide to the Cartagena Protocol on Biosafety IUCN Environmental Policy and Law Paper No. 46, IUCN. (available at: *http://www.iucn.org/themes/law/pdfdocuments/Biosafety%20Guide/Biosafety-guide-prelims.pdf;* accessed on 12 December 2007).
10. OECD. 1992. Safety considerations for biotechnology. Organization for Economic Cooperation and Development, Paris, France, P. 45.
11. Office of Biotechnology Activities. 2006. Recombinant DNA Advisory Committee (available at: *http://www4.od.nih.gov/oba/rac/aboutrdagt.htm*; accessed on 18 June 2007).
12. OIE. 2006. World Organization for Animal Health-Official Acts. (available at: *http://www.oie.int/eng/OIE/actes/en_actes.htm?e1d1*; accessed on 17 February 2008).

13. Sendashonga, C., R. Hill and A. Petrin. 2005. The Cartagena Protocol on Biosafety: interaction between the Convention on Biological Diversity and the World Organization for Animal Health, *Review of Scientific Technologies of Organisation Internationale des Epizooties*, P. 24 (1), 19-30. (available at: *http://www.oie.int/eng/publicat/rt/2401/24-1%20pdfs/03-sendas19-30.pdf*; accessed on 17 February 2008).
14. TWN. 2005. Model National Biosafety Law. (available at: *http://www.biosafety-info.net/article.php?aid=256*; accessed on 18 January 2008).
15. WHO. 2008. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants CAC/GL 45-2003. (available at: *http://www.who.int/foodsafety/biotech/en/codex_guidelines_plants.pdf*; accessed on 16 January 2008).
16. WTO. 2008. The Agreement on Application of Sanitary and Phytosanitary Measures. (available at *http://www.wto.org/english/thewto_e/thewto_e.htm*; accessed on 17 February 2008).

4. BIOSAFETY REGULATIONS OF ASIA-PACIFIC COUNTRIES

Beginning late 1980s, Asia-Pacific countries initiated legislative measures to manage the potential risks associated with GM technology. In 1986, India enacted "Environment Protection Act" and published "The Environment (Protection) Rules" to regulate environmental pollution by managing hazardous substances, including hazardous microorganisms and GMOs. In 1990, "Philippines Presidential Order" established a national biosafety committee and during early 1990s, India and Thailand published the first guidelines on research and environmental release of GMOs.

The biosafety regulatory systems vary across countries; some developing an entirely new biosafety specific system while others making modifications in the existing regulatory systems to address biosafety issues. The legal instruments used for the purpose have been new or modified laws, acts, decrees, guidelines, rules etc. Alongside, administrative systems have been developed to operationalize the legal instruments. Following one or the other approach, a number of countries have currently in place regulations on development, contained use, environmental release, commercialization and import of GM crops and products. Several other countries have their biosafety regulations either in drafting or implementation phase.

With the aim of assisting countries to comply with the Protocol, the Global Environment Facility of the United Nations Environment Programme (UNEP-GEF) has supported since 2001 several countries in the development of their National Biosafety Frameworks (NBFs). NBF is a "combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health" (UNEP-GEF, 2006). NBF has five components:

(a) A National Biosafety Policy: A stand-alone policy on biosafety; or part of policies on biotechnology, agricultural production, food production and/or food safety, biosecurity and/or quarantine, biodiversity conservation, environmental protection, science and technology or sustainable development;

(b) A Regulatory Regime that comprises legislations, laws, acts, regulation, decrees, or guidelines, etc. that may include, for example the following elements:

- **General provisions:** Objective, scope, definition of terms, institutional arrangements, general obligations;
- **Operational provisions:** Contained use, experimental environmental release, placing on the market/commercialization (including food/feed), import/export/transit, decision making procedures, mechanisms for public participation;
- **Other elements:** Information and public participation, monitoring, enforcement, offences and penalties, confidentiality, liabilities and redress, transition period, labeling and traceability;

(c) An administrative system that includes:

- The component authority(ies) responsible for receiving and handling requests for permits (import, export, domestic use, including placing on the market, intentional introduction into the environment, field trials, contained use, transit etc);
- The system(s)/ procedures for handling notification and requests for permits;
- The system(s) for risks assessment; the system(s) for decision-making;
- Meeting obligations under the BCH and national participation in the BCH;

(d) Mechanisms for public awareness, education and participation:

- Public access to information on GMOs;
- Public involvement in the decision-making process for GMOs;
- Awareness and education;
- Informing public about the means of public access to the Biosafety Clearing House;

(e) Systems for follow up, including

- Monitoring for environmental effects and effects on human, animal or plant life or health;
- Enforcement to ensure compliance;
- Offences and Penalties.

A procedure for consultation and analysis required to develop the NBF has been proposed in the ISNAR Briefing Paper N0. 47 (McLean *et al*., 2002). The countries of Asia-Pacific region which have developed or are in the process of developing their biosafety frameworks under the UNEP-GEF project are Bangladesh, Bhutan, Cambodia, China, Indonesia, Iran, Jordan, Kazakhstan, Korea DPR, Republic of Korea, Kyrgyzstan, Lao PDR, Lebanon, Maldives, Mongolia, Myanmar, Nepal, Niue, Papua New Guinea, the Philippines, Samoa, Sri Lanka, Syria, Tajikistan, Tonga, Vanuatu, Viet Nam and Yemen (UNEP-GEF, 2008). Among these, Bangladesh, Iran, Indonesia and the Philippines had some form of regulatory regime in place before joining the NBF.

The following section lists and gives brief details of national acts/decrees/guidelines/rules/ frameworks etc. of 39 Asia-Pacific countries that contribute to their biosafety regulatory systems. Drafts of regulations that are under consideration for approval of respective competent authorities are also listed. Sources of information have been included with the country regulation details to facilitate access to additional country specific information.

4.1 AUSTRALIA

4.1.1 Gene Technology Act 2000 (2001)

The GT Act provides the framework for the Australian system of regulation for GMOs (including plants, animals and microorganisms). It is the Australian Government's component of the nationally consistent regulatory scheme for gene technology.

The objective of the gene technology legislation is to protect the health and safety of people and to protect the environment by identifying risks posed by or as a result of gene technology, and by managing those risks.

The Act establishes the position of the Gene Technology Regulator (the GT Regulator), an independent statutory officer, to administer the legislation. It prohibits anyone dealing with a GMO (e.g. for research, manufacture, production, breeding, propagation, commercial release or import) unless the dealing is an exempt dealing or a notifiable low risk dealing (classes of

contained GMO work demonstrated to pose minimal risk to people and the environment, specified in the Regulations); or on the GMO Register; or licensed by the GT Regulator.

The use of GM products is regulated by other regulatory agencies. The GT Regulator does not directly regulate the use of GM products that are not live and viable. The GT Regulator provides advice on the genetic modification aspects of such products to other regulatory authorities for food, therapeutic goods, industrial chemicals, and agricultural and veterinary chemicals.

The GT Regulator is required to maintain a publicly available record of GMO and GM product dealings, including information on licensed dealings, notifiable low risk dealings, dealings on the GMO Register, and GM products approved by other regulatory authorities.

4.1.2 Gene Technology (Consequential Amendments) Act 2000

The Act requires that the existing regulators of GM products, which operate under the existing schemes for the regulation of food, therapeutic goods, industrial chemicals, and agricultural and veterinary chemicals must consult the GT Regulator in relation to any application for approval of a GM product.

4.1.3 Gene Technology Regulations 2001

(Amended in 2007 by the Gene Technology Amendment Regulations 2006)

4.1.4 Guidelines issued by the GT Regulator

The Guidelines support the implementation of the GT Act by providing technical details, such as the categorization of different dealings with GMOs, as well as specifying administrative processes and procedures.

The Amendment Regulations 2006 commenced on 31 March 2007, amending the 2001 Regulations.

Various technical and procedural guidelines, issued by the GT Regulator under the GT Act, describe additional requirements in relation to dealings with GMOs.

Source:

1. *The Office of the Gene Technology Regulator. 2004. Handbook on the Regulations of Gene Technology in Australia – A users guide to the Gene Technology Act 2000 and related legislation (pdf). (available at: http: www.ogtr.gov.au; accessed on 26 November 2007).*
2. *Peter Thygesen, Manager, Policy & Secretariat Section, Policy & Compliance Branch Office of the Gene Technology Regulator, PO Box 100, Woden Act 2606 Australia, email: Peter.Thygesen@health.gov.au (Personal communication).*

4.2 BANGLADESH

4.2.1 Biosafety Guidelines of Bangladesh (2005)

The Guidelines are applicable to all research and development activities of modern biotechnology conducted in laboratories of the government research institutes, state enterprises, universities, international organizations, private companies or non-governmental organizations located in Bangladesh. The Guidelines cover laboratory and field trials, trans-boundary movement, transit, handling and use of all GMOs with potential for adverse effects on the conservation and sustainable use of biological diversity, taking also into account risk to human health. They also cover aspects of risk assessment and safety requirements needed for

undertaking laboratory work, field trial and commercial use, involving microorganisms, plants and animals.

The Guidelines categorize the laboratory experiments based on different biosafety levels like work bearing minimal risk, low risk, considerable risk and high risk and the precautionary measures to be taken to avert such risks. These also propose a decision-making framework that allows experimental field testing based on (a) the testing agency's familiarity with plant and genetic modification, (b) the ability to confine the bioengineered plant, and (c) the perceived environmental impact, should the plant escape confinement.

4.2.2 National Biosafety Framework (2006) (Draft)

The draft NBF provides the basis for future regulation for the management of biotechnology products in Bangladesh. The objectives of the NBF are two-fold – provide oversight of the existing systems, and identification of future needs for an effective and transparent legislation and administrative system.

Source:

1. *Biosafety Guidelines of Bangladesh (available at: http://www.doe-bd.org/biosafety_Guidelines.pdf; accessed on 17 September 2007).*
2. *USDA Foreign Agricultural Service, GAIN Report No. BG6005 Bangladesh Biotechnology Annual 2006. (available at: http://www.fas.usda.gov/gainfiles/200607/146208489.pdf; accessed on 17 September 2007).*
3. *Mohammed Solaiman Haider, Assistant Director (Technical) & Project Director, Development of the National Biosafety Framework Project, Department of Environment, Dhaka, Bangladesh, email: haider@doe-bd.org (Personal communication).*

4.3 BHUTAN

4.3.1 Food Act (2005)

The Act addresses the issue of food safety, including that resulting from GM food.

4.3.2 Draft National Biosafety Framework (2007)

The draft NBF has been prepared according to the National Environment Commission, Bhutan. The draft has been submitted for approval of the Royal Government.

Ministerial Decree 2000

Banned all import of GMOs.

Other Related Regulations

4.3.3 Plant Quarantine Act (1993)

The Act safeguards agricultural and wild flora from introduced pests, defined as "any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant product." It also ensures that all imported plants are quarantined and screened prior to entry into the country.

4.3.4 Seed Act (2000)

The Act regulates import and export of agriculture seeds with the purpose of preventing the

introduction of pests and diseases and also promoting the seed industry in the country to enhance rural income and livelihood.

4.3.5 Environmental Assessment Act (2000)

The Act applies to strategic plans, policies, programs and projects which may have an impact on the environment.

4.3.6 Livestock Act (2000)

The Act ensures the quality control in terms of appropriate breeds of livestock, poultry and fish introduced into Bhutan.

4.3.7 Biodiversity Act (2003)

The Act ensures the national sovereignty of the Royal Government of Bhutan over its genetic resources in accordance with Convention on Biological Diversity.

Source:

1. *Ugen Tenzin, Chief Programme Officer, Policy and Planning Division, National Environment Commission, Bhutan, email: utenzin@nec.gov.bt (Personal communication).*

4.4 CAMBODIA

4.4.1 Natural Resource and Environment Law (Annex 4) (1996)

The Law is aimed at protecting and upgrading the environmental quality and public health by means of prevention, reduction and control of pollution; assessing the environmental impacts of all proposed projects; ensuring rational and sustainable preservation, development and management and the use of natural resources; encouraging public participation in the protection of natural resources and the environment including any acts which may affect the environment. Articles 2 to 11 are related to biosafety and biodiversity conservation

4.4.2 Sub-decree on Production of Import, Export and Commerce of Traditional Medicine in Public Sector (1998)

The objective of this Sub-decree is to manage the import and export production and commerce of traditional medicines in Cambodia. The Sub-decree covers the right to run traditional medicine business, traditional medicine production, import-export, and commerce. This is related to plants and animals, but may include the uses of LMO based products because the Sub-decree does specify the nature of the traditional medicines.

4.4.3 Environmental Impact Assessment Sub-decree (Annex 9) (1999)

The Sub-decree has the objectives to: (a) identify and carry out environmental import assessment on all private and public projects which are under the responsibility of Ministry of Environment, before these are submitted to the government; (b) define types of projects and activities in both private and public sectors that need to be assessed for environmental impacts; and (c) encourage public participation in the process of environmental import assessment as well as collecting feedback for consideration in the adoption process. Articles 4 to 9, 14, 15 and 22 are related to the assessment of development projects that include field trial and field release of LMOs.

4.4.4 Law on the Management of Quality and Safety of Products and Services (Annex 10) (2000)

The Law is focused on all commercial enterprises, all manufacturing for commercial purposes, importers, exporters and merchants, service providers, advertisers of products, goods, and services and civic association and non-governmental agencies engaged in manufacturing, commerce or humanitarian relief activities. The Law is related to biodiversity and biosafety in articles 8, 10, 12, 13, and 21. Any import of GM foods might be subject to inspection for quality and safety control.

4.4.5 Phyto-Sanitary Inspection Sub-decree (Annex 5) (2003)

The Sub-decree is meant to identify and inspect phytosanitary measures to prevent the spread of diseases and dangerous pests, from one area to another in Cambodia. This could be brought about by all articles including transgenics, which are imported into or are in transit in Cambodia.

4.4.6 Protected Areas Management Law (Annex 6) (2003) (draft)

The Law aims at managing public domains in protected areas. Among its various objectives is the implementation of international conventions, protocols and agreements on biodiversity and ecology protection in protected areas; and define liability and punitive measures for defaulters who destroy resources and public properties in the protected areas.

4.4.7 National Biosafety Framework (2004)

The NBF contains details of the draft law on biosafety and the sub-decree on LMO management even though these have yet to be ratified. Major aims of the NBF are to legally protect the public from possible adverse risks caused by LMOs, when they are allowed to be released into the environment, and also to provide a clear procedure for submission of an application for release of LMOs.

4.4.8 National Law on Biosafety (Annex 3) (2004) (draft)

The objectives of the Law are to:

(a) Prevent adverse impact on the conservation of biodiversity and natural resources caused by the transboundary movement, development, handling, transfer, use, storage, and release of LMOs resulting from modern biotechnology;

(b) Ensure effective conservation of biodiversity and sustainable use of biological resources, taking also into account risks to human health;

(c) Provide a transparent process for making and reviewing decisions on LMOs and related activities and operations;

(d) Develop biotechnology education while preventing environmental and health hazards associated with the use and release of LMOs;

(e) Implement the Protocol to which Cambodia is a Party.

The Cambodian Biosafety Law does not regulate LMOs that are pharmaceuticals for human use, LMOs in transit not destined for use in Cambodia; any other categories of LMOs that may be exempted by the Competent National Authority; and any processed products containing dead modified organisms or nonliving components of GMOs.

4.4.9 Sub-decree on LMOs Management and Control (Annex 7) (2004) (draft)

The objective of this Sub-decree is to implement the Law on Biosafety and to provide a transparent process for review and decision making on LMOs and related activities. The Sub-decree regulates risk that might occur from handling, transfer, transport and use of LMOs in Cambodia.

Source:

1. *Pisey Oum, Technical Advisor for MOE and Deputy-Director, Department of Planning and Legal Affairs, Ministry of Environment, Kingdom of Cambodia, email: cambio_coor@online.com.kh (Personal communication).*
2. *National Biosafety Framework. 2004. Ministry of Environment, Kingdom of Cambodia. P 138. (available at: http://www.unep.org/biosafety/files/CMNBFrep.pdf; accessed on 29 March 2008).*

4.5 CHINESE TAIPEI

4.5 Food Sanitation Law (2001) (amended in 2002)

The Law relates to GM food labeling and registration and is applied to soybeans and corn and their products.

According to the Law, no GM soybean and corn may be produced, processed, prepared, packed, and imported or exported unless it has been registered and approved by the Department of Health's Food Sanitation Bureau.

Source:

1. *USDA Foreign Agricultural Service, GAIN Report TW5019 Taiwan Biotechnology Annual Report 2005. (available at: http://www.fas.usda.gov/gainfiles/200506/146130141.doc; accessed on 17 October 2007).*

4.6 DPR OF KOREA

4.6.1 Regulations on the Safe Management of GMOs (2004) (draft)

The draft legislation calls for safe storage and maintenance of genes and GMOs, risk assessment as an integral part of introduction and use of GMOs, and supervision and control by authorized committees/institutions.

4.6.2 National Biosafety Framework in DPR of Korea (2004)

The NBF is aimed to protect life and health of the people from the possible harmful effect of modern bioengineering products. It also contributes in protection of ecological environment, safe development of biotechnology of the country and also promotes cooperation with international organizations and other countries.

Source:

1. *NBF in DPR of Korea. 2004. National Coordinating Committee for Environment, D P R of Korea. P 55. (available at: http://www.unep.org/biosafety/files/KPNBFrep.pdf; accessed on 29 March 2008).*

4.7 FIJI

4.7.1 National Biosecurity Bill (Submitted in 2004)

Biosafety regulations form a part of the Biosecurity Bill which has been developed with particular emphasis on border control. Once the consultations are completed, the Bill will be presented to the cabinet for consideration and decision.

Source:

1. *Press release entitled "Quarantine undergoes corporatisation" dated 26 September 2007, 18:28 on Fiji Government online portal http://www.fiji.gov.fj/publish/page_10169.shtml.*

4.8 HONG KONG

4.8.1 Hong Kong Food Labeling Guidelines (2007) (draft)

Under the draft voluntary guidelines, products carrying "GM free" claim will be subject to random GM testing. Zero tolerance approach will be adopted for "GM free" claimed products.

The draft Guidelines are based on the following four principles:

(a) The labeling of GM food will comply with the existing food legislation;

(b) The threshold level applied in the guideline for labeling purpose is 5%, in respect of individual food ingredient;

(c) Additional declaration on the food label is recommended when significant modifications of the food, e.g. composition, nutrition value, level of anti-nutritional factors, natural toxicant, presence of allergen, intended use, introduction of an animal gene, etc, have taken place;

(d) Negative labeling is not recommended.

The Guidelines are advisory in nature and have no legal effect. Adoption is entirely voluntary and is not binding. It applies to prepackaged food.

Source:

1. *http://www.fehd.gov.hk/safefood/gmf/pamphlets/labelGMF.pdf; accessed on 16 October 2007.*
2. *USDA Foreign Agricultural Service, GAIN Report HK6015 Hong Kong Biotechnology Annual (2006). (available at: http://www.stat-usa.gov/agworld.nsf/505c55d16b88351a852567010058449b/23961623de089dfa852571ce00632a42/$FILE/HK6015.PDF; accessed on 17 October 2007).*

4.9 INDIA

4.9.1 Environment Protection Act (1986) and Environment (Protection) Rules (1986)

The Act relates to the protection and improvement of environment and the prevention of hazards to human beings, other living creatures, plants and property. The Act mainly covers the rules to regulate environmental pollution and the prevention, control, and abatement of environmental pollution.

The Environment (Protection) Rules cover management and handling of hazardous wastes, manufacture, storage and import of hazardous chemicals and rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells.

4.9.2 Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells. (notified under the EP Act, 1986) (1989)

These Rules include the rules for pharmaceuticals, transit and contained use of genetically engineered organisms, microorganisms and cells and substances/products and food stuffs of which such cells, organisms or tissues form a part, LMOs for intentional introduction into the environment, handling, transport, packaging and identification.

These rules are applicable to the manufacture, import and storage of microorganisms and gene technology products.

The rules are specifically applicable to:

(a) Sale, storage and handling;

(b) Exportation and importation of genetically engineered cells or organisms;

(c) Production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of genetically engineered products that make use of genetically engineered microorganisms in any way.

4.9.3 Recombinant DNA Safety Guidelines (1990)

The Guidelines prescribe safety measures for research, field cultivation and also the environmental impact during field applications of genetically altered material products.

They are applicable to research involving genetically engineered organisms originating from genetic transformation of green plants, rDNA technology in vaccine development, and also large scale production and deliberate/accidental release of organisms, plants, animals and products derived by rDNA technology into the environment.

The Guidelines also prescribe the criteria for ecological assessment on a case-by-case basis for planned introduction of rDNA organism into the environment.

4.9.4 Foreign Trade (Development & Regulation) Act, 1992 (2006) (draft amendment)

The Act provides for the development and regulation of foreign trade by facilitating imports into and augmenting exports from India and for matters connected with it. In 2006, the government made draft amendment in the foreign trade policy, making labeling of imported GM products mandatory.

4.9.5 Revised Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts (1998)

The Guidelines cover rDNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. It also includes LMOs for contained use and intentional introduction into the environment, and LMOs for use as food or feed or for processing, pharmaceuticals and transboundary movement. The Guidelines also specify requirements for import and shipment of GM plants for research use only.

4.9.6 Guidelines for Generating Preclinical and Clinical Data for rDNA Vaccines, Diagnostics and other Biologicals (1999)

The Guidelines cover preclinical and clinical evaluations of rDNA vaccines, diagnostics and other biologicals/pharmaceuticals. The objectives of the preclinical studies are to define physiological, toxicological and efficacious potential of r-DNA products prior to initiation of human studies. Both *in vitro* and *in vivo* studies can contribute to evaluating the effects of r-DNA products.

The Guidelines also cover safety, purity, potency and effectiveness of the rDNA products, *in vitro* diagnostic recombinant reagents and monoclonal antibodies, and describe in detail procedures for generating monoclonal antibodies. Sensitivity and specificity required for diagnostics of infections of widespread diseases like HIV-I/II are also prescribed.

4.9.7 Plant Quarantine (Regulation of Import into India) Order (2003)

The Order allows import of transgenics/GMOs into India for the purpose of agricultural research or experimentation purpose only. No commercial imports are allowed under this order.

4.9.8 The Seed Bill (2004) (draft)

The Bill provides for regulating the quality of seeds for sale, import and export and to facilitate production and supply of seeds of quality and other related matters. Apart from other provisions related to seed, the Bill has special provisions for registration of transgenic varieties. Clause 15 of the draft bill covers specific provisions for transgenic varieties requiring clearance under the provisions of the Environment (Protection) Act, 1986.

4.9.9 The Food Safety and Standards Act (2006)

The objective of the Act is to bring out a single statute relating to food and to provide for a systematic and scientific development of food processing industry. The Act incorporates the salient provisions of the Prevention of Food Adulteration Act, 1954 (37 of 1954) and is based on international legislations, instrumentalities and Codex Alimentarius Commission Guidelines. The Act is in tune with the international trend towards modernization and convergence of regulations of food standards with the elimination of multi-level and multi-departmental control. The emphasis is on (a) responsibility with manufacturers, (b) recall, (c) GM and functional foods, (d) emergency control, (e) risk analysis and communication and (f) food safety and good manufacturing practices and process control viz., hazard analysis and critical control point.

Source:

1. *Manoranjan Hota, Additional Director, Ministry of Environment and Forests, New Delhi, India, 110 003, email: hota@nic.in, (Personal communication).*
2. *http://envfor.nic.in/legis/env/env1.html; accessed on 27 September 2007.*
3. *http://www.envfor.nic.in/divisions/csurv/geac/annex-6.pdf; accessed on 27 September 2007.*
4. *http://exim.indiamart.com/act-regulations/ftrd.html; accessed on 27 October 2007.*
5. *http://www.envfor.nic.in/divisions/csurv/geac/groundrules.htm; accessed on 27 October 2007.*
6. *http://envfor.nic.in/divisions/csurv/biosafety/Files/Biologicals.PDF; accessed on 27 September 2007.*
7. *http://www.plantquarantineindia.org/pdffiles/Consolidated%20Version%20PQ%20Order% 20ason-7May2007.pdf; accessed on 27 September 2007.*
8. *http://agricoop.nic.in/seeds/seeds_bill.htm; accessed on 16 October 2007.*
9. *http://envfor.nic.in/legis/hsm/hsm3.html; accessed on 27 September 2007.*
10. *http://www.pfndai.com/Food_Safety_and_Standards_Act.doc; accessed on 27 September 2007.*

4.10 INDONESIA

4.10.1 Joint Decree of the Minister of Agriculture, the Minister of Forestry and Estate Crops, the Minister of Health and the State Minister of Food and Horticulture (1997)

The Decree ensures the biosafety and food safety for human health, biodiversity (including animals, fish, and plants), and the environment in relation to the utilization of genetically engineered agricultural products.

The Decree covers genetically engineered agricultural products, defined as transgenic animals, materials originated from transgenic animals and its processed products, transgenic fish, materials originating from them and their processed products, transgenic plants and their parts, and transgenic microorganisms.

It regulates the kinds, requirements, procedures, rights and obligations, monitoring, controlling, and reporting of biosafety and food safety of the utilization of genetically engineered agricultural products.

4.10.2 Decree of the Minister of Agriculture: Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products (1997)

This Decree is intended to regulate and supervise the utilization of genetically engineered agricultural biotechnology products. It covers the regulation of the kinds, requirements, procedures, rights and obligations, monitoring and reporting the utilization of genetically engineered agricultural biotechnology products and their supervision. The utilization of genetically engineered agricultural biotechnology products originating from both domestic and foreign products besides development of science, research, breeding, production and distribution including trading require to take into consideration the religious, ethical, socio-cultural and aesthetical norms. Separate requirements for the utilization are elaborated for various categories of transgenic organisms and materials originating from them.

The Decree also covers the requirements for transboundary transport of genetically engineered agricultural biotechnology products. Imported/export products need to meet the requirements of quarantine, import and transport documents including packaging and labeling.

4.10.3 Government Regulation of the Republic of Indonesia No 28 year 2004 on Food Safety, Quality and Nutrition (2004)

This regulation covers requirements for food safety, quality and nutrition.

4.10.4 National Biosafety Framework of the Republic of Indonesia (2004)

The objective of the NBF was to prepare Indonesia for the entry into force of the Protocol, by, among others, assisting in the following activities:

(a) Carrying out an assessment of the current technological capacity to manage Biosafety issues, and the implications of this on the implementation of a NBF;

(b) Strengthening national capacity to develop national regulatory biosafety frameworks;

(c) Strengthening national capacity for competent decision making on notifications and requests related to LMOs, including the establishment of appropriate administrative systems;

(d) Support regional and sub-regional collaboration, including harmonization of the implementation of national regulations;

(e) Raise public awareness and improve information flow to the public on the issues involved in the release of LMOs to promote informed debate and to ensure transparency with respect to the regulation of LMOs;

(f) Provide all stakeholders with an opportunity to be involved in the design and implementation of a NBF.

4.10.5 Government Regulation of the Republic of Indonesia No 21 year 2005 on Biosafety of Genetically Engineered Product (2005)

The Regulation includes requirements for research and development of genetically engineered products, their importation from foreign country, procedures for risk assessment, release, and distribution and use and mechanism to control them.

Source:

1. *National Biosafety Framework of the Republic of Indonesia. 2004. Ministry of Environment of the Republic of Indonesia Cooperating with UNEP-GEF Project for the Development of National Biosafety Framework in Indonesia p 103. (available at: http://www.unep.org/biosafety/files/IDNBFrep.pdf; accessed on 29 March 2008).*
2. *USDA Foreign Agricultural Service, GAIN Report ID7026 Indonesia Biotechnology Annual Report 2007 p 7. (available at: http://www.fas.usda.gov/gainfiles/200707/146291737.pdf; accessed on 18 October 2007).*
3. *Inez H.S. Loedin, Head of Molecular Biology Division, Research and Development Center for Biotechnology, Indonesia Institute of Sciences, Jakarta, Indonesia, email: islamet@indo.net.id. (Personal communication).*

4.11 IRAN

4.11.1 National Biosafety Framework (2007) (draft)

The NBF includes the following features:

(a) The country's macro policy regarding modern biotechnology, agricultural products, health, environmental protection and sustainable development;

(b) The laws, regulations and administrative systems;

(c) The development of a suitable system to deal with requests regarding specific and legal activities such as the release of LMOs in the environment and, if necessary, farm experiments. This system also deals with procedures and decision making methods of risk assessment;

(d) The development of a system for the assessment and supervision of possible harmful effects of LMOs on the environment and human health;

(e) The application of methods for informing, educating and involving interested individuals, institutes and the public regarding the development and the administration methods.

Other Related Regulations

4.11.2 Environmental Protection and Enhancement Act (1974)

Article 1 of the Act acknowledges the necessity to protect and improve the environment and considers any destructive measure which ends in a disturbance of the balance of the environment, a responsibility of the Department of Environment.

4.11.3 Plants Protection Act (1967)

The Act and its relevant directives, requires permits from the Ministry of Agriculture for importing any plant or plant part. Under this Act, an independent department titled the Department of Biosafety, Gene Reserves, Plasmids and Microorganisms was established in 1999 in the Research Institute for Agricultural Biotechnology, a part of the Research and Training Organization of the Ministry of Agricultural Jihad.

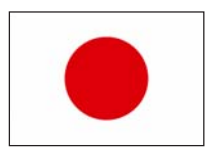
4.11.4 Executive By-Law on Sanitary Supervision and Control of Poisonous and Chemical Materials (1999)

Producers of chemicals and poisonous materials are bound to use special labels, and provide adequate warning with regard to the utilization of used chemicals and containers. In addition, sellers/dealers of poisonous and chemical materials are bound to avoid the sale of such materials that do not bear an adequate label on their package.

Source:

1. *Draft National Biosafety Framework 2004. Department of Environment, Islamic Republic of Iran. (available at: http://www.unep.org/biosafety/files/IRNBFrep.pdf; accessed on 28 March 2008).*
2. *Nasrin S. Esmailzadeh, BCH Focal point, Islamic Republic of Iran, email: nasrin@nrcgeb.ac.ir (Personal communication).*

4.12 JAPAN



4.12.1 Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003) (2004)

The Law includes all use, import and export of LMOs including GM food. It aims to secure precise and smooth implementation of the Protocol by taking measures to regulate the use of LMOs for the conservation and sustainable use of biological diversity in cooperation with other nations.

Under the Law, two types of applications can be submitted to the competent minister by applicants based on type of the LMO:

(a) Type 1 LMO – (the use of LMOs without preventive measures against their dispersal into environment);

(b) Type 2 LMO – (the use of LMOs while taking preventive measures against their dispersal into environment).

This implies that approval is granted for LMOs based on the following:

(a) Containment measures to be taken are stipulated by the ordinance of the competent ministries;

(b) Containment measures to be taken are not stipulated and measures to be taken as previously confirmed by the competent ministry.

Other Related Regulations

4.12.2 Food Sanitation Law in Japan (Law No 233) (1947, last amended in 2005)

The Law also deals with the approval of GM plants that are used for food. The Food Safety Commission reviews the food safety of GM products. The Commission conducts scientific review and provides risk assessment conclusions. Similar approvals are also required for GM products that are used as feed.

The feed safety on livestock animals is also evaluated and food safety commission also reviews the possible human health effects from consumption of livestock products from animals fed with GM event under review. Based on all the reviews, approval for the feed safety of GM plants is granted.

4.12.3 Labeling Standard for Genetically Modified Foods (Notification No. 517) (2000)

The Standard is applicable to processed foods and to perishable foods including both GM and non-GM food. The various commodities requiring labeling and the format in which labeling has to be done has been categorized based on whether the agricultural product has been treated under a "identity preserved handling" system or not. The agricultural products with known commercial cultivation of transgenics require compulsory labeling (soybean including green soybeans and soybean sprouts, corn, potato, rapeseed and cotton seed). The list of products from these crops mandated for labeling is also given. The Standard also details the products not requiring any labeling.

Source:

1. *Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants). (available at: http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf; accessed on 11 February 2008).*
2. *http://www.bch.biodic.go.jp/english/law.html; accessed on 3 October 2007).*
3. *Regulations related to the Enforcement of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Tentative Translation). (available at: http://www.bch.biodic.go.jp/download/en_law/en_regulation.doc; accessed on 11 February, 2008).*
4. *The Establishment of the Food Safety and Consumer Affairs Bureau: Delivering Food Safety ~The New Role of the Ministry of Agriculture, Forestry and Fisheries: Towards Creating New Industries and Public Confidence Sorimachi Speaks 'THE SHAPE OF JAPAN IN THE 21st CENTURY' SERIES, No. 29. (available at: http://www.lec-jp.com/speaks/info_029.html; accessed on 16 October 2007).*
5. *The Food Sanitation Law in Japan. (available at: http://www.jetro.go.jp/en/market/regulations/pdf/food-e.pdf; accessed on 16 October 2007).*
6. *USDA Foreign Agricultural Service, GAIN Report JA7040 Japan Biotechnology Annual Report 2007. (available at: http://www.fas.usda.gov/gainfiles/200707/146291858.doc; accessed on 18 October 2007).*
7. *Labelling Standard for Genetically Modified Foods (Notification No. 517 of the Ministry of Agriculture, Forestry and Fisheries of March 31, 2000) (UNOFFICIAL TRANSLATION). (available at: http://www.maff.go.jp/soshiki/syokuhin/hinshitu/organic/eng_yuki_gmo.pdf; accessed on 16 October 2007).*

8. *Ryoko Sakuramata, Ministry of the Environment Japan, Tokyo. e-mail bch@env.go.jp, (Personal Communication).*

4.13 JORDAN

4.13.1 National Biosafety Framework of Jordan (2004)

The main priority actions for biosafety at the national level in the NBF are to:

(a) Improve a regulatory system of biosafety;

(b) Establish a technical system for risk assessment and management of LMOs, which includes the method and technical system for analyzing the potential risks of LMOs, the system of risk assessment and the rules for classifying the risk levels, the technical guidelines for risk assessment, the technical specifications, procedures and guidelines for risk management and a system for environmental monitoring of LMOs;

(c) Strengthen the scientific researches on biosafety;

(d) Establish the system of biosafety monitoring which includes the operational mechanism of networking of biosafety monitoring, the risk monitoring tools and processing techniques, the environmental monitoring facilities for LMOs and specialized team for biosafety monitoring;

(e) Undertake publicity and education on the development of biosafety;

(f) Undertake international cooperation.

Source:

1. *National Biosafety Framework of Jordan. 2004. Ministry of Environment, The Hashemite Kingdom of Jordan, p 76. (available at: http://www.unep.org/biosafety/files/JONBFrep.pdf; accessed 29 March 2008).*

4.14 KAZAKHSTAN

4.14.1 National Biosafety Framework Document of the Republic of Kazakhstan (2004)

The national framework system on biosafety is directed to provide proper control over GMOs and GM products, with potential to cause negative impact on biological diversity and human health, and also provides for public information and participation in their use. The NBF covers the interests of different government, public and scientific structures. It also reflects on all the necessary activities on effective functioning of the system.

4.14.2 The Law of Republic Kazakhstan on Safety in Gene-engineering Activity (2004) (draft)

The draft law defines legal and organizational bases of safety in genetic engineering activity and is directed towards protection of the environment and health of the population against adverse impact of GMOs. The provisions of the law are applicable to all kinds of activity related to:

(a) Reception, duplication, test and use of GMOs in the closed systems for various purposes, with application of methods of genetic engineering;

(b) Deliberate release of GMOs, including any living structures capable of reproduction like seeds, tubers, cuttings, pollen, spores, etc. into the environment;
(c) Indeliberate release of GMOs into the environment;
(d) Any kind of research on GMOs, including laboratory, clinical, field trial, industrial tests;
(e) Illegal transboundary movement of GMOs;
(f) Storage, disposal and destruction of GMOs.

Other Related Regulations

4.14.3 The Law of the Republic of Kazakhstan on Environmental Protection N160 (1997)

The law regulates the issue of biosafety taking into account environmental requirements.

4.14.4 The Law of the Republic of Kazakhstan on Plant Protection N 331-II (2002)

The law defines legal, economic and organizational basis of plant protection from pests and plant diseases. It is directed on conservation of the crop, its quality and prevention of hazardous impact on human health and environment while conducting phytosanitary activities in the territory of Kazakhstan.

4.14.5 The Law of the Republic of Kazakhstan on Protection, Reproduction and Use of Animal Species, on Especially Protected Natural Territories N 162-1 (1997)

The law regulates biological safety of animal and plant species.

4.14.6 The Law of the Republic of Kazakhstan on Citizen Health Protection in the Republic of Kazakhstan, N 111-1 (1997), and on Sanitary-Epidemiological Safety of the Population of the Republic of Kazakhstan, N 361-II (2002)

Both the laws regulate separate issues of biosafety in the area of health protection and medicine.

Source:

1. *National Biosafety Framework Document of the Republic of Kazakhstan. 2004. Ministry of Environmental Protection of RK, Forestry and Hunting Committee of the Ministry of Agriculture of RK, P 37. (available at: http://www.unep.org/biosafety/files/KZNBFrep.pdf; accessed on 30 March 2008).*

4.15 KYRGYZ REPUBLIC

4.15.1 National Biosafety Framework (2005)

The NBF is the basis for the national sustainable biosafety system development, taking into account proposed legal norms and intersectoral interactions and partnerships, which is in the process of the national capacity building in the field of biosafety. The NBF contains the basic components of policy in the field of biosafety; regulatory aspects of biosafety; its administrative structure; coordination mechanism and partnership; risk assessment; monitoring, control and liability and mechanism of public information and participation in decision making.

4.15.2 Law of the Kyrgyz Republic on Biological Safety (2005) (draft)

The draft law regulates types of activities related to safe creation of LMOs/GMOs by genetic engineering methods, their testing, usage in closed systems and introduction into the environment, realization and transboundary movement as well as determines competence of entities to ensure its implementation for the protection of human health and biodiversity and limit the risk of negative impacts on the environment.

Source:

1. *National Biosafety Framework. 2005. Ministry of Ecology and Emergencies of the Kyrgyz Republic, p 91. (available at: http://www.unep.org/biosafety/files/KGNBFrep.pdf; accessed on 30 March 2008).*

4.16 LAO PEOPLE'S DEMOCRATIC REPUBLIC

4.16.1 National Biosafety Frameworks of Lao People's Democratic Republic (2004)

The Framework is a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology. It covers the government policy on biosafety, the regulatory regime for biosafety; administrative systems for biosafety; mechanisms for public education, awareness and participation; capacity building programs to implement the Protocol and the priorities of the government to implement the Biosafety Framework.

4.16.2 Biosafety Law (2005) (draft)

The Law covers all functions pursuant to the Protocol regarding animals, fishes, microorganisms, plants, human health: handling, transport, packaging and identification, intentional introduction into the environment, LMOs for use as food or feed or for processing, pharmaceuticals, public awareness and participation, transboundary movement (import/export), transit and contained use.

Other Related Regulations

4.16.3 Environmental Protection Law (1999)

The Law specifies necessary principles, rules and measures for managing, monitoring, restoring and protecting the environment in order to protect public, natural resources and biodiversity, and to ensure the sustainable socio-economic development of the nation.

Source:

1. *National Biosafety Frameworks of Lao People's Democratic Republic. 2004. Science Technology and Environment Agency, Lao PDR. Available at www.unep.org/biosafety/files/LANBFrep.pdf; accessed on 28 March 2008.*

4.17 LEBANON

4.17.1 Biosafety Lebanon – National Biosafety Framework (2005)

The framework aims to:

(a) Establish a regulatory regime for biosafety, and legalize the research, development and

testing of GMOs and GM products, assessment of environmental release, commercialization, sales and use of all products resulting from modern biotechnology;

(b) Establish an administrative system for the management of biosafety related issues;

(c) Establish a transparent decision-making system that outlines processes for handling notifications involving GMOs (e.g. transboundary movement, transit, domestic use, contained use, placing on the market, intentional release into the environment). This system also includes a system for risk assessment and management, and specific strategies for promoting access to information and public participation;

(d) Establish systems for the monitoring and enforcement of biosafety measures;

(e) Capacity building for biosafety management by promoting and facilitating public awareness, education and participation and human resource development.

Source:

1. *Biosafety Lebanon – National Biosafety Framework Ministry of Environment – Lebanon, p 88. (Available at: http://www.unep.org/biosafety/files/LBNBF rep.pdf; accessed on 29 March 2008).*

4.18 MALAYSIA

4.18.1 Biosafety Act (2007)

The Act establishes a National Biosafety Board to regulate the release, import, export and contained use of LMOs, and the release of products of such organisms with the objective of protecting human, plant and animal health, environment and biological diversity.

The Act empowers the National Biosafety Board to appoint various committees and subcommittees for its various functions. Part III of the Act deals with approval for release and import of LMOs. Part IV deals with the notification for export, contained use and import for contained use of LMOs. Reporting requirements for risk assessment and risk management and emergency action plans are covered under Part V of the Act. An enforcement officer is also appointed under the Act to carry out investigations for its proper enforcement. The Act also requires that all LMOs, items containing LMOs and products of such organisms be labeled in the prescribed manner.

4.18.2 National Guidelines for the Release of Genetically Modified Organisms (GMOs) into the Environment (2007) (draft)

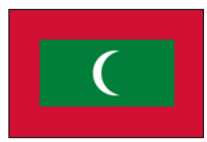
The Guidelines address the need for mechanisms of risk assessment and management, a need for international exchange of information in particular between neighboring countries with regards to release of GMOs and capacity building in order to adequately address safety in genetic modification research. It provides a more defined procedure for risk assessment on the release of GMOs into the environment and also takes into account factors for international harmonization of the existing Biosafety Guidelines.

The Guidelines covers GMOs at all stages of research, development, use, release and placing on the market. It covers, but is not limited to, GM plants, animals (including for example, insects, mollusks and fish) and microorganisms and products consisting of or containing GMOs. It also covers safety issues regarding agriculture, public health, the environment and transboundary issues pertaining to release of GMOs and products containing, or consisting of GMOs.

Source:

1. *Release of Genetically Modified Organisms (GMOs) into the Environment – full text. (available at: http://www.cbi.pku.edu.cn/mirror/binas/Regulations/full_regs/malaysia/malgmo.html; accessed on 11 February, 2008).*
2. *Laws of Malaysia, Biosafety Act 2007 (Act 678) Percetakan Nasional Malaysia Berhad, Kuala Lumpur, p 56.*
3. *Kangayatkarasu Nagulendran, Principal Assistant Secretary, Conservation and Environmental Management, Division Ministry of Natural Resources and Environment, Putrajaya, Malaysia, email: nagu@nre.gov.my (Personal communication).*

4.19 MALDIVES



4.19.1 National Biosafety Framework for the Republic of Maldives (2006)

The NBF proposes an administrative system for handling applications on request for authorization, a system for risk management and follow up including monitoring and enforcement of impacts on the environment and human health, and responsible institutions; and mechanisms for public education, awareness and participation in relation to biosafety issues.

Source:

1. *National Biosafety Framework for The Republic of Maldives, Ministry of Environment, Energy and Water. P 75. (available at: http://www.unep.org/biosafety/files/MVNBFrep.pdf; accessed on 29 March 2008).*

4.20 MONGOLIA

4.19.1 National Biosafety Framework (2005)

The NBF proposes to establish a National DNA Recombinant Technology Advisory Council and to combine both regulatory and research potential of the country into one unit. It also aims to issue guidelines and technologies to work with new organisms/GMOs and check imported food items for the presence of GMOs. The framework also calls for harmonization of risk assessment strategies at regional and international level and to develop human resources in biotechnology development and its safety issues.

Source:

1. *National Biosafety Framework. 2005. Ministry of Nature and Environment. (available at: http://www.unep.org/biosafety/files/MNNBFrep.pdf; accessed on 29 March 2008).*

4.21 MYANMAR

4.21.1 Myanmar National Biosafety Framework (2006)

The NBF for Myanmar includes policy, regulatory regime, mechanism to handle notifications to ensure safe transfer, to develop a system for "follow up" for enforcement and monitoring and to develop mechanisms for public awareness, education and participation.

Source:

1. *Myanmar National Biosafety Framework. 2006. Ministry of Agriculture and Irrigation, Myanmar, p 53 (available at: http://www.unep.org/biosafety/files/MMNBFrep.pdf; accessed on 29 March 2008).*

4.22 NEPAL

4.22.1 National Biosafety Framework (2007)

The Bill is applicable to the development, production, contained use, field test, intentional introduction into the environment, and import and export of GMOs that may have an adverse effect on the conservation and sustainable use of biological diversity, and environment taking also into account the risks to human health.

The proposed Biosafety Policy (framework) covers the following aspects of GMOs and use of modern biotechnology:

(a) The existing or potential use of GMOs in laboratory or in an open space;

(b) Human health, biodiversity, natural environment, agricultural products, foods and drinking products, animal feed and areas of sewerage management;

(c) Regulation of experiment, flow of information, review, assessment of risks including socioeconomic and ethical effects;

(d) Monitoring of import and export, laboratory and field test;

(e) Research and development in academic and industrial sectors;

(f) Safety of the place where functions relating to GMOs are carried out;

(g) Public participation on the issues of modern biotechnology and biosafety.

The technical framework of biosafety mainly covers the scientific research and testing of seed, plants, food, feed and animals with GMOs, which may be imported or produced within the country. The tests aim to identify the components of GMOs, and identify whether the tested GMOs pose any adverse risks to biological diversity and human health. On these grounds, decision will be made whether to allow or restrict the import of the tested GMOs. It also covers the management of risks from the use of GMOs.

Source:

1. *National Biosafety Framework Nepal. 2006. Ministry of Forests and Soil Conservation, Kathmandu, Nepal. (available at: http://www.unep.org/biosafety/files/NPNBFrep.pdf-Nepal; accessed 27 September 2007).*

2. *Ananta V. Parajuli, Chief, Environment Division, Ministry of Forests and Soil Conservation, Singha Durbar, Kathmandu, Nepal, email: mfsced@wlink.com.np (Personal communication).*

4.23 NEW ZEALAND

4.23.1 Hazardous Substances and New Organisms Act (1996)

The Act is aimed to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms. It prohibits the import, manufacture, development, field testing, or release of any hazardous substance imported, or manufactured or new organism imported, developed, field tested, or released.

Approvals are issued for import, development, field testing, or release of any new organism based on the provisions of the Second Schedule to this Act.

When any organism receives approval for importation into containment it is considered as a new organism and would not require further approval for any subsequent importations.

4.23.2 Hazardous Substances and New Organisms Act (Amendment 1999)

The Amendment gives revised definitions of several terms such as "new organism" which includes a GMO. An organism ceases to be a new organism when an approval has been given in accordance with this Act for the importation for release or release from containment of an organism of the same kind as the organism in question.

4.23.3 Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act (2002)

The Act requires the Environmental Risk Management Authority (the Authority) to consider additional matters when considering certain applications in relation to GMOs and, if it approves the applications, to include particular controls for field tests and certain developments.

It also imposed restriction, from 29 October 2001 to the close of 29 October 2003, on the Authority for considering or approving applications to import of new organisms for release or to release new organisms from containment if the new organisms are GMOs and provides few exceptions to this restriction.

It also provides transitional provisions for approved applications relating to certain GMOs. Several new definitions have also been introduced.

4.23.4 Hazardous Substances and New Organisms (Low-risk genetic modification) Regulations (2003)

This regulation is specific to GMOs designated as presenting a low risk. It has categorized the risk groups “risk group 1” meaning micro-organisms that are unlikely to cause disease in humans, animals, plants, or fungi and “risk group 2” means microorganisms causing disease in humans, animals, plants or fungi but are unlikely to be a serious hazard to laboratory personnel, the community, animals, or the environment and have effective treatment and preventive measures with respect to any infections that they may cause and thus present a limited risk of the spread of infection.

4.23.5 Interpretations and Explanations of Key Concepts (2003)

This protocol is principally meant to bring consistency in use and interpretation of terminology among various related functions, or organizations that use similar methods and techniques.

It includes explanation of the key concepts relevant to the Authority's decision making. It provides further explanation of both definitions in Section 2 of the Hazardous Substances and New Organisms Act and the important concepts introduced in the methodology but not described in the Act.

4.23.6 Imports and Exports (Living Modified Organisms) Prohibition Order (2005)

The Order prohibits the export of LMOs from New Zealand unless ministerial consent is obtained, in which case, a LMO can be exported, subject to certain conditions which depend on the purpose of the export, as required by the Protocol.

Specific conditions of exports of LMOs permitted have been mentioned when LMO is a

pharmaceutical for humans or when it is intended for contained use or for direct use as food or feed, or for processing or for intentional introduction into environment.

As per the regulation, separate consents are required for exportation of LMO that falls into more than one category of exportation.

Other Related Regulations

4.23.7 Biosecurity Act (1993)

Biosecurity Amendment Act (1993)
Biosecurity Amendment Act (1994)
Biosecurity Amendment Act (1996)
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Biosecurity Amendment Act (2005)

This Act along with its amendments provide for the effective management of risks associated with the importation or introduction of risk goods which mean any organism, organic material, or other thing or substance, that (due to its nature or origin) is suspected to pose a risk and consequently result in exposure of organisms in New Zealand to damage, disease, loss, or harm; or interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms.

Source:

1. *Your Guide to the Hazardous Substances & New Organisms Act. (available at: http://www.mfe.govt.nz/publications/hazardous/guide-to-hsno-act-jul01.html; accessed on 5 October 2007).*
2. *About the Hazardous Substances and New Organisms Act 1996. (available at: http://www.mfe.govt.nz/laws/hsno.html; accessed on 5 October 2007).*
3. *Law changes for new and genetically modified organisms. (available at: http://www.mfe.govt.nz/issues/organisms/law-changes/index.html; accessed on 5 October 2007).*
4. *Interpretations and Explanations of Key Concepts. ERMA New Zealand Policy Series: Protocol 3. ER-PR-03-18 05/06. (available at: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-PR2-03-9.pdf; accessed on 6 October 2007).*
5. *Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (available at: http://www.knowledge-basket.co.nz/regs/regs/text/2005/2005012.txt; accessed on 6 October 2007).*
6. *Biosecurity Act 1993. (available at: http://www.biosecurity.govt.nz/what-is-biosecurity/the-biosecurity-act; accessed on 5 October 2007).*

4.24 NIUE

4.24.1 Niue's Draft National Biosafety Framework – Tokaga Motu (2006)

The key elements of the NBF include a national biosafety policy, a regulatory regime, a system to handle requests (administrative, risk assessment, risk management and decision making processes), follow up actions (monitoring, inspections and enforcement); and systems for public awareness and participation.

4.24.2 Biosafety (Genetically Modified Organisms) Regulation (2006) (draft)

The draft Regulation aims to manage import, development, field testing, release or export of LMOs and GMOs; protect the biodiversity, people and environment from their adverse effects; manage import and release of organisms that are not GM and are not found in Niue; regulate GMOs and modern biotechnology applications in Niue to manage their adverse effects on the environment and protect human health; facilitate economic development through beneficial use of products of modern biotechnology and ensure community awareness on matters relating to GMOs.

Source:

Draft National Biosafety Framework - Tokaga Motu. 2006. Government of Niue. (available at: http://www.unep.org/biosafety/files/NUNBFrep.pdf; accessed on 29 March 2008).

4.25 PAKISTAN

4.25.1 National Biosafety Guidelines (2005)

The Guidelines include regulation of all GM materials (DNA and RNA preparations, viroids, viruses, cells and organisms, modified or constructed through genetic engineering), derivatives thereof and wastes or by-products of genetic engineering practices (containing viable organisms or otherwise).

The scope of these Guidelines embrace all works related to gene manipulation employing rDNA technology for all purposes including the development of transgenic plants, animals and microorganisms; production of vaccines; industrial manufacturing of GMOs and products thereof, and their release into the environment for field trials as well as for commercial uses.

The Guidelines consist of two parts; the first part relates to regulated work in laboratory research and field trials; and the second part deals with procedures for approvals which must be obtained to deregulate the regulated materials to allow their free movement and commercial uses.

Enforcement of various clauses of the National Biosafety Guidelines will be administered by the three monitoring implementation bodies, as per legal authority of the Pakistan Environment Protection Act 1997.

4.25.2 Pakistan Biosafety Rules (2005)

These rules are applicable to the:

(a) Manufacture, import and storage of microorganisms and gene technological products for research whether conducted in laboratories for teaching and research, research and development institutes or private companies involved in the use and application of (GMOs) and products thereof;

(b) All work involved in the field trial of genetically manipulated plants, animals (including poultry and marine life), microorganisms and cells;

(c) Import, export, sale and purchase of LMOs, substances or cells and products thereof for commercial purposes.

The rules also detail the various Committees constituted viz., National Biosafety Committee, Technical Advisory Committee, Institutional Biosafety Committee, their functions, approvals required for various categories of material etc.

Source:

1. *National Biosafety Guidelines Pakistan Environmental Protection Agency, Government of Pakistan, Ministry of Environment, Notification No. F.2(7)95-Bio (available at: http://www.environment.gov.pk/act-rules/BiosftyGlines2005.pdf; accessed on 3 October 2007).*
2. *Pakistan Biosafety Rules notified under SRO (I) 336(I)/2005 Pakistan Environmental Protection Act 1997. (available at: http://www.environment.gov.pk/act-rules/Biosftyrules.pdf; accessed on 3 October 2007).*

4.26 PAPUA NEW GUINEA

4.26.1 Papua New Guinea's National Biosafety Framework (2005) (draft)

The draft biosafety framework has been designed to address the following key issues in the light of the country's limited human and institutional capacities in handling, using, managing and developing GM products:

(a) Increase awareness on biosafety and biotechnology;

(b) Conduct an inventory to establish number of GMOs in the country either as food, feed, food processes or pharmaceuticals;

(c) Develop an institutional framework for the assessment of GMOs;

(d) Develop regulations and guidelines for the safe assessment, handling, use, management and transfer of a GMOs;

(e) Strengthen and improve human and institutional capacities for the identification and assessing risks related to GMOs;

(f) Formulate policy and regulatory framework on biosafety and biotechnology;

(g) Strengthen and promote the precautionary approach;

(h) Strengthen and promote community participation in assessment, use, management and transfer of a GMO;

(i) Strengthen institutional networking and coordination.

4.26.2 Biosafety and Biotechnology Bill (2005) (draft)

The main objectives of the Bill are:

(a) Protect the health and safety of people and the environment, by identifying risks posed by modern biotechnology, and by preventing, reducing and eliminating them through regulation;

(b) Ensure both the long-term and short-term social, economic and environmental considerations and to prevent threats posed by GMOs on the country's biodiversity;

(c) Protect and sustain the potential of natural and physical resources against threats posed by GMOs to meet the foreseeable needs of future generations and safeguard eco-systems;

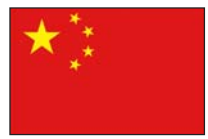
(d) Avoid or mitigate any adverse effects of activities on the environment by regulating the activities related to GMOs;

(e) Ensure regulation of dealings with GMOs consistent with national interests.

Source:

1. *Papua New Guinea's National Biosafety Framework. 2005. National Department of Environment and Conservation of Papua New Guinea, p 134. (available at: www.unep.org/Biosafety/files/PGNBFrep.pdf; accessed on 29 March 2008).*

4.27 PEOPLES REPUBLIC OF CHINA



4.27.1 Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering (1996)

The regulation is aimed at promoting research and development in the area of agricultural genetic engineering in China, strengthening safety administration, preventing possible hazards caused by GMOs and their products to human health and environment on which human beings rely for existence and agricultural ecological equilibrium.

The genetic engineering items covered in the Implementation Regulation include rDNA technology using vector systems, and introduction of rDNA into an organism by using physical, chemical and biological means.

The "Implementation Regulation" is applicable to agricultural organisms whose genome constitution has been changed by using genetic engineering technologies. The agricultural organism includes plants and animals related to agricultural production, plant-related microorganisms, veterinary microorganisms, aquatic animals and plants.

The organisms that are not included are:

(a) Plants obtained by spontaneous generation, and by using artificial selection and hybridization technologies; from mutagenesis via chemical or physical means; and by using organ culture, tissue culture and cell culture as well as protoplast fusion technology and chromosome ploidy manipulation;

(b) Animals obtained via spontaneous generation and by using artificial selection, artificial insemination (excluding rDNA), superovulation, embryo chimera, embryo partition, and nucleus transfer or ploidy manipulation technology;

(c) GM microorganisms (excluding virus and subvirus) obtained by using chemical and physical mutagenesis; transfer of non-recombinant DNA via transduction, transformation or conjugation processes.

4.27.2 Regulation on the Administration of Agricultural Transgenic Biosafety (2001)

The regulation covers the activities of research, testing, production, processing, marketing, import or export of agricultural GMOs within the territories of the People's Republic of China. These have been formulated for the purpose of strengthening safety administration of GMOs, safeguarding human health and safety of animals, plants and microorganisms, protecting the environment, and promoting research on agricultural GMOs.

4.27.3 Procedure for the Administration of Assessing Agricultural Transgenic Biosafety (2002)

4.27.4 Procedure for the Administration of the Safe Import of Agricultural Genetically Modified Organisms (2002)

4.27.5 Procedure for the Examination and Certification of the Labels of Genetically Modified Organisms (2002)

The procedures focus on the report management and approval, the administration procedures applied to the GMOs imported for different purposes and on application, reviewing, cancellation and other procedures of agricultural GMOs labeling.

4.27.6 Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (2004)

The Implementation Regulations cover the activities of research, testing, production, processing, marketing, import or export with respect to agricultural GMOs within the territories of the People's Republic of China that are required for safety evaluation.

These Implementation Regulations are formulated in accordance with the "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purposes of strengthening the safety assessment administration of agricultural GMOs, safeguarding human health and safety of animals, plants and microorganisms, and protecting the environment.

4.27.7 Implementation Regulations on Labeling of Agricultural Genetically Modified Organisms (2004)

The Implementation Regulations are formulated in accordance with the "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purpose of strengthening the labeling administration of agricultural GMOs, standardizing the marketing activities of agricultural GMOs, guiding the production and consumption of agricultural GMOs, and protecting consumers' right of full access to the information about the products.

The marketing of any agricultural GMOs listed in the labeling catalogue needs to comply with these implementation regulations. All agricultural GMOs listed in this catalogue and intended for marketing need to be labeled.

As per the regulation, any agricultural GMO without a label or whose label is not in conformity with the requirements of these implementation regulations would be banned for import or marketing.

4.27.8 Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms (2004)

The Implementation Regulations are formulated in accordance with "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purposes of strengthening the safety administration on imported agricultural GMOs, and applies to the safety administration of any activity of importing agricultural GMOs and their products into the territories of the People's Republic of China. It covers the import of the agricultural GMOs for research and testing; commercial production and as raw material for processing.

4.27.9 Regulation on Inspection and Quarantine of Import and Export of Genetically Modified Commodities (2004)

This Regulation is applicable for the inspection and quarantine of GM commodities imported and exported in all ways including, but not limited to, trading, raw material processing, mail, carrying, production, entrusted reproduction, research, exchange, exhibition, aid and grant.

It has been formulated to strengthen the inspection and quarantine of import and export of GM commodities, safeguarding the human health, ensuring the safety of animals, plants and

microorganism and protecting the ecological environment, based on the Law of The People's Republic of China on Import and Export Commodity Inspection, the Law of The People's Republic of China on Food Hygiene, the Law of The People's Republic of China on Quarantine of Import and Export Animal and Plants and respective administrative rules as well as the Regulation on the Safety Management of Agricultural GMOs.

4.27.10 Measures on Approval of Agricultural Genetically Modified Organisms Processing (2006)

The Measures have been formulated in accordance with "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering" for the purpose of strengthening the safety administration on approval of agricultural GMOs processing.

It stipulates the qualifications of those who process agricultural GMOs, the procedures of applying the processing permit, the permit administration, etc.

4.27.11 Decree 10 (CH7053) Labeling Regulation (2007)

Decree 10 states that the reason for the regulation is "to strengthen the administration of GMO labeling, standardize the selling activities of agricultural GMOs, guide the production and consumption of GMOs and protect consumers' right to be informed." The regulation spells out the type of labeling required as well as the specific language that is required on the individual labels.

Source:

1. *Yu Wenxuan, China University of Political Science and Law, China, email: wenxuan_yu@sohu.com, ywenxuan@clapv.org (Personal communication).*
2. *USDA Foreign Agricultural Service, GAIN Report CH7055: China, Peoples Republic of Biotechnology Annual 2007. (available at: http://www.fas.usda.gov/gainfiles/200707/146291718.doc; accessed on 16 October 2007).*

4.28 PHILIPPINES

4.28.1 Philippine Biosafety Guidelines (1990)

The Guidelines cover research, development, production/manufacture involving biological materials especially where genetic manipulation is involved or where there is introduction of exotic or imported plants, microorganisms or animals.

They are applicable to all research, production and manufacturing work and/or institutions in the country, whether public or private, national or international engaged in genetic engineering work.

The Guidelines also cover work involving genetic engineering, and activities requiring the importation, introduction, field release and breeding of non-indigenous or exotic organisms even though these are not GM.

Its contents include the national policies on biosafety; organizational structure of biosafety committees; procedures for evaluation of proposals with biosafety concerns; procedures and guidelines on the introduction, movement and field release of regulated materials; and physico-chemical and biological containment and procedures.

4.28.2 Guidelines on Planned Release of Genetically Manipulated Organisms (GMOs) and Potentially Harmful Exotic Species (PHES) (1998)

The Guidelines establish criteria for deliberate release of GMOs and potentially harmful exotic species into the Philippine environment. It excludes from its coverage work performed under contained conditions; accidental releases from contained facilities; use of pharmaceutical, processed food, animal feed, industrial, and other products that are already being regulated by other departments, agencies or instrumentalities of the Philippine government; work involving organisms which result from natural reproduction or the use of traditional breeding practices; and such other activities as the National Committee on Biosafety of the Philippines may in future declare to be excluded. It also establishes criteria for evaluating the release of GMOs and potentially harmful exotic species into the open environment.

4.28.3 Administrative Order No. 8: Rules and regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology (2002)

The Order covers the importation or release into the environment of:

(a) Any plant which has been altered or produced through the use of modern biotechnology if the donor organism, host organism, or vector or vector agent belongs to any of the genera or taxa classified by the Bureau of Plant Industry of the Philippines as a plant pest or is a medium for the introduction of noxious weeds

or

(b) Any plant or plant product altered or produced through the use of modern biotechnology which may pose significant risks to human health and the environment based on available scientific and technical information

It provides for the approval process and requirements for importation for contained use, field testing, propagation or commercialization, importation for direct use as food or feed or for processing, and delisting of regulated articles. It also provides that no regulated article intended for contained use shall be allowed for importation or be removed from the port of entry unless duly authorized by Department of Agriculture/Bureau of Plant Industry upon the endorsement of National Committee on Biosafety of the Philippines.

The Order also requires mandatory risk assessment of GM plants and plant products prior to importation or release into the environment. As per the procedures, experiments must first be conducted under contained conditions, then the products tested in field trials and finally when all safety and bioefficacy data are obtained, the product is reviewed for commercial release. Risk assessment is done according to the principles provided for by the Protocol.

4.28.4 National Biosafety Framework for the Philippines (2006)

The NBF covers all activities related to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles. The NBF also covers products of modern biotechnology, exotic species and invasive alien species.

The National Committee on Biosafety of the Philippines and concerned departments and agencies may apply, when allowed by law, the principles, mechanisms and processes developed

and implemented under the NBF to similar problems such as addressing the issue of exotic species and invasive alien species. Where appropriate, they may adopt the administrative and decision-making systems established in this NBF.

The objective of the NBF is to strengthen the existing science-based determination of biosafety to ensure safe and responsible use of modern biotechnology for the benefit of the Philippines and its citizens; enhance the decision-making system on the application of products of modern biotechnology to make it more efficient, predictable, effective, balanced, culturally appropriate, ethical, transparent and participatory, and serve as Guidelines for implementing international obligations on biosafety.

Source:

1. *The National Biosafety Framework for the Philippines, 2004. Department of Environment and Natural Resources-Protected Areas and Wildlife Bureau. 2004. Quezon City, Philippines. p 77 (available at: http://www.unep.org/Biosafety/files/PHNBFrep.doc; accessed on 14 May 2008).*
2. *Julieta Fe Estacio, Technical Secretariat Office of the Undersecretary for R&D, Department of Science and Technology, National Committee on Biosafety of the Philippines DOST Building, Gen. Santos Avenue Bicutan, Taguig City, Metro Manila, Philippines, 1630. email: jce.komen@planet.nl; jfle@dost.gov.ph; irma@dost.gov.ph (Personal communication).*

4.29 REPUBLIC OF KOREA

4.28.1 Regulation on the Genetic Recombination Experiment (1997)

The regulation was the first to notify safe treatment procedures for genetic recombination experiments. It gives the basics for the categorization of experiments, containment methods, treatment of genetic recombinant etc.

4.29.2 Regulation on the Test and Treatment of Genetically Re-combined Organisms related with Agricultural Research (1999)

The regulation notified the safe treatment and safety test methods of genetically re-combined organisms related to agriculture research. It gives the duties and composition of the various safety committees, safety assessment etc.

4.29.3 The Inspection Guidelines on Risk Assessment Documents for GM Foods and Additives (1999)

The Guidelines detail the procedures for the safety assessment of GM foods. The contents include details of risk assessment, food additives etc.

4.29.4 Mandatory Labeling of GM Agricultural Products and GM Foods (2000)

The regulation provides details of identification items, identification standards and the methods of labeling of LMOs.

4.29.5 The Standard on Marking for GM Foods (2000)

The Standard was developed with a purpose of ensuring awareness amongst consumers that they have the right to choose in respect of GM foods, to verify GM food marking and related documents on importation of GM foods and to trace and monitor the stage of domestic distribution.

It requires that the "genetic recombined food," "genetic recombined contained," "genetic recombination" or "genetic recombined" be put next to the names of the ingredients in the labels on food packets having such products.

4.29.6 Regulation on the Quality Control of Fishery Products (2001)

The regulation notifies quality control procedures and provides details of the identification of GM fish, quality control items, inspection of fisheries processed products and processed foods.

4.29.7 Regulation on the Sampling and Testing Methods of Transgenic Crops (2001)

The regulation details the sampling and testing procedures of transgenic crops including, duties of sample testing authority, and judgment (analysis, interpretation) of test results.

4.29.8 Biotechnology Support Act (2001)

The Act has the purpose to support and promote biotechnological research and covers procedures for collection and release of technical information, biotechnological support guidelines, guidelines on experiments, etc.

4.29.9 Guidelines for the Environmental Risk Assessment of GM Agricultural Products ("GMAPs") (2002)

The Guidelines are aimed to protect the agricultural environment and to facilitate safe marketing of GM Agricultural Products produced domestically or abroad.

They give details of procedures for the environmental risk assessment of GM Agricultural Products and the risk assessment requirements.

4.29.10 The Notice on Marking Items and Methods for Genetically Modified Fisheries Products (2002)

The regulation has the purpose to notify the identification method for transgenic fishery products so as to give accurate information on GM fishery products to the consumers. It also gives details of the standards and methods of identification of fisheries transgenic products.

4.29.11 Food Sanitation Act (2002.8) (as amended) and the Enforcement Ordinance to the said Act (2003.4) (2002)

The Act requires that the risk assessment of GM foods will be mandatory with effect from 27 February 2004.

4.29.12 The Act on Transboundary Movements of Living Modified Organisms (2003)

The Act covers all functions pursuant to the Protocol including animals, fishes, microorganisms, plants and human health.

The objective of this Act is to prevent in advance the risk of LMOs to national health and their adverse effects on the conservation and sustainable use of biological diversity, thereby promoting international cooperation and assuring the safety of the development, production, import, export and distribution of LMOs.

This Act applies to the development, production, import, export, and distribution of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

4.29.13 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms (2003)

The Enforcement Ordinance stipulates matters necessary for the enforcement of the Act on Transboundary Movements of LMOs.

This regulation applies to development, production, import, export, and distribution of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

4.29.14 National Biosafety Framework of Republic of Korea (2004)

The NBF establishes a more reasonable and efficient national biosafety system. The NBF in Korea includes the development of legal and administrative systems as well as risk assessment and management systems.

4.29.15 Bioethics and Biosafety Act (2005)

The Act, mainly concerned with human safety, is aimed to enhance the health of human beings and the quality of human life by creating conditions that allow for the development of life sciences and biotechnologies that can be used to prevent or cure human diseases.

Additionally, this Act aims to protect human dignity and to prevent harm to human beings by ensuring that these life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics.

Source:

1. *National Biosafety Framework (NBF) of Republic of Korea. 2004. Ministry of Environment, Republic of Korea, National Institute of Environmental Research (NIER). (available at: http://www.unep.org/biosafety/files/KRNBFrep.pdf; accessed on 3 April 2008).*
2. *USDA Foreign Agricultural Service, GAIN Report No. KS7050 Republic of Korea Biotechnology, Agricultural Biotechnology Report 2007. (available at: http://www.fas.usda.gov/gainfiles/200707/146291775.pdf; accessed on 3 October 2007).*

4.30 SAMOA

4.30.1 Samoa's National Biosafety Framework (2004) (draft)

Samoa's NBF is a combination of policy, legal, administrative and technical instruments to ensure adequate level of protection for the safe transfer, handling and use of GMOs. It aims to safely manage GMOs that may have adverse effects on conservation and the sustainable use of biological diversity, also taking into account possible risks to human health.

4.29.2 Biological Diversity Protection Bill (2004) (draft)

The bill aims to protect Samoa's biological diversity and to regulate the development, use, handling, and transboundary movement of GMOs and the applications of modern biotechnology. The main objectives of the bill are to:

(a) Manage importation, development, field testing, fermentation, release, or export of GMOs;

(b) Protect Samoa's biodiversity, environment, and people from adverse effects from GMOs;

(c) Manage import and release of organisms that are not GMOs and are also not found in Samoa.

4.30.3 Biosafety (Genetically Modified Organisms) Regulations (2004) (draft)

The regulation is supporting to the Draft Biological Diversity Act for transboundary movements of GMOs.

Source:

1. *Samoa's National Biosafety Framework. 2004. Minister of Natural Resources and Environment, P 140. (available at: http://www.unep.org/biosafety/files/WSNBFrep.pdf; accessed on 29 March 2008).*

4.31 SINGAPORE

4.31.1 Singapore Guidelines on the Release of Agriculture-Related Genetically Modified Organisms (1999)

These Guidelines provide a framework for the approval procedure and the assessment of risks to human health and the environment posed by deliberate introduction of GM plants, animals, fishes, insects, microorganisms and vaccines used in agriculture, as well as primary food such as meat, eggs, fish, vegetables and fruit. The Guidelines cover agriculture-related organisms with genetic material that has been altered in a way that is unlikely to occur naturally by mating or natural recombination.

They provide a common framework for assessment of risks of agriculture-related GMOs to human health and the environment; and approval mechanisms for their release in Singapore.

These also address issues related to food safety based on the concept of substantial equivalence.

4.31.2 Biosafety Guidelines for Research on GMOs (2006)

The Guidelines are a strategy by the advisory committee to strive towards ensuring public safety while allowing for the commercial exploitation of GMOs and GMO-derived products by companies and research institutions in Singapore. It is the first local Guidelines specific to genetic modification research.

These Guidelines cover experiments that involve the construction and/or propagation of all biological entities (cells, organisms, prions, viroids or viruses) which have been made by genetic manipulation and are of a novel genotype and which are; unlikely to occur naturally or which could cause public health or environmental hazards. The experiments have been categorized into three categories based on level of risk 'A' being that posing the highest risk where the type or level of hazard is unclear. Category 'B' includes experiments which have a low risk to laboratory workers, the public or the environment, and experiments which do not pose a significant occupational or public health risk or environmental risk fall into the exemption category 'C'.

Large-scale and intentional release of genetically manipulated organisms will be regulated by the Singapore Guidelines on the Release of Agriculture-related GM Organisms.

Source:

1. *USDA Foreign Agricultural Service, GAIN Report Number: SN5005 Singapore Biotechnology Agricultural Biotechnology Report 2005. (available at: http://www.fas.usda.gov/gainfiles/200507/146130251.pdf; accessed on 6 October 2007).*

2. *Singapore Guidelines on the Release of Agriculture-Related genetically Modified Organisms (GMOs), P 31. (available at: http://www.gmac.gov.sg/Guidelines/download/Agriculture_Guidelines.pdf; accessed on 6 October 2007).*

4.32 SRI LANKA

4.32.1 Food Act, No.26 (1980) (amended in 1991)

The Act covers the LMOs for use as food or feed or for processing. The Act and its amendments prohibit the importation, manufacture for commercial purposes, transportation, storage, distribution, sale, or offer for sale of any food, raw or processed, or any ingredient of food or food additive that has been subjected to genetic modification using DNA recombination technology or any food that contains one or more ingredient or additive that has been subjected to genetic manipulation.

Schedule 1 of the Act lists foods that may not be imported without a certificate to the effect that they do not contain any material or ingredient that has been subjected to genetic modification.

4.32.2 The Plant Protection Act (1999)

The Act makes provisions against the introduction into Sri Lanka and the spreading therein of any organism harmful to, or injurious or destructive to plants, and for the sanitation of plants in Sri Lanka. This Act repealed an older Act and includes GMOs as well as LMOs in the general definition of "organism".

4.32.3 National Biosafety Framework of Sri Lanka (2005)

The biosafety framework is based on the precautionary approach. The overall objective of Sri Lanka's NBF is to ensure that the risks likely to be caused by modern biotechnology and its products will be minimized and biodiversity, human health and environment will be protected to the maximum by regulating the transboundary movements through formulation of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms.

4.32.4 National Guidelines for Import and Planned release of Genetically Modified Organisms and Products thereof (2005) (draft)

The Guidelines are aimed at regulating the transboundary movement of GMOs.

4.32.5 Guidelines for the Safe Use of Recombinant DNA Technology in the Laboratory (2005) (draft)

The Guidelines are meant for the safe use of rDNA technology under contained conditions.

Other Related Regulations

4.32.6 Fauna and Flora (Amendment) Act (1993)

The Act provides for the protection, conservation and preservation of the fauna and flora of Sri Lanka; for the prevention of the commercial exploitation of such fauna and flora; and to provide for matters connected therewith or incidental thereto.

4.32.7 Fisheries and Aquatic Resources Act (1996)

The Act is aimed to protect the aquatic resources of Sri Lanka, prohibit or regulate the export

from, or import into, Sri Lanka of any species of fish including live fish or any eggs, roe or spawn or any products prepared from such fish, eggs, roe or spawn or other aquatic resources for such period of time as may be specified.

4.32.8 Animal Diseases Act (1992)

This Act provides for the control of diseases in animals; for the control of the import and export of animals, animal products and veterinary drugs and veterinary biological products; and for matters connected therewith or incidental thereto.

4.32.9 Food (Labeling & Advertising) Regulation (2005)

The regulation covers labeling of packaged food for consumer awareness, health, safety, and nutrition reasons. Labeling and control of GM products was introduced in the regulation 2007.

Source:

1. *National Biosafety Framework of Sri Lanka. 2005. Ministry of Environment and Natural Resources, Colombo, Sri Lanka. (available at: http://www.unep.org/biosafety/files/LKNBFrep.pdf; accessed on 1 April 2008).*
2. *USDA Foreign Agricultural Service, GAIN Report CE7003 Sri Lanka Biotechnology Annual 2007. (available at: http://www.fas.usda.gov/gainfiles/200707/146291816.pdf; accessed on 17 October 2007).*

4.33 SYRIAN ARAB REPUBLIC

4.33.1 Biosafety Guidelines in Syria (2001)

The guidelines regulates research in GMOs, handling, in laboratories, greenhouses and release into environment.

4.33.2 National Biosafety Framework for the Syrian Arab Republic (2006)

The NBF includes mechanisms of import, export and handling of GMOs and systems of handling of applications, notifications covering the existing Biosafety Guidelines for laboratories, for field experiments and release to environment and for greenhouse experiments with emphasis on risk analysis, assessment and management, monitoring post field release to the environment, accidents and emergency plans.

4.33.3 Biosafety Bill/By-law (2007) (draft)

The Biosafety by-law covers all biosafety issues including the regulation of the import, export, handling of GMOs in Syria and systems of handling of applications. This also covers the BCH and access method to information and data related to GMOs.

Source:

1. *National Biosafety Framework for the Syrian Arab Republic. 2006. Ministry of Local administration and environment. (available at: http://www.unep.org/biosafety/files/SYNBFrepEN.pdf; accessed on 29 March 2008).*

4.34 TAJIKISTAN

4.34.1 National Biosafety Framework of the Republic of Tajikistan (2004)

The most important objectives at the first phase of NBF are:

(a) Adopting the Law on Biosafety;

(b) Development and introducing amendments into the acting legislation;

(c) Development and adopting of relevant legislative documents on realization of Law on Biosafety to ensure implementation of the legislation developed;

(d) Preparation of guidelines for the national competent institution and authorized agencies;

(e) Development of inter-institutional guidelines on cooperation in the process of decision making;

(f) Development of instructive documents on inter-institutional procedures of biosafety regulation;

(g) Development of marking system for GMO products.

The draft Law on Biosafety is currently submitted to the parliament for group discussions. The main goal of the Law is the creation of a legislative base for regulation of the activity attracting GMOs, and protection of human health and the environment.

4.34.2 Republic of Tajikistan Law on Biological Safety (2005) (draft)

The Law aims to minimize risks of adverse impact of GMOs on human health, biological diversity, ecological balance and environment by regulating activity on production, testing, import, export, placing at market and release into environment of GMOs. The activities are related to:

(a) Production, reproduction, import, export, testing and contained use of microorganisms, plants and animals, GM with application of modern biotechnology;

(b) Deliberate release into the environment and placing at market living organisms that were GM including any living organisms able to reproduce, that is seeds, cuttings, pollen, tubers, spores, etc.;

(c) Non-deliberate release of GMOs into the environment;

(d) Deliberate release into the environment and at the market of the processed products containing GMOs and/or processed or non-processed non-living components of GMOs;

(e) Any type of investigation of GMOs including laboratory, clinic, field and production testing;

(f) Non-deliberate or illegal transboundary movement of GMOs;

(g) Storage, burial, elimination of GMOs and/or their products, waste utilization being the result of modern biotechnology methods;

(h) Deliberate import and export of genetic modified organisms and their products.

The Law is applicable to all organisms produced by genetic engineering, and provides rules for acquiring permission and licensing of activities on producing, testing, use and selling of GMOs, refined products including pharmaceuticals for people and for use in veterinary, transportation activity not depending on the way of transportation, as well as activities on selling, import and export regulated by other legal documents of the Republic of Tajikistan.

Source:

1. *National Biosafety Framework Republic of Tajikistan. 2004. National Biodiversity and Biosafety Center. Republic of Tajikistan (available at http://www.unep.org/biosafety/files/TJNBFrep.pdf; accessed on 28 March 2008).*

4.35 THAILAND

4.35.1 Thailand Biosafety Guidelines (1992)

The Guidelines embrace all work related to gene manipulation employing r-DNA technology for all purposes including the development of transgenic plants, animals and microorganisms, production of vaccines, commercial and industrial manufacturing of r-DNA derived products, and releases of transgenic materials and products into the environment.

The Guidelines consist of two parts; the first one concerns transgenic work in laboratories and the second on field testing. Both parts have common Guidelines as follows:

(a) The classification of work relating to GMOs according to level of risk and safety. There are three categories: work bearing no risk, work bearing low risk, and work with high risk. On the basis of the risk, risk management and controls are made in three levels.

(b) Three groups of personnel and organizations have been identified for institutional arrangement in monitoring and control of risk. The Guidelines also gives details on roles and responsibilities of these persons and committees.

4.35.2 Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release (1992)

The Guidelines cover all research work involved in the field test/trial of GM plants and microorganisms.

As a standard practice, GM organisms from laboratory work must be field tested before planned commercial application or planned release into the environment. Such GM field work is meant to address the following underlying objectives to:

(a) Confirm the observations made during laboratory work, and the results from tests conducted at the laboratory level;

(b) Gather accurate information/data on the stability, transmission/heredity and expression of transgenes under field conditions;

(c) Assess the viability (e.g. survival, propagation, competitive ability) of genetically manipulated organisms under field conditions;

(d) Assess the adaptive or evolutionary potential of genetically manipulated organisms under changing environmental conditions.

4.35.3 Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work (1992)

The Guidelines are applicable for all research work- whether conducted in laboratories of the government, of state enterprises, of independent research institutes or of private companies involved in the construction and/or propagation of viroids, viruses, cells or organisms, carrying novel genetic material which are either improbable to arise naturally or are potentially detrimental towards public safety and environmental health.

The Guidelines define regulated work and refer to all GM materials (DNA and RNA preparations, viroids, viruses, cells and organisms, modified or constructed through genetic engineering), derivatives thereof and the wastes or by-products of genetic engineering practices (containing viable organisms or otherwise).

Classification of laboratory genetic engineering and biotechnological work has been done in accordance with levels of risk and safety:

Category 1: Exempted Work (requiring minimal direction from the Institutional Biosafety Committee).

Category 2: Work bearing low levels of risk towards laboratory personnel, the community or the environment.

Category 3: Work bearing an appreciable level of risk towards laboratory personnel, the community or the environment; gene therapy work; and work for which the risks have yet to be clearly identified and assessed.

4.35.4 Plant Quarantine Act (1964) (amended in 1994)

In 1994 the Department of Agriculture, Ministry of Agriculture and Cooperatives, made a "Ministerial Declaration" under the "Plant Quarantine Act" prohibiting import and transit of all transgenic plants, unless permission is granted by the Director General of Department of Agriculture and only for experimental purposes.

4.35.5 Food Act 1965 (Amendment 2002)

Ministerial Order (2002) requires labeling of GMO products.

4.35.6 Cabinet Order 31 August 2002

The Order halts field trial and commercial adoption of GM crops till biosafety legislation is put in place.

4.35.7 National Biosafety Framework (2006)

The NBF aims to monitor and enforce laws on biosafety management. The legislation seeks to establish the necessary framework for ensuring the safety of agricultural GM products in Thailand, and is being developed in line with their commitments as a party to the Protocol. The NBF covers eight concepts:

(a) Sustainable use and conservation of biotechnology;

(b) Risk assessment and management;

(c) Risk classification;

(d) Risk communication;

(e) Cautionary preparedness;

(f) Freedom of choice;

(g) Domestic capacity building;

(h) Encouraging education and public comment.

Source:

1. *Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release (1992). (available at: http://www.opbw.org/nat_imp/leg_reg/Thailand/biosafety.pdf; accessed on February 12, 2008).*

2. *USDA Foreign Agricultural Service, GAIN Report Number TH7090: Thailand Biotechnology Agricultural Biotechnology Report 2007. (available at: http://www.fas.usda.gov/gainfiles/200707/146291754.pdf; accessed on 12 February 2008).*
3. *Thailand Country Report on Biosafety – Risk Assessment and Management by Nipon Iamsupasit, Thailand Biodiversity Center, 73/1, 4th Floor, National Science and Technology Development Agency Building, Rama VI Road, Rajdhevee, Bangkok 10400, Thailand. (available at: http://roksait-cbik.ait.ac.th/data/Thailand_biosafety_ and_risk_assessment%5B1%5D.pdf; accessed on 26 August 2007).*
4. *http://bch-thai.onep.go.th/law_e.html; accessed on 7 October 2007.*

4.36 TONGA

4.36.1 Tonga National Biosafety Framework (2004) (draft)

The NBF targets the following:

(a) Protection of natural plants and animals of Tonga from accidental escape of the LMO's novel engineered gene into the wild or domesticated relative;

(b) Minimizing the risk to biodiversity and human health from LMOs in trade;

(c) Development of effective and efficient pest risk assessment for LMOs;

(d) Facilitation of trade while protecting the interest of the country pertaining to LMOs through effective boarder management;

(e) Minimizing the incidence of food borne diseases due to LMO-FFP;

(f) Monitoring aquatic LMOs to minimize effect on biodiversity from aquaculture practices

(g) Monitoring of LMOs to minimize effect on biodiversity;

(h) Promotion of public awareness and participation through the media, and village meeting such as *faikava* and *fono*;

(i) Development, implementation and enforcement of biosafety regulatory regime.

Source:

1. *Tonga National Biosafety Frameworks. 2004. (available at: http://www.unep.org/biosafety/files/TONBFrep.pdf; accessed on 12 April 2008).*

4.37 VANUATU

4.37.1 National Biosafety Framework (2005)

The NBF is aimed to minimize the risks from both the intentional and accidental introduction and spread of organisms with potential to have adverse impacts, including GMOs and their derivatives and processed products. Biosafety management under the NBF includes:

(a) Risk analysis and decision making framework;

(b) Control introduction, release and establishment of new species or varieties of organisms (including monitoring, reporting and containment);

(c) Border control, surveillance and emergency response for the exclusion and eradication of unwanted organisms and associated pathogens;

(d) Information, education and awareness to allow informed use of organisms with potential

to cause harm (including labeling of foods and animal feeds) and to facilitate community responsibility;

(e) A precautionary approach with respect to new organisms, including GMOs and their derivatives and processed products;

(f) A system for liability and redress.

Source:

1. *National Biosafety Framework. 2005. Department of Vanuatu Quarantine and Inspection Services, P 71. (available at: http://www.unep.org/biosafety/files/VUNBFrep.pdf; accessed on 29 March 2008).*

4.38 VIET NAM

4.38.1 The National Action Plan to 2010 for Implementation of the Cartagena Protocol on Biosafety (2004)

The National Action Plan fulfils the requirements posed to the Parties to the Protocol, at the same time minimize the risks resulting from modern biotechnology and its products. The specific targets to 2010 are:

(a) Formulating policies and regulations on safety management of GMOs and GM products, including policies and regulations on scientific research, technology development, field trial, commercialization, use, import, export, storage and transport of GMOs and their products;

(b) Promoting capacity-building for the state management agencies in biosafety;

(c) Promoting capacity-building in biosafety research;

(d) Establishing the Biosafety Clearing House;

(e) Raising public awareness of biosafety;

(f) Subjecting all GMOs and their products to risk assessment and to labeling requirements under appropriate monitoring;

(g) Establishing cooperation with international organizations in risk management of GMOs and their products.

Source:

1. *The National Action Plan to 2010 for Implementation of the Cartagena Protocol on Biosafety. 2004. (available at: http://www.unep.org/biosafety/files/VNNBFrep.pdf; accessed on 29 March 2008).*

4.39 YEMEN

4.39.1 National Biosafety Framework of the Republic of Yemen (2005)

The NBF document consists of six parts and several annexes related to different domains of the biosafety framework.

(a) Part one gives background information about Yemen's commitment towards the Protocol;

(b) Part two of the NPF deals with national policies and strategies in biosafety;

(c) Part three deals with the draft national biosafety by-law intended to be ratified and issued;

(d) Part four forms the guidelines to create a system for applications, notification and authorization. Information and regulations on import and export of GMOs as well as labeling and identification and facing emergency situations is also covered;

(e) The issue of risk management is highlighted with detailed analysis in part five. Part five also covers monitoring and enforcement;

(f) Part six deals with public awareness. Capacity building is also highlighted as a priority issue in public awareness.

Source:

1. *National Biosafety Framework of the Republic of Yemen. 2005. Ministry of Water and Environment, p 133. (available at: http://www.unep.org/biosafety/files/YENBFrep.pdf; accessed on 29 March 2008).*

References

1. McLean, M.A., R.J. Frederick, P. Traynor, J.I. Cohen, J. Komen, 2002. A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation, International Services for National Agricultural Research, Briefing Paper No. 47 P 12. (available at: *http://www.checkbiotech.org/pdf/implementingbiosafety.pdf*; accessed on 6 May 2008).
2. UNEP-GEF Biosafety Unit. 2006. A Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety Projects. UNEP-GEF. P. 50.
3. UNEP-GEF. 2008. National Biosafety Frameworks. 2008. (available at: *http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx*; accessed on 29 March 2008).

5. OVERVIEW OF BIOSAFETY REGULATORY SYSTEMS IN ASIA-PACIFIC

The Asia-Pacific countries fall into two broad groups with respect to their biosafety regulatory systems. The first group comprises countries that have developed their biosafety regulations independently while the second comprises 28 countries which have developed their NBFs with UNEP-GEF assistance. The latter countries have structured the NBFs according to a common format comprising: description of the government policy on biosafety; description of existing law and enforcement system of the country including principal acts related to biosafety and institutions responsible for their implementation; administrative system for handling requests for authorization of import, export, domestic use, field trials, intentional introduction into the environment, etc; system of risk management and follow up including monitoring and enforcement to ensure compliance; and mechanisms for public education, awareness and participation. These address all the implementation provisions of the Protocol.

The regulatory systems are more diverse in countries that have developed them independent of UNEP-GEF or, like Bangladesh, Indonesia and the Philippines, which had some or the other form of regulatory system already in place before joining the NBF. Table 5.1 summarizes the status of legislative preparedness of these countries to address various biosafety issues. In addition, a brief account of the systems for risk assessment and management, monitoring and inspection, and public information and participation is given below for countries whose regulatory systems are well evolved with actual experiences in GMO regulatory management.

5.1 PROVISIONS FOR RISK ASSESSMENT AND MANAGEMENT

The Australian biosafety guidelines impregnated in the GT Act require detailed assessment of biosafety risks posed by GM products, imposing limitations on how the GM products may be used. The Act establishes an independent statutory officer, The Gene Technology Regulator, who ensures that any GMO one is working with should be covered under Notifiable Low Risk Dealing (classes of GMOs posing minimal risk to people and the environment) or is on the GMO register or is licensed by the Regulator.

The biosafety regulations of New Zealand are part of a larger legislation on biosecurity and the mechanism for risk assessment and management is given along with that of non-LMOs, and is not spelt out separately. The HSNO and Biosecurity Acts work together in terms of approval processes. The HSNO Act covers the assessment of new organisms intended for introduction into New Zealand, while the Biosecurity Act covers border control for managing pest species already in New Zealand. Another important link between the two Acts is that any containment facilities operated under the HSNO Act must be registered under the Biosecurity Act. Besides, under the HSNO (Low-risk Genetic Modification) Regulations 2003, the risk assessments are based on the categorization of risk (risk group I and risk group II).

The biosafety regulations in China have a well-defined risk assessment mechanism called as the “safety assessment system”, and risk management system called as the “safety system” with clear-cut implementation bodies and measures to be adopted. Agricultural GMOs are

Table 5.1 Current status of legislative preparedness on biosafety related issues

Country	Compliance to Cartagena Protocol								Labeling
	Defined Risk assessment/ management criteria	Transboundary movement		Coverage includes				National BCH focal point notified *	
		Import	Export	Plants	Animals	LMOs FFPs	Microbes and others		
Australia	✓	✓	✓	✓	✓	✓	✓	✓	✓
Bangladesh	✓	✓	✓	✓	✓	✓	✓	✓	–
India	✓	✓	✓	✓	–	–	–	✓	✓ (draft bill in 2006)
Indonesia	✓	✓	✓	✓	✓	✓	✓	✓	✓ (not implemented)
Japan	✓	✓	✓	✓	✓	✓	✓	✓	✓
Malaysia	✓	✓	✓	✓	✓		✓	✓	✓
New Zealand	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pakistan	✓	✓	✓	✓	✓	✓	–	✓	–
Peoples Republic of China	✓	✓	✓	✓	–	✓ (import only)	✓ (in laboratory)	✓	✓
Philippines	✓ (case-by-case)	✓	–	✓	–	✓ (import only)	–	✓	–
Republic of Korea	✓	✓	✓	✓	✓	–	–	✓	✓
Thailand	✓	✓ (research only)	✓	✓	✓	microorganisms only	–	✓	–

* National BCH focal point also notified by Afghanistan, Bhutan, Brunei Darussalam, Cambodia, Cook Islands, Democratic Peoples Republic of Korea, East Timor, Kazakhstan, Kyrgyz Republic, Kiribati, Hong Kong, Maldives, Micronesia, Mongolia, Myanmar, Nepal, Niue, Papua New Guinea, Polynesia, Samoa, Singapore, Solomon Islands, Sri Lanka, Syria, Taiwan, Vanuatu, Vietnam and Yemen.

classified into classes I, II, III and IV according to their potential risk to human beings, animals, plants, microorganisms and the environment. The standards for safety evaluation of agricultural GMOs are formulated by the Biosafety Committee. The testing of agricultural GMOs goes through three stages i.e. restricted field-testing (small-scale test conducted within a contained system), enlarged field-testing (medium-scale test conducted under natural conditions) and productive testing (large-scale test prior to commercial production and application).

The Indian biosafety guidelines cover research in genetically engineered organisms, genetic transformation of green plants, rDNA technology in vaccine development and on large scale production and their deliberate/accidental release into the environment. The guidelines prescribe specific safety procedures for rDNA research, production and release to the environment and setting up containment conditions for certain experiments. The guidelines suggest compliance through voluntary as well as regulatory approach.

The mechanism outlined in the GM regulation of Indonesia requires the risk assessment of GM products to be based on "correct scientific method" and certain statistics. Assessment includes document verification, testing of GM products along with related social and economic factors. Evaluation and technical assessment of GM products consist of engineering technique, efficacy and requirements of test facilities (laboratory and field).

Korea has two separate approval systems for conducting environmental risk assessments for GM food and crops. At present, food safety approvals for biotechnology crops are mandatory but environmental risk assessments are voluntary. However, environmental risk assessments will become mandatory when the LMO Act comes into effect which in fact would be the legislation for implementation of the Protocol.

In the Philippines, risk assessment is carried out in a "scientifically sound and transparent" manner based on available scientific and technical information and expert advice of international organizations and regulatory authorities of countries with experience in conducting risk assessment. All such assessments are carried out case-by-case, based on the transformation event and may vary in nature and level of detail depending on the regulated article concerned, intended use and the receiving environment.

Four ministries are involved in the assessment of risks from GMOs in Japan; the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Health, Labor and Welfare, Ministry of Environment, and the Ministry of Education, Culture, Sports, Science and Technology. Risk assessments and safety evaluations are performed by ministry's advisory committees and scientific expert panels. The assessments and evaluations are performed by the scientific expert panels, mainly consisting of researchers. The decisions by the expert panels are reviewed by the advisory committees comprising technical experts and opinion leaders from consumers and industry.

Risk assessment is covered elaborately under the Thailand Biosafety Guidelines categorizing the possible risks associated with each part of the bifurcated guidelines i.e., experimental work and field release of the GMO and also considers the kind of GMO i.e., plant or microorganism. The risks are identified into three categories (a) work bearing no risk; (b) work bearing low risk; and (c) work with high risk. Thus, risk management and control appear to be relative to the organism/risk category in question.

5.2 MONITORING AND INSPECTION SYSTEM

The GT Act of Australia ensures that all existing regulators of GM products (e.g. Therapeutic Goods Administration and Australia New Zealand Food Authority) have access to the Gene Technology Regulator's advice on biosafety issues. The system is transparent and prescribes

specific requirements for compliance under different situations, including authorized persons who may undertake notifiable low risk dealings, notification, supervision by Institutional Biosafety Committees and the containment facilities in which the notifiable low risk dealings may be undertaken. Under the HSNO (New Zealand) amendment 2002, the Environmental Risk Management Authority is responsible for risk monitoring in relation to GMOs and provides for restrictions and approvals prior to their use. However till date, GM plants and animals are not commercially grown in New Zealand. But a number of contained research trials involving GMOs are occurring and food products with GM content are legally offered for sale and consumption. The Environmental Risk Management Authority approves all applications from crop/food research to field testing of GM crops in New Zealand.

The Joint-Ministerial Conference for Biosafety Management of Agricultural GMOs in China coordinates biosafety management of agricultural GMOs. The conference consists of seven government agencies under the State Council, of which the Ministry of Agriculture, besides being responsible for approval for import, domestic production and resource distribution for research and development, is also responsible for monitoring and inspection before and after release. However, the State Administration of Environmental Protection is the authority for negotiation and implementation of the Protocol.

In India, there are specific committees constituted under different ministries for effective monitoring and inspection of research activities, large scale use and environmental impact during field application of GM products. Genetic Engineering Approval Committee of the Ministry of Environment and Forest implements the concerned rules; the Department of Biotechnology of the Ministry of Science and Technology provides technical support to the Genetic Engineering Approval Committee and also evaluates and approves biosafety assessment of GM research and development in the country. The Ministry of Agriculture evaluates and approves the commercial release of transgenic crops through multi-locational trials; the Ministry of Health and Family Welfare evaluates and approves the safety assessment of GM crops and products for human consumption. Besides, the state governments monitor the safety measures at GM research facilities, and assess damage, if any, due to the release of GM products.

As per the Indonesian regulatory legislation, the Genetically Engineered Product Commission monitors the biosafety testing and GM product assessment conducted by a biosafety technical team. After satisfactory testing the Commission submits the results to the Indonesian BCH for public comment through mass media in addition to official notification by the Commission for a period of 60 days after the receipt of the technical assessment report.

In the Philippines, monitoring is relatively elaborate requiring certification from National Commission on Biosafety that the regulated article has undergone satisfactory testing under contained conditions. Along with a technical dossier consisting of scientific literature, unpublished studies or test data etc. and a "Public Information Sheet for Field Testing" has to be submitted. The procedural manual/operational guidelines defining scope and delineation of responsibilities of different departments for monitoring and inspection are being developed.

Under the biosafety regulation of Japan, performing early stage agricultural GM experiments in laboratories and greenhouses requires approval from the Ministry of Education, Culture, Sports, Science and Technology. Joint approvals of the Ministries of Agriculture, Forestry and Fisheries and Environment are required for the use of GM plants in an isolated field for the evaluation of impact on biodiversity. A joint expert panel from the Ministries of Agriculture, Forestry and Fisheries and Environment monitors the environmental safety evaluations.

In Thailand, the institutional arrangements for monitoring and control are categorized into three groups viz., principal investigators and researchers, institutional biosafety committees, and

the National Biosafety Committee. The National Biosafety Committee ensures that genetic manipulation work adheres to the Guidelines and reviews the research methodologies, recommends experimental conditions and coordinates public information and education. It also appoints members from the Board of Directors of the National Center for Genetic Engineering and Biotechnology who ensure that genetic manipulation work adheres to the national guidelines, review the research methodologies, and recommend regulatory agencies in setting experimental conditions for work.

5.3 PUBLIC INFORMATION AND PUBLIC PARTICIPATION

In Australia the GT Act creates a public record of GMO dealings and GM products that resides on the Office of the Gene Technology Regulator website: *www.ogtr.gov.au*. The Act also establishes three committees to ensure public participation and to advise the Regulator, the Gene Technology Technical Advisory Committee comprising a group of highly qualified experts who provide scientific and technical advice on applications; the Gene Technology Ethics Committee comprising a group of expert ethicists, to provide advice in areas of law, religious practices, animal welfare, etc. and the Gene Technology Community Consultative Committee comprising a group of people representing the broad interests within the Australian community, including consumers, researchers, and environmentalists. This group looks beyond the science of gene technology to matters of general concern to the community in relation to GMOs.

In New Zealand's HSNO regulation, public consultations are an integral part of the process for commercialization of GM crops. The Korean regulatory mechanism provides for public announcement and gathering of public opinions before import/production approval for GMOs and also calls for public hearings pertaining to approval revocation of import/production approval for GMOs.

In Japan, the guidelines issued by Ministry of Agriculture Forestry and Fisheries require that before field trials are performed, detailed information including preventive measures for crossing with the same plant species in surrounding environment, such as buffer zones, must be made public on websites and through explanatory meetings for local residents. The Prefectural governments host public forums to seek input on revision of GM regulations.

The national biosafety committee coordinates efforts to inform and educate the public in Thailand on biosafety issues and on proposed national policies. Also, the sub-committees under it have to take care of various aspects of public perception and awareness on biosafety.

5.4 CONCLUSION

Biosafety regulatory systems in countries of the Asia-Pacific region are at different stages of development and implementation, the processes having been initiated at different times and following different approaches to creating the required legal and administrative frameworks. Government policies on biotechnology and biosafety vis-à-vis agricultural production, food security, and economic, trade and social considerations have played a role in shaping the regulatory systems. While most of the regulatory systems are being developed in tune with the philosophy of the Protocol, several countries being members of WTO are also committed to the latter regarding their trade policies. In this regard, they have to balance between obligations of free trade under WTO and environmental safety based on "precautionary approach" of the Protocol. Further, certain provisions of the Protocol, such as those on liability and redressal are still being negotiated and yet to be resolved. Responses of national regulatory systems to the outcome of these negotiations are also to be seen.

6. REGULATORY MANAGEMENT – THE WAY AHEAD

The potential of biotechnology for improving agricultural productivity, including that of small-holder farming systems, is well recognized (FAO, 2004; World Bank, 2007). As detailed in Chapter 1, several countries of the Asia-Pacific region support significantly large programs on GM-based crop improvement in a diverse range of crops that constitute the mainstay of their agriculture. Several countries have made policy statements asserting biotechnology and biosafety as being integral to priority planning for agricultural and national development. However, not all countries have been able to follow a policy of steady support to biotechnology within their national systems. Thus, while the federal regulatory authority in Australia approved GM canola for environmental release, state governments banned it. Similarly, while the Thailand biotechnology policy has identified development of self sufficient economy as one of the six goals of biotechnology, the country has banned field cultivation of all GM plants. It is obvious that besides farm productivity and biosafety concerns, trade issues and influence-group opinions play a role in shaping national policies on biotechnology.

In addition to consistent policy support, other steps needed to fully harness the potential of biotechnology, particularly by developing countries, are greater public investment in R&D, thrust on pro-poor orphan crops, capacity building, public-private partnership, and efficient regulatory management.

6.1 ESTABLISHING NATIONAL REGULATORY SYSTEMS

There is an undeniable need to ensure that products of biotechnology are safe to the environment, and human and animal health. In this regard, the progress made towards establishment of biosafety regulatory systems in most of the Asia-Pacific countries is very encouraging. While a few countries like China, India and the Philippines had taken steps to establish their regulatory systems ahead of the UNEP-GEF initiative, 28 other countries of the region benefited from its financial and technical support to develop their NBFs. These NBFs are at various stages of development and implementation. More importantly, all the country NBFs uniformly comprise five important components namely, national biosafety policy, regulatory regime, administrative system, public awareness and participation, and system for follow up. Now, wherever required, the NBFs need to be operationalized through legislative and administrative measures. Along with, properly developed norms, methods and protocols of risk assessment, management and communication should be in place to ensure efficient and transparent decision making.

Participation of non-government stakeholders, besides all concerned government agencies, in the development and implementation of NBFs needs to be emphasized. With proper awareness and education, the non-government agencies can play a key role in building public confidence in the national regulatory system and its decisions.

6.2 INFRASTRUCTURE AND HUMAN RESOURCE DEVELOPMENT

Infrastructure requirements for conducting safety and performance trials are large and diverse,

which when available are often managed by different agencies. Researchers in developing countries with modest budgets often face hurdles in organizing these trials. Development of special facilities with public funding where users could get the trials conducted on contract basis or with some other arrangement could be an option. In this regard, the proposed plan of India's Department of Biotechnology to create a facility for testing safety of GM crops at the International Crops Research Institute for the Semi Arid Topics (ICRISAT) (Koshy, 2008) is a step in the right direction. The facility would undertake GM field trials on a contract basis and provide a "level playing field" that would allow small as well as large organizations to complete the regulatory requirements.

Human resource development is essential for building a robust regulatory management system required for taking critical case-by-case decisions, developing and managing technical information and for ensuring productive public participation in decision making. Public acceptance of biotechnology and its products is intimately linked to the confidence it has in the integrity and technical efficiency of regulatory systems. Hence, well-trained human resources with adequate knowledge and experience in respective areas of biosafety management are imperative.

6.3 REDUCING COMPLIANCE COST

High cost of regulatory compliance has been quoted as one of the reasons why public sector in the developing world has been slow in releasing GM crops. The estimated cost of regulatory compliance for virus-resistant rice in Costa Rica (including field trials but not technology development and molecular characterization) was $2.25 million and for the first Bt cotton in India it was more than US$1 million (Cohen, 2005; World Bank, 2008). Expensive and cumbersome compliance procedures not only add to the cost of GM seed that a farmer has to pay but also delay the availability of improved products to farmers and consumers. It is suggested that regulatory systems rather than being uniformly stringent need to ensure objective assessment of risks and benefits. A number of suggestions to rationalize information requirements that would facilitate compliance and encourage adoption of biotechnology while not compromising safety have been made (Bradford *et al.,* 2005; Delmer, 2005). Some of these are listed below:

(a) Elaborate safety testing need not be repeated every time an event is submitted for approval since biosafety impact would be same irrespective of the crop genotype in which it is transferred, if destined for release in the same country/area. Besides events, even genes could be considered for de-regulation, once extensive data are in place indicating they are safe.

(b) Since not all the events reach the stage of commercialization, ways should be found out to field-test the safety of an event first under low cost conditions that are simple in design but conceptually sound. Large-scale field-testing should be required only for events that are nearing approval.

(c) In case a GM crop is to be approved for an areas where no crossable related species exist, the potential of gene flow would be very limited.

(d) The risks posed by traits like high carotene content are apparently negligible and information requirements for such GM traits should not be as extensive as those for insect resistance or herbicide tolerance.

In fact, majority of national regulations recommend case-by-case assessment of risk, depending on GMO concerned, its intended use and potential environmental impact. But bringing these recommendations into actual practice has often been difficult due to hypothetical and unsubstantiated concerns that sometimes influence regulatory decisions.

6.4 REGIONAL COOPERATION

The need for regional and sub-regional cooperation for effective implementation of biosafety is recognized by the Protocol. It calls for cooperation in human resource development and institutional capacities in the proper and safe management of biotechnology and in the use of risk assessment and management for biosafety. The parties are also encouraged to cooperate on research and information exchange on socio-economic impact of LMOs. Further, the country of export is required to share information with the importing country on risk assessment of an LMO intended for transboundary movement, implying the need for harmonization of information requirements and criteria of risk assessment, and for maintenance of transparency.

The need for regional cooperation in biosafety management is well recognized by many countries; the suggested areas being: resources sharing (technical, material and expertise); experience sharing (methodologies, materials and know-how); information sharing; and regional capacity building (Regional Centers of Excellence) (UNEP-GEF Biosafety Unit, 2006). It is also emphasized that regional cooperation should be country-driven and not in response to external agenda.

Regional harmonization of regulatory systems is proposed along three fronts: authority, administration and analysis (World Bank, 2003). It is recognized that harmonization decisions would be influenced by perceptions about how they impact national prerogatives and priorities. Nevertheless, effective harmonization in areas of documentation requirements, and analysis criteria and procedures is possible provided the countries share common interests in adoption and exchange of biotechnology products. In fact, there does exist strong international and regional interest in collaboration for biosafety regulation (APCoAB, 2006; UNEP-GEF Biosafety Unit, 2006). A conceptual framework for the assessment of regional systems on biotechnology regulations that specifies design options and assessment criteria has recently been proposed by IFPRI (Birner and Linacre, 2008). It identifies key factors for consideration when designing a regional system. On their part, APAARI and APCoAB will continue to facilitate regional collaboration and consensus building so that the gains of biotechnology reach the resource poor farmers of the region and help in alleviating poverty and hunger.

References

1. APCoAB. 2006. Workshop on Biosafety Regulations for Transgenic Crops and the Need for Harmonizing them in the Asia-Pacific Region – Highlights and Recommendations. Asia-Pacific Consortium on Agricultural Biotechnology, New Delhi and International Crops Research Institute for the Semi Arid Tropics, Andhra Pradesh. India. P. 16.
2. Birner, R. and N. Linacre. 2008. Regional Biotechnology Regulation – Design Options and Implications for Good Governance. IFPRI Discussion Paper 00753. International Food Policy Research Institute, Washington, DC. P. 56.
3. Bradford, K.J., A. Van Deynze, N. Gutterson, W. Parrott and S.H. Strauss. 2005. Regulating transgenic crops sensibly: lessons from plant breeding, biotechnology and genomics. *Nature Biotechnology* **23:** 439-444.
4. Cohen, J. I. 2005. Poorer nations turn to publicly developed GM crops. *Nature Biotechnology* **33:** 27-33.
5. Delmer, D.P. 2005. Agriculture in the developing world: connecting innovation in plant research to downstream application. *Proceedings of the National Academy of Sciences, US* **102:** 15739-15746.
6. FAO. 2004. The State of Food and Agriculture 2003-04. Agricultural Biotechnology – Meeting the Needs of the Poor? Food and Agriculture Organization of the United Nations. Rome. P. 209.

7. Koshy, P. 2008. Level playing field for GM crop field trials. *Food Security and Ag-biotech News*. (available at: *http://www.merid.org/fs-agbiotech/more.php?id=6707*; accessed on 5 May 2008).
8. UNEP-GEF Biosafety Unit. 2006. A Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety Projects. UNEP-GEF. P. 50.
9. World Bank. 2003. Biosafety Regulations – A Review of International Approaches. Report No. 26028. The World Bank Rural Development Department. P. 50.
10. World Bank. 2007. World Development Report 2008 – Agriculture for Development. International Bank for Reconstruction and Development/The World Bank. P. 365.

Annexure I

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Annexure II

STATUS OF ASIA-PACIFIC COUNTRIES WITH RESPECT TO THE PROTOCOL

Country	Date of the Protocol		CPB National Focal Point	BCH National Focal Point
	Signature	Ratification		
Afghanistan	–	–	–	**Eng. Hazrat Hussain Khaurin** General Director, Forests and Range Department Ministry of Agriculture, Animal Husbandry and Food (MAAHF), Jamal Mina, Kabul, Afghanistan Email: hussain.khaurin@fao.org Url: http://www.agriculture.gov.af
Australia	–	–	**Mr. David Dutton** Director, Environmental Strategies Section Department of Foreign Affairs and Trade RG Casey Building, John McEwen Cres BARTON ACT 0221, AUSTRALIA Email: David.Dutton@dfat.gov.au	**Ms. Elizabeth Flynn** Office of the Gene Technology Regulator (OGTR), Commonwealth Department of Health and Ageing MDP 54, P.O.Box 100, WODEN ACT 2606 AUSTRALIA Email: elizabeth.flynn@health.gov.au
Bangladesh	24 May 2000	05 February 2004	**Mr. A.H.M. Rezaul Kabir** Secretary, Ministry of Environment and Forests Bangladesh Secretariat, Building No. 6 Room No. 1309 Dhaka, 1000, Bangladesh Email: secretary@moef.gov.bd, env1@moef.gov.bd Url: http://www.moef.gov.bd/	**Mr. A.H.M. Rezaul Kabir** Secretary, Ministry of Environment and Forests Bangladesh Secretariat, Building No. 6 Room No. 1309 Dhaka 1000, Bangladesh Email: secretary@moef.gov.bd env1@moef.gov.bd Url: http://www.moef.gov.bd/
Bhutan	–	26 August 2002	**Mr. Karma C. Nyedrup** Deputy Director Environment Assessment Section National Environment Commission P.O. Box 466, Thimphu, Bhutan Email: kc@nec.gov.bt, nyedrupkc@hotmail.com Url: http://www.nec.gov.bt **Mr. Ugen Tenzin** *Cartagena Protocol Secondary National Focal Point* Policy and Coordination Division National Environment Commission P.O. Box 466, Thimphu, Bhutan Email: utenzin@nec.gov.bt utenzin@gmail.com Web: www.nec.gov.bt	**Mr. Karma C. Nyedrup** Deputy Director, Environment Assessment Section National Environment Commission P.O. Box 466, Thimphu, Bhutan Email: kc@nec.gov.bt, nyedrupkc@hotmail.com Url: http://www.nec.gov.bt

Country	Date of the Protocol		CPB National Focal Point	BCH National Focal Point
	Signature	Ratification		
Brunei Darussalam	–	–	–	**Department of Environment, Parks & Recreation** Ministry of Development, BB 3510 Bandar Seri Bagawan, Brunei Darussalam Email: modenv@brunet.bn
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Cook Islands	–	–	–	**H.E. The Secretary** Ministry of Foreign Affairs and Immigration P.O. Box 105, Rarotonga Cook Islands Email: secfa@foraffairs.gov.ck, register@mfai.gov.ck
DPR Korea	20 April 2001	29 July 2003	**Mr. Yong U Kim** National Coordinator for Biological Diversity and Biosafety National Coordinating Committee for Environment Zhungsongdong Central District Democratic People's Republic of Korea P.O. Box 44 Sungri Street Pyongyang Democratic People's Republic of Korea Email: ri.hyong.chol@undp.org	**Mr. Ri Hyong Chol** National Coordinator for Biological Diversity and Biosafety National Coordinating Committee for Environment Zhungsongdong Central District Democratic People's Republic of Korea P.O. Box 44 Sungri Street, Pyongyang Democratic People's Republic of Korea Email: shkwak@unicef.org
East Timor	–	–	–	–
Fiji	02 May 2001	05 June 2001	**Mr. Cama Tuiloma** Chief Executive Officer Ministry of Local Government Housing Squatter Settlement and Environment P.O. Box 2131 Government Buildings Suva, Fiji Email: camatuiloma@connect.com.fj	**Mr. Epeli Nasome** Director of Environment Department of Environment P.O. Box 2109, Government Buildings Suva, Fiji Email: enasome@govnet.gov.fj, epeli_nasome@hotmail.com
Hong Kong	–	–	–	–

Country	Date of the Protocol		CPB National Focal Point	BCH National Focal Point
	Signature	Ratification		
India	23 January 2001	17 January 2003	**Mr. A.K. Goyal** Joint Secretary to the Govt. of India Ministry of Environment & Forests Paryavaran Bhawan C.G.O. Complex Lodi Road, New Delhi 110 003 India Email: akg@nic.in kr036@ifs.nic	**Dr. Ranjini Warrier** Director, Ministry of Environment and Forests Paryavaran Bhavan, CGO Complex Lodhi Road, New Delhi, 110 003, India Email: warrier@nic.in akg@nic.in
Indonesia	24 May 2000	03 December 2004	**Dra. Masnellyarti Hilman** Deputy Minister for Nature Conservation Enhancement & Environmental Destruction Control Ministry of the Environment Jalan D.I. Pandjaitan Kav. 24 Jakarta, 13410, Indonesia Email: kehati@menlh.go.id, nellyhilman@yahoo.com Url: http://www.menlh.go.id	**Dr. Inez H.S. Loedin** Head of Molecular Biology Division Research and Development Center for Biotechnology Indonesia Institute of Sciences Jl. Raya Bogor Km 46 Cibinong 16911, Jakarta, 12710, Indonesia Email: islamet@indo.net.id Url: http://www.bchindonesia.org
Iran	23 April 2001	20 November 2003	**Mr. Eshagh Alhabib** Director General International Economic Affairs and Specialized Agencies, Ministry of Foreign Affairs Building no. 8.2, Koushk Mesri Street Ferdousi Avenue, Tehran Iran (Islamic Republic of) Email: ealhabib@mfa.gov.ir, jbarmaki@gmail.com nesmailzadeh@excite.com	**Ms. Nasrin S. Esmailzadeh** National Institute of Genetic Engineering and Biotechnology Ministry of Science, Technology and Research Pazhuhesh Blvd, PO Box 14155–6343 17th Kilometer in Tehran–Karaj Highway Tehran, Iran (Islamic Republic of) Email: nasrin@nrcgeb.ac.ir,
Japan	–	21 November 2003	**Mr. Yasuhiro Hamura** Director, Global Environment Division International Cooperation Bureau Ministry of Foreign Affairs 2–2–1 Kasumigaseki, Tokyo, Japan 100–8919Email: yasuhiro.hamura@mofa.go.jp **Mr. Nobuyuki Kikuchi** Deputy Director, Global Environment Division Ministry of Foreign Affairs 2–2–1 KasumigasekiChiyoda–ku, Tokyo, Japan Email: nobuyuki.kikuchi@mofa.go.jp	**Mr. Kazuaki Hoshino** Director, Wildlife Division Nature Conservation Bureau Ministry of Environment, 1–2–2 Kasumigaseki Tokyo, Japan, 100–8919 Email: bch@env.go.jp

Country	Date of the Protocol		CPB National Focal Point	BCH National Focal Point
	Signature	Ratification		
Jordan	11 October 2000	11 November 2003	**H.E. Khaled Anis Irani** Minister, Ministry of Environment P.O. Box 1408, Amman 11941 Jordan Email: moenv@moenv.gov.jo Web: www.moenv.gov.jo **H.E. Eng. Faris Aljunidi** *Cartagena Protocol Secondary National Focal Point,* Secretary General Ministry of Environment, P.O. Box 1408 Amman 11941, Jordan Email: faljunidi@moenv.gov.jo, faljunidi@yahoo.com	**H.E. Eng. Faris Aljunidi** Secretary General, Ministry of Environment P.O. Box 1408, Amman 11941, Jordan Email: faljunidi@moenv.gov.jo faljunidi@yahoo.com
Kazakhstan	–	–	–	**Mr. Talgat Zhamshitovich Abaydildin** Vice–Minister of Environmental Protection/ National Coordinator of CBD Ministry of Environmental Protection 31 Pobeda Avenue, Astana, 473000, Kazakhstan Email: ums@nature.kz
Kiribati	07 September 2000	20 April 2004	**Mr. Tukabu Teroroko** Permanent Secretary Ministry of Environment, Lands and Agricultural Development P.O. Box 234, Bikenibeu, Tarawa, Kiribati Email: tukabut@melad.gov.ki, teiti.ecd@melad.gov.ki	**Mr. Puta Tofinga** Assistant Environment Impact Assessment (EIA) Officer, Environment and Conservation Division Ministry of Environment Lands and Agricultural Development P.O. Box 234, Bikenibeu, Tarawa, Kiribati Email: putatravel@yahoo.com, eiaa.ecd@melad.gov.ki
Kyrgyz Republic	–	05 October 2005	**Mr. Arstanbek Davletkeldiev** Director, State Agency of Environmental Protection and Forestry 228, Toktogul Street, Bishkek, 720001 KyrgyzstanEmail: min–eco@elcat.kg saef–intdep@mail.ruforest@bishkek.gov.kg	**T. Musuraliev** Chairman, State Forest Service 228 Toktogul Street, Bishkek, 720001 Kyrgyzstan Email: mail@forestagency.bishkek.gov.kg, Url: http://www.kyrgyzforest.kg

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Lao People's Democratic Republic	–	03 August 2004	**Dr. Sourioudong Sundara** Director General, Research Institute of Science Science Technology and Environment Agency P.O.Box 2279, Vientiane Lao People's Democratic Republic Email: sourioudong@yahoo.co.uk, admin@erc.gov.mv,Prime Minister Office, secretariat@meew.gov.mv	**Mr. Lanthom Phouthachack** Deputy Director, Center for Science Development Research Institute of Science Science Technology and Environment Agency Research Institute of Science Science Technology and Environment Agency PO Box 10782, Vientiane, Lao People's Democratic Republic Email: lanthom21@hotmail.com
Lebanon	–	–	**Ms. Lara Samaha** Head, Department of Conservation of Natural Wealth Ministry of Environment, Lazarieh Building P.O. Box 11–2727 Beirut, Lebanon Email: l.samaha@moe.gov.lb Web: www.moe.gov.lb **Melle Rasha Kanj** *Cartagena Protocol Secondary* *National Focal Point* Department of Conservation of Natural Wealth Ministry of Environment Lazarieh Bldg, P.O. Box 11–27 27 Beirut, Lebanon Email: r.kanj@moe.gov.lb	**Dr. Ghassan Ramadan Jaradi** Ministry of Environment P.O. Box 11–8281 Beyrouth 8281 Lebanon Email: r–jaradi@cyberia.net.lb
Malaysia	24 May 2000	03 September 2003	**Dr. Teddy Lian Kok Fei** Undersecretary Conservation and Environmental Management Division Ministry of Natural Resources and Environment Level 6, Tower Block 4G3 Precinct 4 Federal Government Administrative Centre Putrajaya Malaysia, 62574 Email: drlian@nre.gov.my, letchu@nre.gov.my Url: http://www.nre.gov.my/nre_bi/kas/bhgn.htm	**Mr. Kangayatkarasu Nagulendran** Principal Assistant Secretary Conservation and Environmental Management Division Ministry of Natural Resources and Environment Level 6, Tower Block 4G3 Precinct 4 Federal Government Administration Centre Putrajaya, Malaysia, 62574 Email: nagu@nre.gov.my, nagu88@yahoo.com Url: http://www.nre.gov.my/nre_bi/kas/bhgn.htm

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	Signature	Ratification		
			Mr. Kangayatkarasu Nagulendran *Cartagena Protocol Secondary National Focal Point* Principal Assistant Secretary, Conservation and Environmental Management Division Ministry of Natural Resources and Environment Level 6, Tower Block 4G3, Precinct 4 Federal Government Administration Centre Putrajaya, Malaysia, 62574 Email: nagu@nre.gov.my, nagu88@yahoo.com Url: http://www.nre.gov.my/nre_bi/kas/bhgn.htm	
Maldives	–	02 September 2002	**Mr. Abdullahi Majeed** Deputy Minister, Environment Research Center Ministry of Environment, Energy and Water 3rd Floor, Jamaluddin Complex Nikagas Magu, Malé, Maldives Email: admin@erc.gov.mv secretariat@meew.gov.mv	**Mr. Ahmed Saleem** Assistant Director General Environment Research Center Ministry of Environment, Energy and Water Jamaluddhin Complex Male, Maldives Email: saleem@erc.gov.mv, admin@erc.gov.mv
Micronesia	–	–	–	**Mr. Akillino H. Susaia** Secretary, Department of Economic Affairs P.O. Box PS–12, Pohnpei FM 96941, Palikir Micronesia (Federated States of) Email: fsmrd@mail.fm, fsmdea@mail.fm Url: http://www.fsmgov.org/ngovt.html
Mongolia	–	–	–	**Mrs. Navaan–Yunden Oyundar** Director, International Cooperation Department Ministry of Nature and Environment Government Building No. 3 Baga Toiruu 44, Ulaanbaatar 11 Mongolia Email: oyundar@mongol.net mne@mongol.net
Myanmar	11 May 2001	13 February 2008	–	**U Tin Htut Oo** Director General, Agriculture Planning Department Ministry of agriculture and Irrigation Myanmar Email: mis–moai@myanmar.com.mm

Country	Date of the Protocol		CPB National Focal Point	BCH National Focal Point
	Signature	Ratification		
Nepal	–	–	**Mr. Ananta V. Parajuli** Chief Environment Division Ministry of Forests and Soil Conservation P.O. Box 3987, Singha Durbar Kathmandu,Nepal Email: mfsced@wlink.com.np Url: http://www.biodiv–nepal.gov.np	**Mr. Ananta V. Parajuli** Joint Secretary, Environment Division Ministry of Forests and Soil Conservation P.O. Box 3987, Singha Durbar Kathmandu,Nepal Email: mfsced@wlink.com.np Url: http://www.biodiv–nepal.gov.np
New Zealand	24 May 2000	24 February 2005	**Mr. Simon Rae** Ministry of Foreign Affairs and Trade Private Bag 18–901, Wellington, 6001 New Zealand Email: simon.rae@mfat.govt.nz	**Dr. Geoff Ridley** New Zealand Environmental Risk Management Authority, ERMA New Zealand, PO Box 131, Wellington New Zealand Email: geoff.ridley@ermanz.govt.nz
Niue	–	08 July 2002	**Mr. Sauni Tongatule** Director, Department of Environment PO Box 77 Alofi Niue Email: biodiversity.ca@mail.gov.nu **Ms Christine Loane** *Cartagena Protocol Secondary National Focal Point* Senior External Affairs Officer Premier's Department, Office for External Affairs P.O. Box 40, Alofi Niue Email: christine.external@mail.gov.nu, external@mail.gov.nu	**Mr. Sauni Tongatule** Director, Department of Environment PO Box 77, Alofi Niue Email: biodiversity.ca@mail.gov.nu
Pakistan	–	–	**Mr. Abdul Manaf Qaimkhani** Deputy Inspector General (Forest II) Ministry of Environment 2nd Floor, Hajvairy Plaza 22-W, Blue Area Islamabad Pakistan Email: amgaimkhani@yahoo.com	**Mr. Asif Shujah Khan** Director General Pakistan Environmental Protection Agency (Pak–EPA) Ministry of Environment, 311, Margalla Road, F–11/3, 44000 Islamabad Pakistan Email: pakepa@isb.compol.com

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Papua New Guinea	–	14 October 2005	**Dr. Wari Iamo** Secretary Department of Environment and Conservation, Somare Foundation Building PO Box 6601, Boroko, Port Moresby, NCD Papua New Guinea Email: odir@daltron.com.pg	**Dr. Wari Iamo** Secretary Department of Environment and Conservation Somare Foundation Building, PO Box 6601 Boroko, Port Moresby, NCD, Papua New Guinea Email: odir@daltron.com.pg
Peoples Republic of China	08 August 2000	08 June 2005	**Ms. Zhang Jieqing** Director, Division of International Organizations Department of International Cooperation State Environmental Protection Administration (SEPA)115 Xizhimennei Nanxiaojie, Beijing, 100035, China 115 Xizhimennei Nanxiaojie, Beijing, 100035, China Email: zhang.jieqing@sepa.gov.cn	**Mr. Zhang Wenguo** Division of Biodiversity Protection Dept. of Nature and Ecology Conservation State Environmental Protection Administration Email: Zhang.Wenguo@sepa.gov.cn, biosafety@sepa.gov.cn
Philippines	24 May 2000	05 October 2006	**Mr. Jose Maria A. Cariño** The Director Division II Office of United Nations and International Organizations (UNIO) Department of Foreign Affairs 2330 Roxas Blvd.Pasay City, Metro Manila Philippines, 1300 Email: hqs@dfa.gov.ph	**Julieta Fe Estacio** Technical Secretariat Office of the Undersecretary for R&D Department of Science and Technology National Committee on Biosafety of the Philippines DOST Building, Gen. Santos Avenue, Bicutan Taguig City, Metro Manila, Philippines, 1630 Email: jfle@dost.gov.ph
Polynesia	–	–	–	–
Republic of Korea	06 September 2000	03 October 2007	Environment Cooperation Division International Economic Affairs Bureau Ministry of Foreign Affairs and Trade 95–1, Doryeom–dong Chongno–ku, Seoul 110–051 Republic of Korea Email: environment@mofat.go.kr **H.E.Mr. Gil–sou Shin** *Cartagena Protocol Secondary National Focal Point* Consul General/Ambassador Consulate General of the Republic of Korea in Montreal, 1 Place Ville–Marie Suite 2015, Montreal, QC, Canada, H3B 2C4 Email: secretary@koreanconsulate.qc.ca	**Mr. Ho–Min Jang** Director, Korea Biosafety Clearing House Korea Research Instt. of Bioscience & Biotechnology (KRIBB), 52, Eoeun–Dong, Yuseong–gu Daejeon 305–333, Republic of Korea Email: kbch@kribb.re.kr, hmjang@kribb.re.kr

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	Signature	Ratification		
Samoa	24 May 2000	30 May 2002	**Mr. Aiono Mose Pouvi Sua** Chief Executive Officer, Ministry of Foreign Affairs and Trade, P.O. Box L1859, Apia Samoa Email: mfat@mfat.gov.ws	
Saudi Arabia	–	09 August 2007	Vice President for Research Institutes Abdulaziz City for Science and Technology (KACST) P.O. Box 6086Riyadh 11442 Saudi Arabia Email: biosafety@kacst.edu.sa	Vice President for Research Institutes Abdulaziz City for Science and Technology (KACST), P.O. Box 6086, Riyadh 11442 Saudi Arabia Email: biosafety@kacst.edu.sa yhafedh@kacst.edu.sa
Singapore	–	–	**Mr. Sim Huat Koay** Assistant Director, International Affairs Agri–Food & Veterinary Authority Ministry of National Development, 5 Maxwell Road #04–00, Tower Block, MND Complex Singapore Singapore, 069110 Email: koay_sim_huat@ava.gov.sg	**Mr. Sim Huat Koay** Assistant Director International Affairs, Agri–Food & Veterinary Authority Ministry of National Development 5 Maxwell Road, #04–00, Tower Block MND Complex Singapore, Singapore, 069110 Email: koay_sim_huat@ava.gov.sg
Solomon Islands	–	28 July 2004	**Mr. Joe Horokou** Acting Director Environment and Conservation Division Department of Forests, Environment and Conservation, P.O. Box G24 Honiara Solomon Islands Email: horokoujoe@hotmail.com	**Mr. Joe Horokou** Acting Director Environment and Conservation Division Department of Forests, Environment & Conservation, Email: horokoujoe@hotmail.com
Sri Lanka	24 May 2000	28 April 2004	**Mr. M A R D Jayathilake** Secretary Ministry of Environment and Natural Resources, 82, “Sampathpaya” Rajamalwatte Road, Battaramulla, Sri Lanka Email: secoffice@menr.lk dgaphamara@sltnet.lk	**Mr. M A R D Jayathilake** Secretary Ministry of Environment and Natural Resources 82, “Sampathpaya”, Rajamalwatte Road Battaramulla, Sri Lanka Email: secoffice@menr.lk dgaphamara@sltnet.lk
Syrian Arab Republic	–	01 April 2004	**Eng. Imad Hassoun Homsi** Deputy Minister Ministry of Local Administration and Environment, Mazraha Eman Mosque Sq. B.O.P. 3773 Damascus Syrian Arab Republic Email: imadh@gmx.net, imadhassoun51@yahoo.co.uk	**Mr. Bilal Alhayk** Agricultural Engineer General Commission for Environmental Affairs Ministry of Local Administration and Environment Iman Mousqu Sq. Jol Jamal St., Mazraa– P.O. Box 3773 Damascus Syrian Arab Republic Email: akramisa@scs–net.org, Env–Min@net.sy

Country	Date of the Protocol		CPB National Focal Point	BCH National Focal Point
	Signature	Ratification		
Taiwan (Chinese Taipei)	–	–	–	–
Tajikistan	–	12 February 2004	**Dr. Neimatullo Safarov** Head National Biodiversity and Biosafety Center 47 Shevchenko street Dushanbe 734025 Tajikistan Email: NSafarov@biodiv.tojikiston.com, biodiv@biodiv.tojikiston.com	**Ms. Anastasia Idrisova** Head, Department of Strategies and Priority Projects Implementation National Biodiversity and Biosafety Center Shevchenko str. 47, Dushanbe 734025 Tajikistan Email: Aldrisova@biodiv.tojikiston.com, anastasia_idrisova@yahoo.com
Thailand	–	10 November 2005	**Dr. Sirikul Bunpapong** Director Biological Diversity Division Office of Natural Resources and Environmental Policy and Planning 60/1 Soi Phibun Wattana 7 Rama VI Road, Bangkok, 10400, Thailand Email: sirikb@yahoo.com, sirikul@onep.go.th Url: http://www.onep.go.th	**Dr. Sirikul Bunpapong** Director, Biological Diversity Division Office of Natural Resources and Environmental Policy and Planning, 60/1 Soi Phibun Wattana 7, Rama VI Road, Bangkok, 10400, Thailand Email: sirikb@yahoo.com, sirikul@onep.go.th Url: http://www.onep.go.th
Tonga	–	18 September 2003	Ministry of Lands Survey and Natural Resources P.O. Box 917 Nuku'alofa Tonga Email: uilousamani@hotmail.com, usamani@environment.gov.to	
Vanuatu	–	–	–	**Mr. Ernest Bani** Head, Vanuatu Environment Unit Private Mail Bag 9063, Port Vila Vanuatu Email: environ@vanuatu.com.vu, environment@vanuatu.gov.vu Web: www.biodiversity.com.vu

Country	Date of the Protocol		CPB National Focal Point	BCH National Focal Point
	Signature	Ratification		
Viet Nam	–	21 January 2004	**Dr. Tran Hong Ha** Director General Viet Nam Environment Protection Agency (VEPA) Ministry of Natural Resources and Environment (MONRE) 67 Nguyen Du Str. Hoan Kiem dist. Hanoi Viet Nam Email: nlinh@nea.gov.vn	**Ms. Thi Thanh Nhan Hoang** Deputy Director of Natural Conservation Division Vietnam Environmental Protection Agency (VEPA) Ministry of Natural Resources and Environment 67 Nguyen Du, Hanoi Viet Nam Email: hnhan@nea.gov.vn
Yemen	–	01 December 2005	–	**H.E. Eng. Dr. Mahmoud M. Shidiwah** Chairman, Environment Protection Agency PO Box 19719, Sana Yemen Email: epa–yemen@yemen.net.ye, environment@yemen.net.ye Web: www.yemenenvironment.org

Annexure III

CHRONOLOGY OF GLOBAL DEVELOPMENTS IN BIOSAFETY REGULATIONS

Year	Country/ Organization	Development
1973	USA	Discussions at a June 1973 Gordon Conference led the organizers to call for moratorium on some recombinant research and for the US National Academy of Sciences to set up a committee to study questions about the safety of certain laboratory projects.
1974	USA	Committee of the US National Academy of Sciences examined the possible hazards of cloning recombinant DNA molecules. As a consequence, the National Institute of Health (NIH) established the Recombinant Advisory Committee (RAC).
1976	USA	The first "NIH guidelines for research involving recombinant DNA molecules" published.
1977	USA	The NIH guidelines revised and made much less restrictive and by 1981, most cloning experiments in *E. coli* K-12, certain strains of *Bacillus subtilis* and *Saccharomyces cerevisiae* exempted from NIH guidelines.
1982	USA	A major revision of the NIH guidelines; complete exemption granted for most recombinant DNA research; containment levels lowered, and experiments that were previously prohibited, changed to category requiring review and approval by NIH.
1986	OECD	Organization of Economic Cooperation and Development (OECD) "International Safety Guidelines for Application of Biotechnology" – release of GMOs into the environment based on principles of risk management.
	USA	Office of Science and Technology Policy "Coordinated Framework for Regulation of Biotechnology".
1990	India	Department of Biotechnology "Recombinant DNA Safety Guidelines"–covering research on GM organisms and plants, vaccine development and on their large scale production and release into the environment.
1991	Argentina	Comision Nacional Asesora de Biotecnologia Agropecuaria (The National Advisory Committee on Agricultural Biosafety; CONABIA) – mechanism for environmental release, human food and livestock feed uses of GM plants and animal materials.
	Philippines	"The Philippine Biosafety Guidelines" – work involving genetic engineering, and activities requiring the importation, introduction, field release and breeding of non-indigenous or exotic organisms.

Year	Country/ Organization	Development
1992	OECD	"Good Development Principles" – design of safe, small-scale field trials of GM plants and microorganisms.
	USA	Food and Drug Administration (FDA) "Statement of Policy on Regulation of Food derived from Genetically Modified Plants".
	Thailand	"Thailand Biosafety Guidelines on Genetic Engineering and Biotechnology for Field Work and Planned Release".
1993	USA	USDA-APHIS regulation on "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering which are Plant Pests or for which there is Reason to Believe are Plant Pests".
	Norway	"Gene Technology Act No. 38" – production and use of GMOs.
1994	USA	Environmental Protection Agency (EPA) "Approval and Registration Guidelines" testing chemical, microbial and biochemical pesticides. A plant pesticide defined by EPA as a pesticidal substance.
	Canada	"Regulatory Directive 94-08" – the information used by the Canadian Food Inspection Authority (CFIA) to identify potential adverse environmental impacts associated with the unconfined release of GM plants.
	India	"Guidelines for Safety in Biotechnology" – revised to include R&D activities on GMOs and transgenics, large scale production and release and import of GMOs for laboratory research.
1995	UNEP	The United Nations Environment Programme launched its "International Technical Guidelines for Safety in Biotechnology".
	Brazil	"Biosafety Law (No. 8,974)" – to control the use of genetic engineering techniques and environmental release of GM organisms.
1996	Mexico	"Official Mexican Standard 056-FITO-1995" – specify phytosanitary requirements for the national mobilization, import and establishment of field tests of organisms manipulated by the application of genetic engineering.
1997	EU	"Novel Food Regulation (258 97)" – novel foods and novel food ingredients. To ensure the protection of human health, novel foods to undergo safety assessment before being placed on the EU market and only those products considered as safe authorized for marketing.
	Malaysia	"National Guidelines for the Release of GMOs into the Environment" – address the mechanisms of risk assessment and management.
	South Africa	"Genetically Modified Organisms Act No.15"– to govern procedures for development, use and release of GMOs in South Africa.
1998	Philippines	"Guidelines on Planned Release of Genetically Manipulated Organisms (GMOs) and Potentially Harmful Exotic Species (PHES)"– establishes criteria for deliberate release of GMOs and PHES.
	India	"Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts"– elaborated and revised.

Year	Country/ Organization	Development
1999	New Zealand	"Hazardous Substances and New Organisms Act (Amendment 1999)" – includes GMOs in the list.
	Singapore	"Guidelines on the Release of Agriculture-Related Genetically Modified Organisms"- details the application procedures, risk assessment and release of GMOs into environment.
	India	"Guidelines for Generating Pre-clinical and Clinical Data for r-DNA based Vaccines, Diagnostics and other Biologicals"- defines physiological, toxicological and efficacy of r-DNA products prior to initiation of human studies.
1999	EU	Moratorium imposed on all field release of GM crops from 1999-2003.
2000	CBD	"International Protocol on Biosafety"- popularly called as the Cartagena Protocol adopted in Montreal, Canada after more than a year of its inception.
	OIE	"Manual of Standards for Diagnostic Tests and Vaccines"- describes some tests and vaccines for genetically engineered.
	Canada	"Seed Act" and the "Canadian Environmental Protection Act. Regulatory directive 2000-07" amended to include guidelines for the environmental release of GM plants within confined field trials. Environmental release of GM plants to be regulated by Canadian Food Inspection Authority.
2001	EU	"Directive 2001 18"- common methodology for ecological risk assessment and common objectives for monitoring GMO releases to the environment.
	Australia	"Gene Technology Regulation"- protect the health and safety of people and environment by risks posed by GMOs.
	China	"Regulation on the Administration of Agricultural Transgenic Biosafety"- all activities of research, testing, production, processing, marketing, import or export of agricultural GMOs.
2002	USA	"NIH Guidelines"- specify practices for constructing and handling rDNA and organisms and viruses containing rDNA molecules.
	China	A series of under "Measures and Procedures for the Administration of Assessing Agricultural Transgenic Biosafety"; "Labels of Agricultural Transgenic Living Things; Safe Import of Agricultural Transgenic Living Things" - risk assessment and transboundary movement of LMOs.
	New Zealand	"Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act" 2002 - considers additional matters when considering certain applications in relation to GMOs.
	Australia-New Zealand	"Standard A 18/1.5.2"- Labeling of food made mandatory for food produced using gene technology as part of Australia-New Zealand Food Standards Code.
	Philippines	"Administrative Order 8- Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology"- importation or release into the environment of plants and plant products derived from r-DNA technology.

Year	Country/ Organization	Development
2003	EU	"Traceability and labeling regulation (1830 2003)". "GM Food, Feed Regulation 1829 2003" as a single legislation dealing with import/food/feed etc.
	CAC	Codex Intergovernmental Task Force on Foods Derived from Biotechnology adopted three documents: (a) "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology", (b) "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant – DNA Plants", (c) "Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms".
	Japan	"Law Concerning the Conservation and Sustainable use of Living Modified Organisms" (Law No.97 of 2003).
	Australia	In 2003 and 2004 several state governments (Victoria, New South Wales, South Australia, Western Australia, Tasmania and the ACT), imposed moratoria on the commercial release of products of biotechnology. The moratoria to be reviewed in 2008.
2004	IPPC	International Standards for Phytosanitary Measures (ISPM)-11- "Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms" – revised to include assessment of environmental risks posed by LMOs under ISPM on pest risk analysis.
	Philippines	"National Biosafety Framework"– products of modern biotechnology, exotic species and invasive alien species.
	South Africa	"Regulation Governing the Labeling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification"– largely follow Codex Alimentarius scientific guidelines.
2005	Australia	"Gene Technology Regulation Act 2000"– reviewed.
	New Zealand	"Import and Exports (Living Modified Organisms) Prohibition Regulation"– control the export of LMOs.
	Brazil	"Brazilian Law (11.105)"– regulates activities involving GMOs with a technocratic approach for approval of GMOs for release.
	Bangladesh	"Biosafety Guidelines of Bangladesh"– quarantine of GM plants, food, GMOs in agriculture, animals and health.
	Pakistan	"Biosafety Guidelines" – in laboratory, field trials, and procedures for approvals for free movement and commercial uses. "Biosafety Rules"– implements Biosafety Guidelines.
2006	India	"Food Safety and Standards Act"– amended to cover genetically modified and functional foods.
	Philippines	"National Biosafety Framework for the Philippines" – to ensure safe and responsible use of modern biotechnology.
	Singapore	"Biosafety Guidelines for Research on GMOs" specific to genetic modification research and cover experiments involving all biological entities made by genetic manipulation

Year	Country/ Organization	Development
2007	Bangladesh	"National Biosafety Framework"– basis for regulation and management of biotechnology products.
	Iran	"National Biosafety Framework" – agricultural products, health and environmental protection issues arising from use of modern biotechnology.
	Nepal	"National Biosafety Framework" – applicable to the development, production, contained use, field test, intentional introduction into the environment, and import and export of GMOs.
	China	"Decree 10 (CH7053) Labeling Regulation" – for administration of GMO labeling, standardize selling activities of agricultural GMOs, guide production and consumption of GMOs and protect consumers' right to be informed.
	Malaysia	"Biosafety Act" – to regulate release, import, export and contained use of LMOs and products thereof.

ASIA-PACIFIC ASSOCIATION OF AGRICULTURAL RESEARCH INSTITUTIONS

Asia Pacific Association of Agricultural Research Institutions (APAARI), established in 1990 at the initiative of FAO, is an apolitical, neutral, non-profit forum of Agricultural Research Institutions, National Agricultural Research Systems (NARS) in the Asia-Pacific region, in the pursuit of common objectives.

The 'Mission' of APAARI is to promote the development of national agricultural research systems in the Asia-Pacific region through facilitation of intra-regional and inter-institutional, and international cooperation/partnership. The overall objectives of APAARI are to foster agricultural research for development in the Asia-Pacific Region so as to help address the concerns of hunger, poverty, environmental degradation and sustainability of agricultural production. More specifically, the objectives are as follows:

a. Promote the exchange of scientific and technical know-how and information in agriculture;
b. Encourage the establishment of appropriate co-operative research and training programs in accordance with identified regional, bilateral or national needs and priorities;
c. Assist in prioritizing NARS/Regional needs, strengthening of research organizational and management capabilities of member institutions including information and communication technology;
d. Strengthen cross-linkages among national, regional and international research centers and organizations, including universities, through involvement in jointly planned research and training programs; and
e. Promote collaborative research among member institutions, including need based support to regional research networks.

ASIA PACIFIC CONSORTIUM ON AGRICULTURAL BIOTECHNOLOGY

The Asia Pacific Consortium on Agricultural Biotechnology (APCoAB), was established in 2003 under the umbrella of Asia-Pacific Association of Agricultural Research institutions (APAARI). APCoAB has the mission to "harness the benefits of agricultural biotechnology for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific Region".

APCoAB's main thrust is:

1. To serve as a neutral forum for the key partners engaged in research, development, commercialization and education/learning of agricultural biotechnology as well as environmental safety in the Asia-Pacific region.
2. To facilitate and promote the process of greater public awareness and understanding relating to important issues of IPRs, sui generis systems, biosafety, risk assessment, harmonization of regulatory procedures, and benefit sharing in order to address various concerns relating to adoption of agricultural biotechnology.
3. 3. To facilitate human resource development for meaningful application of agricultural biotechnologies to enhance sustainable agricultural productivity, as well as product quality, for the welfare of both farmers and consumers.

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Achieving food security for all is at the heart of FAO's efforts – to make sure people have regular access to enough high-quality food to lead active, healthy lives.

FAO's mandate is to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy. FAO provides the kind of behind-the-scenes assistance that helps people and nations help themselves. If a community wants to increase crop yields but lacks the technical skills, we introduce simple, sustainable tools and techniques. When a country shifts from state to private land ownership, we provide the legal advice to smooth the way. When a drought pushes already vulnerable groups to the point of famine, we mobilize action. And in a complex world of competing needs, we provide a neutral meeting place and the background knowledge needed to reach consensus. The activities of the Food and Agriculture Organization (FAO) comprise four main areas:

Putting information within reach: FAO serves as a knowledge network. We use the expertise of our staff – agronomists, foresters, fisheries and livestock specialists, nutritionists, social scientists, economists, statisticians and other professionals – to collect, analyse and disseminate data that aid development. A million times a month, someone visits the FAO Internet site to consult a technical document or read about our work with farmers. We also publish hundreds of newsletters, reports and books, distribute several magazines, create numerous CD-ROMS and host dozens of electronic fora.

Sharing policy expertise: FAO lends its years of experience to member countries in devising agricultural policy, supporting planning, drafting effective legislation and creating national strategies to achieve rural development and hunger alleviation goals.

Providing a meeting place for nations: On any given day, dozens of policy-makers and experts from around the globe convene at headquarters or in our field offices to forge agreements on major food and agriculture issues. As a neutral forum, FAO provides the setting where rich and poor nations can come together to build common understanding.

Bringing knowledge to the field: Our breadth of knowledge is put to the test in thousands of field projects throughout the world. FAO mobilizes and manages millions of dollars provided by industrialized countries, development banks and other sources to make sure the projects achieve their goals. FAO provides the technical know-how

and in a few cases is a limited source of funds. In crisis situations, we work side-byside with the World Food Programme and other humanitarian agencies to protect rural livelihoods and help people rebuild their lives.

FAO and Biosafety

Agriculture and food production are the main fields of biosafety applications. FAO attaches strategic importance to biosafety given the importance of the conservation of biological diversity for long-term food security. Conservation and sustainable use of genetic resources food and agriculture and associated agrobiodiversity is priority for the Organisation. Therefore, FAO assists countries in building strong technical, institutional and information sharing capacities for biosafety for the safe use of modern biotechnologies and to enhance sustainable agriculture and food production. This is done through interdisciplinary expertise combined with normative and operational experience in policy and development of regulatory frameworks on modern biotechnology.

The Organization addresses requests for assistance from member governments for strengthening national biosafety systems, including through development and implementation of regulations, training of personnel of regulatory bodies in risk assessment and detection of genetically modified organisms (GMOs), upgrading infrastructure, and improving communication and public participation in biosafety decision making. Since 2002, a number of projects have been formulated and delivered with a focus on building national capacities at the policy and institutional level to implement the Cartagena Protocol and establish effective linkages among all relevant stakeholders including the Ministries of Agriculture, Environment, Science and Technology, research and technology centres, private sector and the civil society. Activities at the regional level include establishment of a regional biosafety networks, delivery of issue-specific training (GMO detection, GM food safety etc.) and organization of technical meetings for regional harmonization of rules and regulations. FAO has also taken the lead in expanding knowledge base in areas such as public communication, post–release monitoring, socio-economic issues and consumer concerns arising out of use of modern biotechnology through expert workshops, consultations and technical publications. All of these activities are carried out in full partnership with national agencies, international agriculture research centres, donors, other UN bodies and the civil society members. Most of the publications and other related information are available in FAO website (www.*fao.org/biotechnology*)