

Biosafety Regulations for GM Crops in Asia-Pacific






Asia-Pacific Consortium on Agricultural Biotechnology
Asia-Pacific Association of Agricultural Research Institutions

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FOREWORD

Genetically modified crops have been under cultivation in the Asia-Pacific region since early 2000 when India and the Philippines adopted Bt cotton and Bt maize, respectively, for commercial cultivation. Both the countries experienced enthusiastic response from farmers with 95% of the total cotton growing area in India and 62% of the maize growing area in the Philippines covered under these crops by 2013-14. In China, Pakistan and Myanmar, the rate of GM crops adoption has been similarly encouraging. During this period, a large volume of peer reviewed literature has appeared which establishes the fact that cultivation of pest resistant GM cotton and maize has resulted in substantial increase in production, reduction in pesticide use and increase in farmers' income. Such technological interventions have led to farm profitability, which is vital for the success of agriculture as an enterprise. As such, GM technology has specific relevance to the global objective of food and nutrition security.

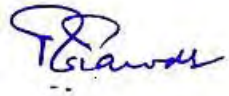
Despite these benefits, GM crops have evoked concerns about their perceived risks to environment and human health. Regulatory systems are in place in several countries to assess the potential risks and manage them through appropriate preventive measures. Though risk assessment and management objectives are similar among countries, specific operational procedures very among them. All nations interested in GM technology, need to strengthen their regulatory systems for building much needed public confidence for adoption of this promising technology.

The Asia-Pacific Association of Agricultural Research Institutions (APAARI) through its program on biotechnology namely, the Asia-Pacific Consortium of Agricultural Biotechnology (APCoAB), has been promoting better understanding and much needed confidence among all stakeholders for development of agriculture sector in the region. Expert meetings on biotechnology and biosafety held during the past several years have highlighted the need to compile information on biosafety regulations of all countries to have better understanding. Accordingly, APCoAB had brought out in 2008 a publication namely, "Biosafety Regulations of Asia-Pacific Countries", which included biosafety regulations of 39 countries. The document was widely appreciated for providing authentic information on biosafety regulatory systems and related aspects in different countries.

In the recent past, several countries have either revised their regulations on biosafety and related aspects or enacted some new ones. Also, trade in GM products and issues of GM labelling, low level presence etc. are being discussed at various fora. It is thus laudable that the present publication, "Biosafety Regulations for GM Crops in Asia-Pacific", has been brought out by APCoAB to give an update on current biosafety regulatory systems operating in the region. Efforts of its authors, Dr. Kavita Gupta, Dr. J.L. Karihaloo and Dr. R.K. Khetarpal are, therefore, very much appreciated.

It is my hope that this publication will serve equally useful purpose as the previous one and stimulate cooperation among AR4D partners in the region towards sharing resources

and knowledge for the common good of agriculture in Asia-Pacific. APAARI and APCoAB will continue promoting use of GM and non-GM technologies suited for smallholder farmers. It will also pursue its efforts on policy advocacy, partnership building and capacity development beside scientific knowledge dissemination.



Dr. Raj Paroda
Executive Secretary
APAARI

PREFACE

In response to the recommendations of regional expert meetings on biotechnology and biosafety organized by APCoAB, a publication entitled "Biosafety Regulations of Asia-Pacific Countries" was brought out in 2008. The compilation detailed regulations existing in 39 countries of Asia and the Pacific and addressed the need for a consolidated document on biosafety regulatory systems of the region. Such information resources are expected to facilitate better understanding and efforts towards regional and sub-regional cooperation in GM technology application for product development and exchange.

Over the past six years since its publication, new developments have taken place in a number of Asia-Pacific countries with respect to framing and implementation of biosafety regulations and other related areas. Besides, new scientific knowledge and tools have been developed that address some of the safety concerns related to GM products.

"Biosafety Regulations for GM Crops in Asia-Pacific", a revised, rewritten and updated version of the previous book lists and gives brief details of the regulatory instruments comprising laws/acts/decrees/regulations/rules related to biosafety of products of biotechnology for agriculture and food existing in 48 countries of Asia and the Pacific. Original sources of country information have been included to enable access to more details, if desired. Besides, new chapters on risk analysis case studies and trade related issues have been added.

Information regarding national biosafety regulations has been obtained from diverse sources. Besides official documents of respective countries, unofficial documents and translations were also used to obtain a complete perspective. Websites of CBD, National Biosafety Clearing House, United Nations Environment Programme – Global Environment Fund, Food and Agricultural Organization (FAO) and USDA-GAIN Reports were frequently consulted and are accordingly quoted in this publication. The information thus obtained was communicated to CBD NFPs of respective countries for verification, several of whom responded with their comments and suggestions. We are especially grateful to Pisey Oum, Cambodia; Yu Wenxuan, China; N.S. Esmailzadeh, Iran and Julieta Fe Estacio, the Philippines who provided their important inputs and advice first in 2007 and again in 2014. We are also grateful to Tri Joko Santoso, Indonesia; Sativaldi Jatayev, Kazakhastan; Johnny Andrew, Malaysia; Muhusina Abdul Rahman, Maldives; S. Bayarkhuu, Mongolia; Sagar Rimal, Nepal; Kirsty Allen, New Zealand; Marcus Ong, Singapore; B.M.U.D. Basnayake, Sri Lanka; Belal Alhayek, Syria; Dalad Senthong, Thailand and Nhan Thi Thanh Hoang, Vietnam who verified and provided latest information on their national regulations in 2014. Our acknowledgement would not be complete without special thanks to Peter Thygesen, Australia; Mohammed Solaiman Haider, Bangladesh; Ugen Tenzin, Bhutan; Inez H.S. Loedin, Indonesia; Ryoko Sakuramata, Japan; Kangayatkarasu Nagulendran, Malaysia and Ananta V. Parajuli, Nepal who provided information when we first started compiling the information in 2007.

We hope this publication will be useful to all stakeholders in biotechnology and biosafety regulation and stimulate trans-boundary collaboration for safe access to biotechnologies and their products in the region.

Kavita Gupta and R.K. Khetarpal are grateful to APAARI/APCoAB for supporting their participation in the biotechnology and biosafety expert consultation meetings held by these organizations. Kavita Gupta is also grateful to the Director, NBPGR, ICAR for his kind support and encouragement to undertake this collaborative work.

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JL Karihaloo
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ACRONYMS AND ABBREVIATIONS

ABSP II	Agricultural Biotechnology Support Program II
AHTEG	Ad-Hoc Technical Expert Group
AIA	Advanced Informed Agreement
APAARI	Asia-Pacific Association of Agricultural Research Institutions
APCoAB	Asia-Pacific Consortium on Agricultural Biotechnology
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
BAFRA	Bhutan Agriculture and Food Regulatory Authority
BARI	Bangladesh Agricultural Research Institute
BCH	Biosafety Clearing House
BRAI	Biotechnology Regulatory Authority of India
Bt	*Bacillus thuringiensis*
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CFIA	Canadian Food Inspection Agency
CoA	Council of Agriculture
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic acid
DOST-BC	Department of Science and Technology-Biosafety Committee
EC	European Commission
EPA	Environment Protection Act
ERA	Environmental Risk Assessment
EU	European Union
FAO	Food and Agricultural Organization
FDA	Food and Drug Administration
FFP	Food, feed and processing
FSANZ	Food Standards Australia and New Zealand
FSB	Fruit and shoot borer
FSCJ	Food Safety Commission of Japan
GCC	Gulf Cooperation Council
GE	Genetic Engineering
GEAC	Genetic Engineering Appraisal Committee
GM	Genetically modified, genetic modification

GMAC	Genetic Manipulation Advisory Committee
GMM	Genetically Modified Microorganisms
GMOs	Genetically Modified Organisms
GSO	Gulf Standardization Organization
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
KFDA	Korea Food and Drug Administration
LMOs	Living Modified Organisms
MAFF	Ministry of Agriculture, Forestry and Fisheries
mha	Million hectares
mRNA	Messenger RNA
NBB	National Biosafety Board
NBF	National Biosafety Framework
NBSAP	National Biodiversity Strategy and Action Plan
NCB	National Committee on Biosafety
NIH	National Institute of Health
NLRD	Notifiable Low Risk Dealing
OAU	Organization of African Unity
OECD	Organization of Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
OIE	World Organization for Animal Health
PCR	Polymerase chain reaction
PHES	Potentially harmful exotic species
PPP	Public Private Partnership
PRA	Pest risk analysis
PRV	Papaya ring-spot virus
RAC	Recombinant Advisory Committee
RARMP	Risk assessment and risk management plan
rDNA	Recombinant DNA

S3-FT	Stage 3 - Field trial
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TRIPs	Trade Related Intellectual Property Rights
TWN	Third World Network
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNEP-GEF	United Nations Environment Programme – Global Environment Fund
UPOV	Union for Protection of New Varieties of Plants
US	United States
USDA	United States Department of Agriculture
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Chapter 1

STATUS OF GENETICALLY MODIFIED CROPS IN ASIA-PACIFIC

The Asia-Pacific region comprises more than 40 countries of sub-regions Southeast Asia, South and Southwest Asia, North and Central Asia, East Asia and the Pacific (FAO, 2014a). The region possesses about 40% of the global land area while producing 45% to 65% of cereals, roots and tubers, pulses, fruits and vegetables (FAO-RAP, 2012; Figure 1). However, per capita availability of food remains low in several densely populated countries of the region. Increasing food prices have also reduced the access of particularly poor and vulnerable sections to the required quantity and quality of food. Of the estimated 842 million (2011-13) undernourished people in the world, 553 million reside in this region (FAO, 2014b). South Asia and East Asia are home to 35% and 20% of the global undernourished, respectively. There is thus a need for not only increasing agricultural production and productivity but also to improve the nutritional quality of food.

Most countries of the region recognise the importance of agriculture in their economic growth, self-sufficiency and social welfare. In a number of countries, elaborate networks of agricultural research and education systems exist and these have contributed significantly to agricultural growth through development of new crop varieties and animal breeds, and farm technologies (Hazell, 2009). It is also recognized that substantial returns are realised from public sector investment in agricultural R&D (FAO, 2012). Within the Asia-Pacific region, India, China and Thailand are the largest public investors in agricultural R&D including biotechnology. China and India have been making significant increases in public investment in agriculture since the year 2000 while other countries have done so marginally.

The adoptions of agricultural biotechnological tools and processes have shown promising results in the region (Karihaloo and Perera, 2010; FAO, 2011). Tissue culture, induction of mutations, biopesticides and biofertilizers, marker-assisted selection, genomics, diagnostics and animal reproductive technologies have made significant contribution towards producing improved crop varieties, animal breeds, disease diagnosis and pest control. In this chapter, current status and prospects of genetic modification technology for agricultural development in the Asia-Pacific region is presented.

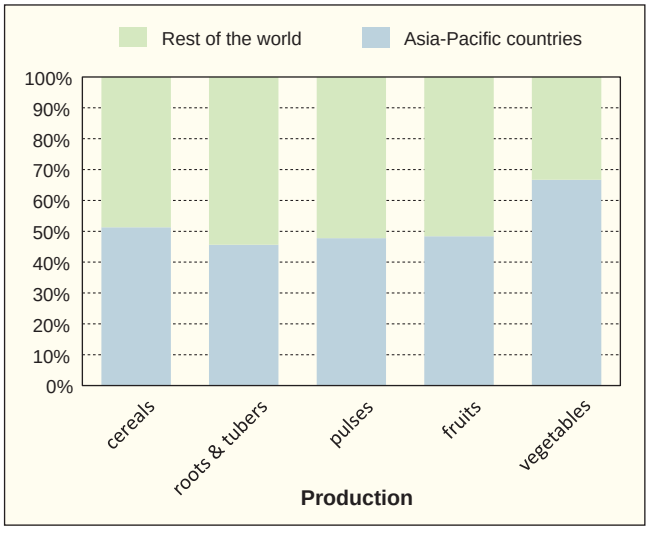
1.1 Status of GM Crop Adoption

In 1996, farmers' fields in the USA were sown to the first GM crops comprising insect resistant maize and herbicide tolerant soybean. Over the years, GM cultivation has spread to all continents and in 2013, 27 countries were growing these crops over an area of 175.2 million hectares (mha) (Khush, 2012; James Clive, 2013). Among the Asia-Pacific countries, Australia, China, India, Myanmar, Pakistan and the Philippines together accounted for 19.8 mha of GM crops (Table 1) major among which were cotton, maize and Argentine canola with traits for herbicide tolerance (ht) and insect resistance (generally Bt). In India, Bt cotton was approved for environmental release in 2002 since when its cultivation has spread to 11 mha in 2013-14, comprising nearly 95% of the total cotton area (James, 2013). The yield reached 552 kg/ha and

Table 1. GM crops under commercial cultivation in Asia-Pacific Countries

Country	Crop	Area (million hectares)
Australia	Argentine canola, cotton	0.7
China	Cotton, papaya, tomato, sweet pepper	4.2
India	Cotton	11.0
Myanmar	Cotton	0.3
Pakistan	Cotton	2.8
Philippines	Maize	0.8

Source: Clive James 2013

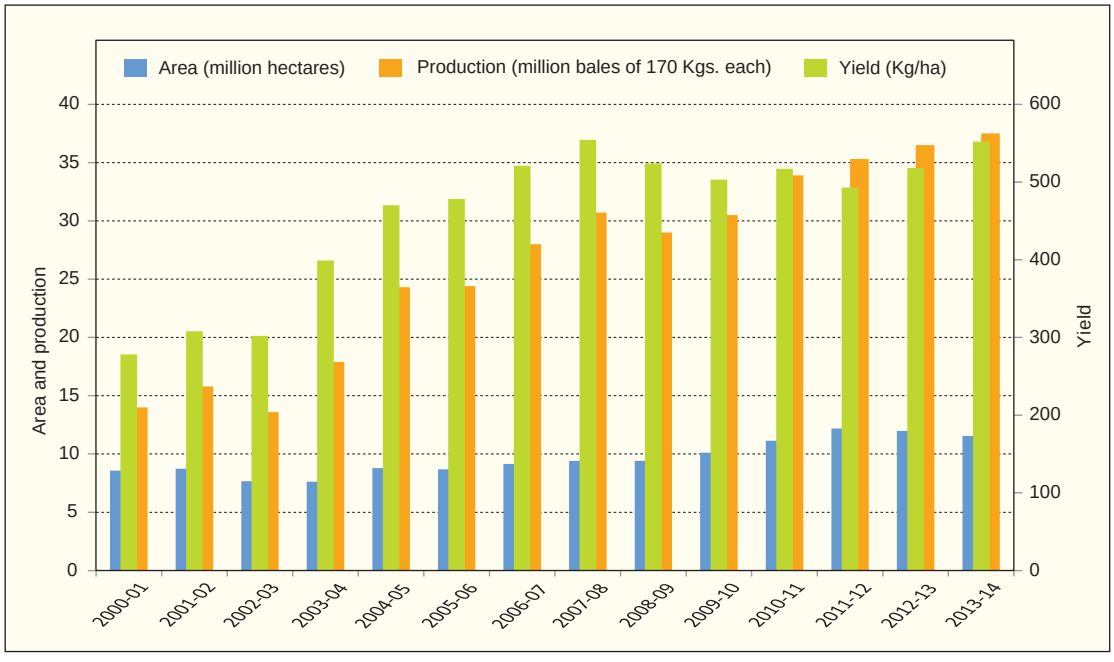


Source: FAO-RAP 2012

Figure 1. Contribution of Asia-Pacific region to global food production

the total production 37.5 million bales, each of 170 kg (total production 6.29 million tonnes) (Fig. 2). Export of cotton from India increased proportionately, positioning the country as the second largest exporter of cotton in 2012, from fourth place in 2002 (FAO-FAOSTAT). Three other countries of the region, China, Pakistan and Myanmar have experienced similar rapid adoption of Bt cotton and substantially increased their production. In Pakistan, Bt cotton was approved for commercial cultivation in 2010 and by 2013, Bt varieties/hybrids were grown over 86% of the 3.2 mha cotton growing area. In the Philippines where GM maize was first field grown in 2003, its coverage reached 800,000 ha in 2013 comprising 62% of the total maize area. Starting with Bt maize, the planting has diversified into herbicide tolerant and stacked Bt and ht hybrids.

Besides the above mentioned crops that are actually under cultivation, more crops and events have been approved for environmental release by the regulatory authorities of a number of countries (Table 2). In addition, several more events have been approved for food/livestock feed. Majority of these represent events/products developed in other countries and imported as ingredients in processed food or feed.



Source: Cotton Corporation of India

Figure 2. Cotton area, production and yield in India from 2000-01 to 2013-14

1.2 Research in GM Crops

The status of GM crops under experimental and field trial phases till 2007 in eight developing countries of Asia-Pacific was presented in the authors' earlier publication (Gupta *et al*., 2008). The survey showed that the countries were undertaking R&D programs of genetic modification in practically all their crops of major importance and for diverse traits including abiotic and biotic resistance, herbicide tolerance, nutritional quality and for industrial use. A more recent survey of GMOs in pipeline (Ruane, 2013) reveals continuing efforts towards application of GM technology for achieving these objectives.

1.3 Economic and Environmental Impact of GM Crops

With the large-scale cultivation of GM crops starting early 21st century, studies on their impact on crop production and farm income were carried out soon afterwards. In the Asia-Pacific region, evaluation of Bt cotton was made in China and India (Huang *et al*., 2002a; b; Arunachalam and Bala Ravi, 2003; Qaim and Zilberman, 2003; Bennett *et al*., 2004) and of Bt maize in the Philippines (Ebora *et al*., 2005). Details of their findings were discussed in our previous publication (Gupta *et al*., 2008).

Several subsequent studies on economic impact of GM crops have been reviewed in a number of recent publications (Karihaloo and Kumar, 2009; Kathage and Qaim, 2012; Nazli *et al*., 2012; Yorobe and Smale, 2012; Anthony and Ferroni, 2012; Carpenter, 2013; Mayee and Choudhary, 2013; Torres *et al*., 2013; Brookes and Barfoot, 2014a). According to Brookes

Table 2. GM crops and events approved for various purposes in Asia-Pacific countries

Country	Environmental release		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, ME), potato (CPBR, PLRVR, PVYR), PLRVR,), sugarbeet (HT)	15	alfalfa (HT), Argentine canola (PC, HT), cotton (HT, IR), maize (HT, IR, ME), potato (CPBR, PVYR), rice (HT), soybean (HT, MO), sugarbeet (HT)	46
Bangladesh	brinjal	1	–		–	
China	cotton (HT, IR), papaya (VR), petunia (MC), poplar (IR), rice (IR), sweet pepper (VR), tomato (AFR, VR)	8	Argentine canola (HT, PC), cotton (HT, IR), maize (HT, IR), rice (IR), soybean (HT, IR)	27	Argentine canola (HT, PC), cotton (HT, IR), maize (IR, HT), rice (IR), soybean (HT), sweet pepper (VR), tomato (AFR, VR)	27
Chinese Taipei	–	–	maize (HT, IR)	1	maize (HT, IR), soybean (HT)	27
Japan	alfalfa (HT), Argentine canola (HT, PC) cotton (IR, HT), maize (HT, IR), soybean (HT, MO), sugarbeet (HT), tomato (AFR)	56	alfalfa (HT), Argentine canola (HT, PC), cotton (HT, IR), maize (AA, HT, IR), potato (CPBR), sugarbeet (HT),	67	alfalfa (HT), Argentine canola (HT, PC), cotton (HT, IR), maize (AA, HT, IR), potato (CPBR, IR, VR), soybean (HT, MO), sugarbeet (HT), tomato (AFR)	77
India	--	3	–	–	–	
Indonesia	sugarcane (DT)	3	maize (HT)	4	maize (HT, IR), soybean (HT)	9
Korea	maize (HT, IR)	2	alfalfa (HT), Argentine canola (HT, PC), cotton (HT, IR), maize (IR, HT), soybean (HT)	41	Argentine canola (HT, PC), cotton (HT, IR), maize (HT, IR), potato (CPBR, PLRVR, PVYR), soybean (HT), sugarbeet (HT)	61
Malaysia	soybean (HT)	6	–	–		–
Philippines	maize (HT, IR)	5	alfalfa (HT), cotton (HT, IR), maize (HT, IR, ME), potato (CPBR, PLRVR), soybean (HT), Argentine canola (HT), sugarbeat (HT)	54	alfalfa (HT), Argentine canola (HT), cotton (IR, HT), potato (CPBR, PLRVR), soybean (HT), sugarbeet (HT)	53
Singapore	–	–	alfalfa (HT)	2	Argentine canola (HT), cotton (HT, IR), maize (HT, IR) soybean (HT, IR, MO), sugarbeet (HT)	17
Thailand	–	–	–	–	maize (HT, IR), soybean (HT, IR)	15

AA: Altered amino acid composition; AFR: Altered fruit ripening; CPBR: Colorado potato beetle resistance; DT: Drought tolerance; HT: Herbicide tolerance; IR: Insect resistance; MC: Modified colour; ME: Modified enzyme activity; MO: Modified oil composition; PC: Pollination control; PLRVR: Potato leaf roll virus resistance; PVYR: Potato virus Y resistance; VR: Virus resistance.

Source: CERA. GM Crop Database

and Barfoot (2014a), the total farm benefits accrued to China, India, Australia, the Philippines, Myanmar and Pakistan during 1996-2012 due to adoption of GM crops have been USD 15,270.40, 14,557.1, 765.5, 378.3, 215.4 and 725.1 million, respectively. The net increase in gross margin has ranged between USD 123 and 559/ha in China and USD 82.66 and 356.85/ha in India.

On the other hand, contradictory reports about the performance and economic benefits of GM crops and their "failure" continue to appear, at least in popular media (Herring and Rao, 2012; Ruane, 2013; Brazeau, 2014). It must be mentioned that such claims generally lack strong empirical evidence.

1.4 Safety of GM Crops

Safety of GM technology and its products has been an area of intense research and debate ever since the development of this technology. Concerns have been raised about the potential risks to environment, and human and animal health, more particularly possible erosion of crop diversity, development of more competitive genotypes and threats posed by them to biodiversity, emergence of resistant pests and diseases, and harmful effects of transgene products or herbicides used along with transgenic crops to human health. Most of these issues were discussed in our previous publication (Gupta *et al*., 2008). Since then, a large volume of literature has appeared much of which supports the contention that in general GM crops are safe to human health (EFSA, 2009, 2012; Snell *et al*., 2012; DeFrancesco, 2013; Wang *et al*., 2013; Romeis *et al*., 2013; Wang *et al*., 2013) and environment (Ammann, 2009; Carpenter, 2011; Lu *et al*., 2012; Singh *et al*., 2013). In fact, attention has been drawn to the environmental benefits accrued due to adoption of GM crops (Mullins and Collier, 2011; Brookes and Barfoot, 2014a, 2014b). On the other hand, there are confirmed cases of development of glyphosate resistant "superweeds" as the result of persistent herbicide application in herbicide tolerant GM crops fields (Gilbert, 2013) and chances of accumulation of transgenes in wild populations through gene flow (Snow *et al*., 2010; Londo *et al*., 2011).

1.5 Conclusion

Adoption of GM crops has been steadily increasing in the Asia-Pacific region. Since the authors' earlier report in 2008, the number of countries growing them has increased from four to six and the area sown to these crops has grown from 10.4 mha to 19.8 mha. More significant increase is observed in the number of GM events approved for food and animal feed. However, public sector investment in research and development remains relatively low in most developing countries of the region. Consequently, the competitive ability of public institutions to develop and commercialize GM crops remains low compared to multinational private sector. Increasing investment in biotechnology research and development along with prioritization to address appropriate practical needs that are also relevant to smallholder farming situations would bring quicker results and earn greater acceptance and benefits to technology adopters as well as developers. In view of the growing body of scientific evidence regarding safety of GM crops, the regulatory systems while remaining efficient and effective need to be dynamic and fine-tune testing requirements and protocols accordingly. The need for effective public communication to overcome continuing negative perceptions about GM crops despite increasing evidence of their safety has been emphasized more than once (Anonymous, 2013; Nicolia *et al*., 2013).

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Chapter 2

INTERNATIONAL DEVELOPMENTS IN BIOSAFETY REGULATION

Measures to analyse the risks posed by recombinant DNA technology were initiated in early 1970s. The aim has been to minimize the potential risks that the technology and its products may pose to the environment and human health. These measures 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.

The Recombinant Advisory Committee (RAC), of the US National Institutes of Health prepared a set of guidelines in 1975 for the laboratory, public and environment safety (Office of Biotechnology Activities, 2014). The guidelines were based on the principles of risk assessment according to which containment experiments were to be conducted in a manner designed to prevent exposure of workers and the public to the microbes being used. The principle of maintaining barriers around the experiment to prevent exposure was the core of the guidelines though it was made clear that the guidelines would need modification with time and experience. The guidelines were voluntary and had no legal standing. Over the years many government agencies and countries have adopted them, or a derivation thereof, as legal requirements (NIH, 2013).

2.1 Key International Instruments on Biosafety

The international organizations involved in the regulation of GM crops and GM foods either directly or through their subordinate legislations along with their broad objectives are:

- The Convention on Biological Diversity (CBD)-1992: Deals with conservation, sustainable use and sharing of benefits by use of biological resources. CBD adopted the Cartagena Protocol on Biosafety, which came into force in 2004 and regulates the transboundary movement of LMOs.
- The World Trade Organization (WTO)-1995: Deals with trade in goods and services and sets rules for transparency and dispute settlement. The Agreement on Application of Sanitary and Phytosanitary (SPS) Measures is based on procedures of risk analysis of plant/ planting materials, food and feed for pests and diseases.
- The International Office of Epizootics (OIE)-1924: Deals with infectious animal diseases that call for harmonization of trade regulations for animals and animal products.
- The International Plant Protection Convention (IPPC)-1952: Deals with pests of plants and plant products and is responsible for setting international standards for phytosanitary measures.
- The Codex Alimentarius Commission (CAC)-1972: Deals with food labelling and food safety standards, and develops international standards and recommendations.

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

Four of the above organizations have an indirect role in the regulation of the products of agricultural biotechnology. The OIE and the IPPC develop standards on the movement of animal and plant pests and pathogens, respectively, which are recognized as reference standards by the SPS Agreement of WTO. The IPPC standard (ISPM 11) on risk analysis includes guidance on risk assessment for LMOs when a transgenic crop may have the potential of becoming a pest. If a country follows an IPPC or OIE standard, it is presumed to be in compliance with SPS Agreement and need not adopt other standards. Countries can use other standards but under SPS rules they have to develop their standards on the basis of risk assessment (FAO, 2001). The sixth organization i.e., OECD develops documents, guidelines and recommendations on harmonized rules, policies and standards for its members. Because the EU and the USA are members of the OECD, any recommendation on how to regulate biotechnology approved in this forum influences future international decisions in other institutions. The Cartagena Protocol, CAC and the WTO are directly involved in trade related issues and the regulations of the products of agricultural biotechnology.

A glimpse of important international and national developments in regulations on biosafety in a chronological order is given in Gupta *et al.,* 2008. The following section highlights the provisions in the international instruments related to risk assessment and monitoring.

Table 3. International instruments for risk assessment and monitoring of GM crops

S.No.	International Instrument	Scientific Principle	Identification of Risk	Risk Assessment	Monitoring Mechanism	Source
1.	**Convention on Biological Diversity - Annex III (Cartagena Protocol on Biosafety)** The Parties to the Convention of Biological Diversity adopted the Cartagena Protocol on the 29th January 2000. The Protocol describes the general principles, methodology and points to consider when conducting a risk assessment for GMOs.	Risk assessment should be carried out in a scientifically sound and transparent manner; Lack of scientific knowledge or scientific consensus should not be interpreted as absence of risk. Risks should be assessed on a case-by-case basis.	The Biosafety Protocol requires Parties to make decisions on import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments (Article 15). It sets out, in Annex III general principles, methodological steps, and points to consider in the conduct of risk assessment.	The methodology described in Annex III of the Protocol follows the conventional risk assessment paradigm, beginning with identification of a potential hazard, such as characteristics of an LMO, which may have an adverse effect on biodiversity. Risks are then characterized based on combined evaluation of the likelihood of adverse effects, and the consequences should those effects be realized.	It recommends that the risk assessment take account of the specificity, sensitivity and reliability of methods used to detect and identify the GMO.	Mackenzie *et al.,* (2003) CBD (2014a)
2.	**WTO-Agreement on Application of Sanitary and Phytosanitary Measures** The Agreement refers to the three international organizations	The SPS Agreement concerns the application of food safety and animal and plant health regulations which should be based on science, applied only to the extent	Risk analysis under SPS is systematically gathered, evaluated, and recorded to arrive at appropriate action. PRA process consists of three stages (a) Stage 1- Initiation identifies	Pest risk analysis (PRA) is based on the probability of a pest entering and establishing in the importing country and its potential impact in the importing county.	The members of WTO need to notify their regulations and standards provide upon request to other Members the regulation and, whenever possible, identify the parts which deviate	WTO (2013b)

S.No.	International Instrument	Scientific Principle	Identification of Risk	Risk Assessment	Monitoring Mechanism	Source
	whose activities are relevant to its objectives for standard-setting: the CAC on food safety, the OIE on human and animal health, and the IPPC on pest prevention, detection and eradication.	necessary and not discriminate between countries with similar conditions. The restrictions imposed should be transparent and based on a scientific risk analysis. The guidelines for pest risk analysis (PRA) are elaborated in the ISPM-2, ISPM-11 and ISPM-21.	pathways and pests to be analyzed; (b) Stage 2- Pest Risk Assessment gives 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.		from international standards, guidelines or recommendations. The dispute settlement framework under the WTO agreement deals with any disputes arising out of international trade. PRA is often fully documented so that when a review or dispute arises it should clearly state the source of information and the rationale used in reaching a particular management decision	
3.	**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	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	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 analysis should be transparent. The exporting country is provided with clear reasons for the imposition of import conditions or refusal to import. The risk identification criteria are case specific for the listed diseases requiring regulation during import and export of animals and animal products.	Risks assessments are categorized into qualitative assessment and qualitative assessment. Quantitative assessments require mathematical models while qualitative assessments are used more 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.	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.	OIE (2014) Senda-shonga, *et al.,* (2005)
4.	**IPPC- ISPM 11- Pest risk analysis for quarantine pests** The ISPM 11 was revised in 2004 to include phytosanitary risks that might be associated with LMOs as they are within the scope of pests as defined in the International Plant Protection	In order to be categorized as a pest, an LMO has to be injurious or potentially injurious to plants or plant products in the PRA area. This damage may be in the form of direct effects on plants or plant products, or indirect effects.	Phytosanitary risk varies with the types of LMOs: – plants for use (a) as agricultural crops, for food and feed, ornamental plants or managed forests; (b) in bioremediation; (c) for industrial purposes; (d) as therapeutic agents	PRA may constitute only a portion of the overall risk analysis for import and release of a LMO. For example, countries may require the assessment of risks to human or animal health, or to the environment, beyond that covered by the IPPC. Phytosanitary risks from LMOs may result from certain traits introduced into the organism, such as those that increase	They are 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	ISPM 11 (2013)

S.No.	International Instrument	Scientific Principle	Identification of Risk	Risk Assessment	Monitoring Mechanism	Source
	Convention (IPPC) and should be considered for pest risk analysis (PRA) to make decisions regarding their risk management. The supplementary text on environmental risks is marked with "S1" and the supplementary text on LMOs is marked with "S2" in the ISPM revised in 2013.		– biological control agents modified to improve their performance in that role.	the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism. 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.	for their success, or by removal of those found to be unnecessary"	
5.	**Codex Alimentarius Commission- Codex guidelines for GM foods include 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.	These principles dictate a case-by-case premarket assessment that includes an evaluation of both direct and unintended effects. The safety assessment of GM foods cover 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 and any unintended effects that could result from the inserted gene.	Risk assessment to encompass not only health-related effects of the food itself, but also the indirect effects of food on human health (e.g., potential health risks derived from outcrossing).	Very little can be known about the potential long term effects of any foods. 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.	Codex principles do not have a binding effect on national legislation, but are referred to specifically in the SPS Agreement of the WTO, and can be used as a reference in case of trade disputes.	Haslberger, (2003) WHO (2013a)
6.	**OECD- Safety considerations for biotechnology, 1986 and 1992** The 1986 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	Proposals to release GMOs are considered on a case-by-case basis. The development and assessment of GMOs should take 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 should generate information	The 1986 report identifies fault trees and event trees as a means to quantify probability of risk.	Quantification of the probability and the magnitude of consequences is done in the first two stages of the risk 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. In such cases	The OECD 1992 report states that scientifically acceptable and environmentally safe field research requires: formulation of a statement of objectives; specific methodologies to introduce, monitor and mitigate the organisms; a precise description of the design of experiments, including planting density and treatment pattern; and a description of specific data to be collected, and	OECD (1992)

S.No.	International Instrument	Scientific Principle	Identification of Risk	Risk Assessment	Monitoring Mechanism	Source
	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.	to predict the safety of the next step. Safety concerns should focus on whether GMOs pose an "incremental risk" above and beyond the background risks of conventional agriculture.		qualitative risk assessment can be used.	of methods for analysis to test for statistical significance.	

Most of the countries of Asia-Pacific have ratified the Cartagena Protocol (Annexure I) and are developing their biosafety frameworks/regulations in conformity with its requirements. The salient features of the Protocol are as below:

2.2 Cartagena Protocol on Biosafety

The Convention on Biological Diversity adopted the Cartagena Protocol on Biosafety (hereafter referred to as the Protocol) in the year 2000 which entered into force on 11 September 2003. The Protocol 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. As of July 2014, the Protocol has 167 Parties (Cartagena Protocol on Biosafety, 2000). The Protocol specifically focuses on transboundary movement of LMOs and attempts to produce a globally harmonized regime for biosafety under the CBD. However, it does not cover products derived from LMOs (e.g., paper from GM trees) and LMOs that are pharmaceuticals for humans. The Protocol also includes a clause clarifying that it does not alter the rights and obligations of parties under the WTO or other international agreements (CBD, 2014a).

2.2.1 Salient Features

The key elements of the Protocol as given in its various articles have been analyzed and reviewed by several researchers (Kinderlerer, 2008, Mackenzie *et al.*, 2003; IISD, 2000; Glass, 2001 and Gupta *et al.*, 2008).

2.2.1.1 Article 7: Advanced Informed Agreement (AIA)

The main mechanism of the Protocol is its requirement of AIA which is a procedure that must be followed before the first intentional transboundary movement of an LMO into the environment of the importing country. Under this procedure, the exporting party must first provide a written notification, as specified in Article 8 (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 within 90 days and whether the notifier should proceed under a domestic regulatory system or under the Protocol procedure. A competent body within the importing country then makes 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, saying that "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" to avoid such adverse impacts. In either case, the importing country must decide whether to allow the import, with or without conditions or deny it within 270 days. 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 this 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 of this fact through the BCH.

2.2.1.2 Article 15: Risk Assessment

As per the Protocol, decisions on proposed imports need to be based on risk assessments, which are undertaken in a scientific manner based on recognized risk assessment techniques, taking into account advice and guidelines developed by relevant international organizations. Risk assessment is carried out on a case-by-case basis. 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 their parental organisms in the potential receiving environment (CBD, 2014c).

2.2.1.3 Article 18: Handling, Transport, Packaging and Identification

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

2.2.1.4 Article 20: Biosafety Clearing House (BCH)

The information sharing mechanism under the Protocol is through the BCH operating through a website (http://bch.cbd.int/) and administered by the Secretariat to the Convention (http://bch.biodiv.org). It was 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.

2.2.1.5 Article 22: Capacity Building

This article calls for cooperation in the development and/or strengthening of human resources among the 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 the same countries to cope with the nature and scale of known and potential risks associated with LMOs. Hence, cooperation for capacity building is a priority.

2.2.1.6 Article 23: Public Awareness and Participation

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.

2.2.1.7 Article 26: Socio-economic Considerations

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.

2.2.1.8 Article 27: Liability and Redress

This is one of the critical articles in the Protocol as it addresses issues of liability and redress for damage resulting from the transboundary movement of LMOs. The liability procedure is still under negotiations and is as yet incomplete.

2.2.1.9 Article 34: Compliance

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

The Protocol is a significant achievement in the light of conflicting views of national governments regarding the risks posed by biotechnology and the policies and procedures to be adopted for mitigating such risks. The Protocol establishes an internationally binding framework of minimum standards. It has operationalized the Precautionary Principle in the decision-making procedure which in the absence of scientific certainty allows countries to use caution and restrict the import of GMOs on account of potential adverse effects. Some of the lacunae in the Protocol are:

- Specific provisions on liability and redress are not yet fully in place. Meanwhile, Parties are already trading in GMOs and the area cropped under GM crops is increasing exponentially by the year.
- Exclusion from the Protocol of GMOs destined for contained use, in transit, for pharmaceutical use, or for food aid.
- Information submitted to a Party of Import, as required by the Protocol, can be claimed to be confidential by the exporter. Thus, the public's right to know is restricted.

2.3 The Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress

The Nagoya–Kuala Lumpur Supplementary Protocol was adopted on October 15, 2010 by the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, which took place in Nagoya, Japan. It was opened for signature at the UN Headquarters in New York on March 7, 2011 and was open for signature until March 6, 2012. Till July, 2014 it has been signed by 51 nations (CBD, 2014b). The Asia-Pacific countries who have signed the Nagoya Protocol have been indicated in Annexure I.

It is a treaty intended to supplement the Cartagena Protocol on Biosafety by providing international rules and procedures on liability and redress for damage to biodiversity resulting from LMOs. The Supplementary Protocol focuses, mainly, on administrative procedures and requirements with respect to response measures that need to be taken in the event of damage by LMOs that adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Parties have an obligation, under the Supplementary Protocol, to provide for rules and procedures that address damage in new or existing domestic law. They need to provide for response measures with a view to prevent or mitigate damage or restore biological diversity. The Supplementary Protocol:

- provides flexibility in regulatory approaches by allowing Parties to apply existing or new domestic laws that may be general or specific as regards response measures to damage
- creates an enabling environment and builds further confidence in the safe development and application of modern biotechnology
- contributes to the prevention or mitigation of damage by creating incentives for operators to ensure safety in the development or handling of LMOs

Alongside the above mentioned international regulations taking shape, several model laws were also brought out with the intention to help developing countries in complying with the provisions of the Protocol and also in developing their own national biosafety regulations. While being not legally binding, they serve as good models for reference while drafting national/ regional legislations.

2.4 EU-Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs

The EU Directive is aimed to provide a common Europe-wide methodology for ecological risk assessment and has the objective to monitoring GMO releases to the environment. In accordance with the Precautionary Principle, the potential direct, indirect, immediate, delayed and cumulative effects of GMOs are to be accurately assessed, on case-by-case basis (European Commission, 2001). Releases are to be carried out in a stepwise fashion and must be field-tested in ecosystems that could be affected by their use. A differentiated procedure is permitted for GMOs that are well known and characterized. The directive does not identify or recommend any hazard assessment technique. It 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 and effects on biogeochemistry. The major factors considered are 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 Directive details the objectives, principles and design requirements of a monitoring plan. The objective of the plan is to confirm the assumptions made in the risk assessment and to identify the occurrence of adverse effects that were not anticipated in the assessment. The latter must be continued for a sufficient period of time to identify delayed and indirect effects.

2.5 Conclusion

Research in biotechnology and the development of transgenics at the regional level (Chapter 1) necessitated the development of biosafety regulatory frameworks which have evolved

over the years. The economic development status also determines the stringency of regulations in many countries. However, the underlying principle of risk assessment remains more or less the same in all the national biosafety regulations. Many of the countries are yet to develop comprehensive biosafety regulations but have incorporated components related to transboundary movement, testing, environmental release of LMOs in other related legislations covering those aspects for non-GM crop/ food etc.

The regulations framed by various countries usually depend on their perception of risks posed by GM crops and their use and release, their trade policies and to the state of political and economic affairs. In this context, harmonization in a regional context would help in building the national capacity within countries where it would be otherwise difficult (Chapter 6). The synergy of national capabilities would ultimately lead to strengthening of regional capabilities.

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21. 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 *Rev. Sci. Sech. Off. Int. Epiz.,* 2005, 24(1), 19-30. Available at: http://www.ncbi.nlm.nih.gov/pubmed/16110874; accessed on July 1, 2014.
22. WHO (2013a) 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 January 16, 2013.
23. WTO (2013b) The Agreement on Application of Sanitary and Phytosanitary Measures. Available at: http://www.wto.org/english/thewto_e/thewto_e.htm; accessed on February 17, 2013.

Chapter 3

BIOSAFETY REGULATIONS IN ASIA-PACIFIC COUNTRIES

Legislative measures to implement biosafety were initiated in the Asia-Pacific countries during 1980s. In 1986, India enacted "Environment Protection Act" under which the "The Environment (Protection) Rules" were formulated in 1989 to regulate environmental pollution by managing hazardous substances, including hazardous microorganisms and GMOs. A national biosafety committee was established in the Philippines in 1990. During 1990s, India and Thailand published their first guidelines on research and environmental release of GMOs.

Rapid progress in the formulation of biosafety systems was made by developing countries through the support of Global Environment Facility of the United Nations Environment Programme (UNEP-GEF). The programme, implemented since 2001, facilitated the development of the National Biosafety Frameworks (NBFs). The NBFs represent "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, 2012). NBFs broadly have five components: i) a national biosafety policy; ii) a regulatory regime comprising legislations, laws, acts, regulation, decrees, guidelines, etc.; iii) 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.); iv) mechanisms for public awareness, education and participation includes public access to information on GMOs and, v) systems for follow-up, including monitoring for environmental effects and effects on human, animal or plant life or health; enforcement to ensure compliance; and offences and penalties (for details, please see Gupta *et al.,* 2008).

Till the end of this programme in 2012, 35 countries of Asia-Pacific region had developed their biosafety frameworks under the UNEP-GEF project: Azerbaijan, Bangladesh, Bhutan, Cambodia, Cook Islands, Democratic People's Republic of Korea, Indonesia, Iran, Islamic Republic of Jordan, Kazakhstan, Kiribati, Republic of Korea, Republic of Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Micronesia, Maldives, Mongolia, Myanmar, Nepal, Niue, Palau, Papua New Guinea, Philippines, Samoa, Solomon Islands, Sri Lanka, Syrian Arab Republic, Tajikistan, Thailand, Tonga, Tuvalu, Vanuatu, Viet Nam, Yemen (UNEP-GEF, 2012). It must be mentioned that Bangladesh, Iran, Indonesia and the Philippines had some form of regulatory regime in place even before UNEP-GEF project.

The following section lists and briefly details the biosafety regulatory systems of 48 Asia-Pacific countries along with their status with respect to GM development and adoption. Draft regulations under consideration for approval are also listed. This compilation represents the updated version of the biosafety regulations detailed earlier in Gupta *et al.* (2008). Inputs received from the BCH national focal points of fifteen countries till June, 2014 have also been incorporated.

3.1 Australia

GM canola, carnation and cotton have been approved for environmental release, of which canola and cotton are reported to be under cultivation. GM sugar beet, canola, soybean, cotton, rice, alfalfa and maize have been approved for food in Australia. GM research and field trials are being conducted on a number of crops, viz. Indian mustard, wheat, sugarcane, grapevines, pineapple and papaya. Initially, most Australian states had put a moratorium on cultivation of GM crops. However in 2007, New South Wales and Victoria lifted the moratoria on GM canola, and in 2008, Western Australia (WA) lifted its ban on cultivation of Bt cotton in the Ord River region (USDA, 2012). In early 2010, WA passed legislation allowing the commercial production of GM canola in the state. South Australia, Tasmania and the Australian Capital Territory (ACT) have till date maintained their moratoria.

Australia has a risk assessment based regulatory framework for dealings with gene technology and GMOs, as well as a process for assessment and approval of GM foods. The Gene Technology Act of 2000 established the regulatory framework to deal with GMOs and related technology. The Gene Technology Regulator serves the key role in assessing, regulating and licensing GMOs and enforcing license conditions.

The standards for GM foods are developed by Food Standards Australia New Zealand (FSANZ) and are contained in the Food Standards Code. Food products derived from GMOs containing more than one percent of GM product, require prior approval from FSANZ before they can be sold in Australia. Such products must also be labelled.

3.1.1 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.

3.1.2 Gene Technology (Consequential Amendments) Act (2001)

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.

3.1.3 Gene Technology Regulations (2001)

(Amended in 2007, 2009 and 2011 by the Gene Technology Amendment Regulations 2006, 2009 and 2011 respectively).

3.1.4 Guidelines for the Transport, Storage and Disposal of GMOs issued by the GT Regulator (2011)

The Guidelines support the implementation of the GT Act by providing technical details, as well as specifying administrative processes and procedures. These guidelines are issued to fulfill for the purposes of paragraph 13(3)(b) of the Gene Technology Regulations 2001.

Secondly, these guidelines may also be invoked as necessary or convenient in the performance of the Regulator's functions under section 27 of Gene Technology Act 2000 ('the Act'), and in the exercise of the Regulator's powers under section 28 of the Act.

In particular these guidelines may be invoked for the purposes of the imposition of licence conditions in accordance with section 61 of the Act and of certification conditions in accordance with section 86 of the Act.

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

3.1.5 The Office of the Gene Technology Regulator Strategic Plan (2010-13)

The legislation has the following prohibitions

- The legislation regulates all dealings (e.g. research, manufacture, production, transport, destruction, commercial release and import) with live viable organisms that have been modified by techniques of gene technology, including the progeny (or descendants) of such GMOs which also share a genetically modified trait
- The legislation revolves around a system of prohibitions and approvals. Every dealing with a GMO needs to be licensed by the Regulator, unless the dealing is an exempt dealing, a Notifiable Low Risk Dealing (NLRD), on the GMO Register or specified in an Emergency Dealing Determination

Other Related Regulations

3.1.6 Therapeutic Goods Act (1989)

The Act provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM & GM-derived therapeutic products, & ensures their quality, safety & efficacy.

3.1.7 Food Standards Australia New Zealand Act (1991)

The Act is responsible for setting standards for the safety, content and labelling of food. FSANZ conducts mandatory pre-market safety assessments for food produced using gene technology.

3.1.8 Quarantine Act 1908 and Imported Food Control Act (1992)

Australian Quarantine & Inspection Service operated under these Acts and regulates the importation into Australia of all animal, plant & biological products that may pose a quarantine pest &/or disease risk. Import permit applications must indicate the presence of GMOs or GM material and the relevant authorization under the Gene Technology Act 2000.

3.1.9 Agricultural & Veterinary Chemicals (Code) Act 1994 and Agricultural & Veterinary Chemicals Administration Act (1994)

The Act operates the national system that regulates all agricultural chemicals (including those produced or used on GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues.

3.1.10 Biosecurity Bill (2012)

The new biosecurity legislation which reflects and replaces the Quarantine Act 1908 aims to provide a modern regulatory tool aimed at better management of risks in the current trading environment. The new biosecurity legislation will primarily comprise two new Bills; the Biosecurity Bill and the Inspector-General of Biosecurity Bill. The bill aims to manage biosecurity risks, the risks of contagion of a listed human disease, the risk of listed human diseases entering Australian territory, risks related to ballast water, biosecurity emergencies and human biosecurity emergencies; and give effect to Australia's international rights and obligations, including the WHO's international health regulations and the Agreement on Application of Sanitary and Phytosanitary Measures of the WTO and the Convention on Biological Diversity. As with the Quarantine Act, the new biosecurity legislation will be jointly administered by the Agriculture and Health Ministers and their departments.

Source:

1. Biosecurity Bill (2012) Available at: http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=s897; accessed on January 30, 2014.
2. Peter Thygesen, Director, Regulatory Practice and Secretariat Section, Regulatory Practice and Compliance Branch, Department of Health and Ageing, Office of the Gene Technology Regulator, MDP54 GPO Box 9848, Canberra, ACT 2601, Australia. email: Peter.Thygesen@health.gov.au (Personal Communication in 2007).
3. 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 November 26, 2013.
4. USDA (2012) Australia Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Canberra_Australia_7-17-2012.pdf; accessed on January 30, 2014.

3.2 Azerbaijan (Republic of)

Azerbaijan ratified the Protocol on April 1, 2005 and developed its NBF in 2005.

3.2.1 National Biosafety Framework (2005)

The National Biosafety Framework calls for

- Setting up a network of laboratories meeting contemporary needs for testing GMOs
- Building capacity on the assessment and regulation of risks posed by GMOs on human health and the environment based on practical observations and scientific findings
- Establishing a mechanism and strategy of control, mitigation and management of risks in the country and a monitoring mechanism for an effective management of risks
- Drafting a national law on biosafety governing the manufacturing, processing, transportation, transfer, import, export, storage of GMOs and products, the use of seeds of GMO origin in agriculture, safety of releasing into the environment, mechanism of responsibility and control
- Making appropriate amendments to existing laws (environmental, agricultural, health, etc.) and regulatory legal acts in accordance with the requirements of the Protocol
- Development of regulations on the application of special labelling of GMO products and their submission for approval
- Development of regulations on the state registration and testing of GMO plant varieties in Azerbaijan

3.2.2 Law on Environmental Safety (1999)

The objective of the Law is to identify the legal basis to prevent human life and health; society with its material and spiritual values; the environment, including atmospheric air, cosmic space, water Source, subsoil, soil, natural landscape, the plants and animal kingdom from hazards of natural and human factors.

3.2.3 Law on Environment Protection (1999)

The Law aims to protect environmental balance thus ensuring environmental safety, prevent the hazardous impact of industry and other activities to natural ecological systems, preservation of biological diversity and proper use of natural resource. As outlined in the Law, goods and technologies produced in, or imported in to the Republic of Azerbaijan, which may pose risks to the environment, human life and health, rehabilitation and proper use of natural resource, shall be considered as items which are subject to standardization and certification as part of environment protection.

Other Related Regulations

3.2.4 Law on Plants Quarantine (1996)

The Law interprets plants quarantine (phytosanitary quarantine) as a legal regime envisioning a system of measures intended for the protection of plants, products thereof, their seeds, saplings, other products and cargoes of plant origin from quarantine targets.

3.2.5 Law on Plants Protection (1996)

The Law interprets plants protection as implementation of scientifically justified complex actions on the protection of plants and products thereof from diseases and pests.

3.2.6 Law on Food Products (1999)

The Law governs the management of safety and quality of agricultural, fishery products and fish used as food products and raw materials, determines the rules of their manufacturing and sales in the market and regulates relationships arising from these activities. The Law states that in case there are discrepancies between the provisions of the present law and regulations set forth in multilateral agreements signed by the state in this area, provisions of the multilateral agreements shall apply.

Source:

1. National Biosafety Framework of Azerbaijan. Available at: http://www.unep.org/biosafety/files/AZ_NBF_eng_final.pdf; accessed on July 7, 2014.

3.3 Bangladesh (Peoples Republic of)

Bangladesh approved Bt eggplant (brinjal) for limited farm level cultivation in October 2013. Confined field trails are being conducted on golden rice and GM potato having resistance to late blight.

Bangladesh has signed and ratified the Protocol. The Biosafety Guidelines were framed in 2005 and the NBF was developed in 2006. The Biosafety Rules of Bangladesh were reviewed in 2012 and are the key legal elements that regulate development, import, export, use, and movement of all GMO products.

The National Committee on Biosafety (NCB) affiliated to the MoEF is the national focal point and national coordinating authority for implementation of the biosafety regulations. The NCB coordinates activities of biosafety committees at sub-national levels through Institutional Biosafety Committee, Field Level Biosafety Committee and Biological Safety Officers (USDA, 2006). The NCB formulates and reviews policies, guidelines, acts, rules, standards, and manuals on biosafety; supervises risk assessment, risk management and implementation of activities, and regulates and monitors work on GMOs.

3.3.1 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. It applies to laboratory and field trial, trans-boundary movement, transit, handling and use of all GMOs/LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks 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.

3.3.2 National Biosafety Framework (2006)

The 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.

The Framework provides the basis for future regulation of the management of GMOs in Bangladesh. The NBF consists of the following elements: (1) National Policy and Guidelines on Biosafety, (2) Legal Regime, (3) Administrative Systems, (4) Monitoring and Enforcement Systems, and (5) Public Participation, Education and Awareness procedures.

3.3.3 Biosafety Rules of Bangladesh (2012)

The Rules are the key legal document that regulates development, import, export, use, and movement of all GMO products. The law provides for punitive measures against misuse of GMO products. Biosafety Guidelines of Bangladesh is legally binding under the Biosafety Rules. The Ministry of Environment and Forests is the national authority to enforce the Biosafety Rules. These rules are applicable to the GMOs, micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc. of which such cells, organisms or tissues hereof form part. These rules shall also be applicable in the following specific cases; of sale, export, production and all work involved in the field trial of genetically modified plants, animals (including fisheries, poultry, animal and marine life), micro-organisms and cells.

Source:

1. Biosafety Guidelines of Bangladesh (2005) Available at: http://www.doe-bd.org/biosafety_Guidelines.pdf; accessed on September 17, 2012.
2. Mohammed Solaiman Haider, Deputy Director, Department of Environment, E-16 Agargaon, Dhaka-1207, Bangladesh. Email: haider@doe-bd.org (Personal Communication in 2007).
3. USDA (2006) Foreign Agricultural Service, GAIN Report No. BG6005 Bangladesh Biotechnology Annual. Available at: http://www.fas.usda.gov/gainfiles/200607/146208489.pdf; accessed on September 17, 2012.

3.4 Bhutan (Kingdom of)

Bhutan does not grow GM crops nor does it import materials containing GMOs. The country ratified the Protocol in August 2002 and developed its NBF in 2006 which was implemented in 2010. Bhutan Agriculture and Food Regulatory Authority (BAFRA) is the National Competent Authority for implementing the NBF.

3.4.1 Ministerial Decree (2000)

Banned all import of GMOs.

3.4.2 Food Act (2005)

The Act addresses the issue of food safety, including that resulting from GM food. This Act regulates the import, export and trade of food in Bhutan. It establishes a National Food Quality and Safety Commission and empowers the BAFRA to implement the provisions of this Act. The BAFRA is responsible for food inspection activities.

3.4.3 Food Rules and Regulations of Bhutan (2006)

These Rules and Regulations aim at preventing the introduction and spread of feed-borne hazards into food for human consumption by properly managing and controlling the production, processing, transport, storage, distribution, preparation, trade, import and export of food.

The Rules and Regulations stipulate that the National Food Quality and Safety Commission, the Bhutan Agriculture and Food Regulatory Authority and the National CODEX Committee shall function in accordance with provisions set out in the Food Act.

In addition, the Rules and Regulations define hygienic minimum requirements for food businesses and requirements and procedures for the licensing of food businesses and their operators, and of food handlers.

The Rules and Regulations further provide for: the labelling and advertising of food; minimum qualifications of food inspectors; requirements for the commercial importation and exportation of food; offences and penalties; etc.

3.4.4 National Biosafety Framework (2007)

The NBF has been prepared according to the National Environment Commission, Bhutan and has been approved by the Royal Government.

3.4.5 Biosafety Bill (2013) (draft)

The regulation shall address the transit, transboundary movement, safe handling and use of all genetically modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health. The bill established BAFRA, National Biosafety Commission, Regulatory guidelines for reporting and monitoring, guidelines for risk assessment and database for GMOs and products

Other Related Regulations

3.4.6 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.

3.4.7 Seed Act (2000)

The Act regulates import and export of agricultural 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.

3.4.8 Environmental Assessment Act (2000)

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

3.4.9 Livestock Act (2000)

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

3.4.10 Biodiversity Act (2003)

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

Source:

1. Food Act (2005) Available at: http://faolex.fao.org/cgi-bin/faolex.exe?rec_id=047683&database=faolex&search_type=link&table=result&lang=eng&format_name=@ERALL; accessed on July 3, 2014.
2. Food Safety Rules and Regulations (2006) Available at http://faolex.fao.org/cgi-bin/faolex.exe?rec_id=081373&database=faolex&search_type=link&table=result&lang=eng&format_name=@ERALL; accessed on July 3, 2014.
3. Yangzom Tashi (2013) Biosafety Regulation of GM/GM Plants in Bhutan. In: South Asia Biosafety Conference and workshops, September 18-20, 2013, New Delhi. South Asia Biosafety Program, Biotech Consortium India Limited, the Bangladesh Academy of Science and the Centre for Environmental Risk Assessment, pp 12.

3.5 Cambodia (Kingdom of)

Cambodia is yet to adopt any biotechnology product in agriculture. Research in modern biotechnology is still in infancy and so is the capacity for biotechnology regulation.

The country is a Party to the Protocol since September 17, 2003 and ratified it in December 16, 2003. Cambodia has also signed the Supplementary Protocol on Liability and Redress in May 2013. The NBF was developed in 2004. The National Biosafety Law was approved in 2008 and the Sub-decree on the Management and Control of Living Modified Organism in 2010. In 2011, a National Action Plan on Biosafety and Modern Biotechnology was signed (NAPBB, 2010).

3.5.1 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 resource; encouraging public participation in the protection of natural resource and the environment including any acts which may affect the environment. Articles 2 to 11 are related to biosafety and biodiversity conservation.

3.5.2 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.

3.5.3 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.

3.5.4 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.

3.5.5 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.

3.5.6 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 resource and public properties in the protected areas.

3.5.7 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.

3.5.8 Law on Biosafety (2008)

The objectives of the Law are to:

- Implement the precautionary approach on biosafety
- Prevent adverse impact on the conservation of biodiversity and natural resource in the Kingdom of Cambodia caused by the transboundary movement, development, handling, transfer, use, storage, and release of living modified organisms resulting from modern biotechnology
- Ensure effective conservation of biodiversity and sustainable use of biological resource, taking also into account risks to human health
- Provide a transparent process for making and reviewing decisions on living modified organisms and related activities and operations
- Develop biotechnology education while preventing environmental and health hazards associated with the use and release of living modified organisms
- 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 non-living components of GMOs

3.5.9 Sub-decree on Mechanisms and Procedures for Implementing the Law on Biosafety (2010)

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. Annex III of Sub-decree is nearly identical to Cartagena Protocol's Annex III on General Principles of Risk Assessment.

Source:

1. NAPBB (2010) National Action Plan on Biosafety and Modern Biotechnology (2010-2014). Available at: http://www.bch-moe.gov.kh/userfiles/image/document/National%20Action%20on%20Biosafety%20and%20Modern%20Biotechnology_2010-2014.pdf; accessed on July 16, 2014.
2. National Biosafety Framework (2004) Ministry of Environment, Kingdom of Cambodia. 138p. Available at: http://www.unep.org/biosafety/files/CMNBFrep.pdf; accessed on March 29, 2013.
3. National Biosafety Law (2008) Ministry of Environment, Kingdom of Cambodia. P 49. Available at http://bch.cbd.int/database/record.shtml?documentid=102845; accessed on February 25, 2013.
4. 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 in 2007 and 2014).
5. Sub-Decree on Mechanisms and Procedures for Implementing the Law on Biosafety (2010) Ministry of Environment, Kingdom of Cambodia. 38p. Available at http://bch.cbd.int/database/record.shtml?documentid=103004 accessed on February 25, 2013.

3.6 China (People's Republic of)

GM cotton is under cultivation in China since 1998. Bt cotton is well reported as a successful case of biotechnology adoption in China. In 2013, China was the sixth largest producer of GM crops in the world with a total area of four million hectares (ISAAA, 2013). Biosafety approval have been given to Bt rice, ring-spot resistant GM papaya and other crops but these are not under commercial; cultivation. China has approved import of GM maize and soybean and the country imports large quantities of the two crops for feed purposes. However, there is a zero threshold level for import of non-approved GM products in food (USDA, 2013).

China ratified the Protocol on April 27, 2005. The Ministry of Environmental Protection (MEP) is the lead authority in implementing and developing Chinese regulations in compliance with the Biosafety Protocol.

China's labelling regulations, governed by the Ministry of Agriculture Decree 10 (CH7053), require the labelling of approved agricultural biotech products and prohibit the importation and sale of any unlabeled or mislabeled products.

3.6.1 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:

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

3.6.2 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.

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

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

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

The Procedure focuses 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 labelling.

3.6.6 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.

3.6.7 Implementation Regulations on Labelling 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 labelling 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 labelling 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.

3.6.8 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.

3.6.9 Technical Standards for Agricultural Biosafety (2003-06)

The Ministry of Agriculture issued 26 technical standards of agricultural biosafety from 2003 to 2006. The standards are mainly about technical specifications and inspection standards of GMOs and their products. 7 standards were released in 2003, 5 were released in 2006 and 14 in 2007. On March 1st, 2008, 27 another standards were put into effect. In April 2009, the Ministry of Agriculture published three national standards for agricultural genetically modified organism safety.

3.6.10 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.

3.6.11 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.

3.6.12 Decree 10 (CH7053) Labelling Regulation (2007)

Decree 10 states that the reason for the regulation is "to strengthen the administration of GMO labelling, 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 labelling required as well as the specific language that is required on the individual labels.

3.6.13 Regulations on Production Permission of Livestock's Genetic Materials (2010)

The Regulations were formulated by The Ministry of Agriculture to strengthen the management of producing livestock's frozen semen, embryos, eggs and other genetic materials. It provides that the units and individuals, engaging in the production of livestock's genetic material, shall obtain the License to Breed Stock and Fowl Production and Trade according to these regulations. It also presents some provisions on application, site assessment, examination and approval, supervision and administration of production permission of livestock's genetic materials.

3.6.14 Implementing Rules for the Regulations of the People's Republic of China on the Protection of New Varieties of Plants (Agriculture Section) (2011)

The Rules were formulated by the Ministry of Agriculture. It prescribes that the new plants include grain, cotton, oilseed, hemp, sugar crop, vegetable (including Cucumis melo L.), tobacco, mulberry, tea plant, fruit tree(excluding dried fruit), ornamental plants (excluding woody plant), grass, green manure, herbal medicine, edible fungi, algae, rubber tree, etc. The Rules present some provisions on the ownership and contents of the variety rights, conditions for granting variety rights, application and acceptance, examination and approval. The Rules also provide the submission, delivery and duration of the application and approval documents.

Source:

1. USDA (2013) Foreign Agricultural Service, GAIN Report NZ13033 Agricultural Biotechnology Annual China. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_8-12-2013.pdf; accessed on June 20, 2014.
2. Xiaobing Wang, Jikun Huang, Huaiju Liu, Cheng Xiang, and Wei Zhang (2013) Adoption and Uptake Pathway of GM Technology by Chinese Smallholders: Evidence from Bt Cotton Production. Center for Chinese Agricultural Policy, Chinese Academy of Sciences: Beijing, China. Available at http://www.isaaa.org/programs/specialprojects/templeton/adoption/china/China-Adoption%20and%20Uptake%20Pathways.pdf; accessed on January 23, 2014.
3. Yu Wenxuan, Associate Professor, School of Civil, Commercial and Economic Law, Director of R&D Section, Center for Legal Assistance to Pollution Victims (CLAPV), China University of Political Science and Law, 25 Xitucheng Road, Haidian District, Beijing 100088, China. E-mail: wenxuanyu@126.com (Personal Communication in 2007 and 2014).

3.7 Chinese Taipei (Republic of China-Taiwan)

Chinese Taipei has implemented GM technology in a number of crops, including cereals, vegetables and ornamentals. However, no products have been approved for environmental release although corn and soybean are approved for food, feed and processing (USDA, 2013).

Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) under the Council of Agriculture (COA) is the lead agency on the biotechnology issues. The environmental release of GM crops is covered under the Taiwan Plant Varieties and Plant Seeds Act (http://law.coa.gov.tw/GLRSnewsout/EngLawQuery.aspx). However, the regulation governing propagation and production of GM crops is still at drafting stage.

3.7.1 Plant Variety and Plant Seed Act (2005)

The Law relates to GM food labelling 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.

Chinese Taipei has adopted a US style interagency approach.

- The Department of Health's Food and Drug Administration (TFDA) is responsible for food safety risk assessment, while the Council of Agriculture (COA) has oversight on events to be used in livestock and crop production or aquaculture. COA is also in charge of trans-boundary movement of LMOs (living modified organisms) and the environmental risk assessment for new events
- The Bureau of Standards, Metrology, and Inspection (BSMI) under the Ministry of Economic Affairs is responsible for import inspection. BSMI currently assists TFDA in monitoring grain and oilseed shipments for the presence of biotech events. BSMI takes samples at the ports of entry for TFDA to conduct monitory import inspections on biotech soybean and corn events
- TFDA also conducts market surveillance testing for all biotech food products, not limited to corn and soybeans and compliment of biotech labelling regulation
- The National Science Council (NSC) supervises safety laboratory works in biotechnology
- The final authority of Taiwan's biotechnology regulatory system is held by an appointed minister without portfolio. The convener of the advisory committee for GM products special task force, and the Science and Technology Advisory Group (STAG) under the Executive Yuan serves as Secretariat to the interagency advisory GM products special task force

3.7.2 Rules for Approving Import/ Export Transgenic Plants (2005)

The commodities for food, feed and processing use have been excluded from the ruling and are not required to apply for additional approval registration to the Taiwan authority at the Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ).

3.7.3 The Administrative Regulations for the Field Testing of the Transgenic Plants (2012, revised in 2014)

These Regulations are enacted in accordance with Article 52, Paragraph 3 of the Plant Variety and Plant Seed Act and covers the various requirements and lays down the conditions for proper field testing of transgenic plants. A central competent authority would constitute the transgenic plant evaluation committee to review field testing and relevant management matters. The Committee would review of application cases for a field testing institution, review of genetic characteristics testing application cases and its investigation reports; review of biosafety assessment application cases and assess the emergency incident handling measures during the field testing period, decide the matter of test results in conjunction with the testing specified in Article 3 and provide technical and policy consultation.

Source:

1. http://law.coa.gov.tw/GLRSnewsout/EngLawQuery.aspx; accessed in July 12, 2014.
2. USDA (2011) Foreign Agricultural Service, GAIN Report TW11013 Taiwan Agricultural Biotechnology Annual An Update. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Taipei_Taiwan_10-6-2011.pdf; accessed on February 25, 2013.
3. USDA (2013) Foreign Agricultural Service, GAIN Report TW13024 Taiwan Agricultural Biotechnology Annual Report. Available at: (http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Taipei_Taiwan_8-6-2013.pdf; accessed on October 17, 2013.

3.8 Cook Islands

The Cook Islands Government signed the Protocol in May 2001 and the NBF was completed in August 2008.

3.8.1 National Biosafety Framework of Cook Islands (2008) (draft)

The Framework covers the areas of, and provides proposals on policy, a regulatory regime including monitoring and enforcement, and system to handle applications, systems for risk assessment, and mechanisms for public awareness and participation. The key elements of the NBF are: national biosafety policy; regulatory regime; system for handling applications; monitoring and enforcement; and public awareness and participation.

The framework also proposes to have a Biosecurity Act to manage the transboundary movement of LMO; an Independent Biosecurity Agency to be set up; biosafety legislation under the Biosecurity Act along with competent authorities.

Other Related Regulations

3.8.2 The Fruit and Vegetables Export Regulations (1982)

The regulation comes under the Plant Act 1973 and covers the export standard of fruits and vegetables.

3.8.3 Plant Quarantine Regulation (1993)

This also comes under the Plant Act 1973 and is meant to prevent importation of plant pests and diseases

3.8.4 Domestic Plant Quarantine Regulations (1993)

The regulation is meant to prevent spread between islands of the Cook Islands of disease and invasive species

Source:

1. National Biosafety Framework of Cook Islands (2008) Available at: http://www.unep.org/biosafety/files/Cook_Islands_Draft_NBF.pdf; accessed on July, 7, 2014.

3.9 Fiji (Republic of)

Fiji became a party to the Protocol in May 2001. Fiji drafted its NBF in 2007 and established its BCH in 2012.

3.9.1 National Biosafety Framework (2007)

The NBF of Fiji was developed with UNEP-GEF support. The objective for Fiji was to ensure adequate level of protection in the field of the safe transfer, handlings of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements.

3.9.2 Biosecurity Promulgation (No. 28) (2008)

Biosafety is integrated into the biosecurity promulgation which has been developed with particular emphasis on border control. Under the law biosecurity has been defined to covers food safety, zoonoses, the introduction of animal and plant diseases and pests, the introduction and release of living modified organisms (LMOs) and their products (e.g. GMOs), and the introduction and management of invasive alien species. The law aims to prevent the entry of animal and plant pests and diseases into the Fiji islands; to control their establishment and spread in the Fiji islands; to regulate the movement of animal and plant pests and diseases and of animals and plants and their products; to facilitate international cooperation in respect of animal and plant diseases. This Promulgation is in addition to the requirements relating to the specified imports and exports and do not displace any other statutory requirements relating to imports and exports, trade in endangered species, biosafety, biodiversity or environmental laws.

Source:

1. Fiji National Progress Report Submitted to the Third Series of Sub-regional Workshops (2003/2004): National Biosafety Framework. Available at: http://www.unep.ch/biosafety/old_site/development/countryreports/FJprogressrep.pdf; accessed on July 3, 2014.
2. Interim Government of the Republic of the Fiji Islands Biosecurity Promulgation (2008) Available at: http://www.biosecurityfiji.com/docs/Biosecurity-Promulgation.pdf; accessed on July 3, 2014.

3.10 Hong Kong (Special Administrative Region of People's Republic of China)

Hong Kong initiated biosafety implementation with the issue of voluntary labelling guidelines in 2011 which stipulates import documentation requirements for products containing GMOs. Also, prior approvals are required for LMOs which are intended to be released into the environment.

A Genetically Modified Organisms Register has been established which lists the application and approval status of LMOs intended to be released into the environment. In 2013, the government launched public consultation towards pre-market safety assessment for GM foods (USDA, 2013).

Hong Kong has not released any GM crop for commercial cultivation, nor does it conduct field trials. Research on GM rice is being carried out at Chinese University of Hong Kong while field trials are conducted in China.

3.10.1 Hong Kong Food Labelling Guidelines (2006)

Adopted in order to answer the public's call for consumers' right to make informed choices, the guidelines are advisory in nature and do not have any legal effect. Adoption is entirely voluntary and is not binding. The guidelines apply to pre-packaged food.

The Guidelines are based on the following four principles:

- The labelling of GM food will comply with the existing food legislation
- The threshold level applied in the guideline for labelling purpose is 5%, in respect of individual food ingredient
- 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
- Negative labelling is not recommended

Under the 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.

3.10.2 Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation (2011)

The Ordinance and the associated regulation requires for shipments containing LMOs to conform to the requirements stipulated by the Cartagena Protocol. Documentation is required for the following categories of LMOs:

- LMOs intended for direct consumption as food, feed or for processing (LMOs-FFP)
- LMOs intended for contained use
- LMOs intended for release into the environment

Source:

1. USDA (2013) Foreign Agricultural Service, GAIN Report HK1327 Hong Kong Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Hong%20Kong_Hong%20Kong_6-11-2013.pdf; accessed on June 17, 2014.

3.11 India (Republic of)

Bt cotton is the only GM crop approved for commercial cultivation in India. The commercial cultivation of Bt cotton events is approved for seed, fibre, and feed production/consumption. Bt eggplant was approved in 2009 but in 2010, the Ministry of Environment and Forest (MoEF) announced a moratorium on the approval of Bt eggplant (USDA, 2013). Development of GM crops is being done for in public sector mainly for pest resistance, herbicide tolerance, nutritional enhancement, drought tolerance and yield enhancement (http://igmoris.nic.in/status_gmo_products.asp). The crops being developed by public sector institutions include banana, cabbage, cassava, cauliflower, chickpea,

cotton, eggplant, rapeseed/mustard, papaya, pigeon pea, potato, rice, tomato, watermelon and wheat. The private seed companies are focusing on cabbage, cauliflower, corn, rapeseed/mustard, okra, pigeon pea, rice and tomato, and next generation technologies (stacked events) for cotton. However, due to issues regarding permission from the state governments, field trials in 2012 were conducted only for cotton, corn, and rice against nine crops in 2011.

On January 17, 2003, India ratified the Protocol and has since established rules for implementing the provisions of the articles. A BCH has been set up within the MoEF to facilitate the exchange of information on GMOs.

The regulatory framework for GM crops, animals and products in India is governed by the Environmental Protection Act (EPA) of 1986 and the Rules for the Manufacture, Use/ Import/ Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989 which lays the foundation for India's biotechnology regulatory system. Six competent authorities have been identified under the Rules -

- Genetic Engineering Appraisal Committee (GEAC) is the nodal agency responsible for implementing the Environment Protection (EP) Rules of 1989 and is the authority for final approval of GMOs. The other authorities although housed in different ministries support GEAC in specific purposes
- Department of Biotechnology (DBT) under the Ministry of Science and Technology-
  - Recombinant DNA Advisory Committee (RDAC) provides guidelines and technical support to GEAC
  - Review Committee on Genetic Manipulation (RCGM) evaluates and approves biosafety assessment of biotech research and development in the country
- Ministry of Agriculture (MoA) evaluates and approves the commercial release of transgenic crop varieties after conducting field trials
- Ministry of Health and Family Welfare evaluates and approves the safety assessment of biotech crops and products for human consumption
- State Governments give 'No Objection Certificate' for field testing, monitor the safety measures at biotech research facilities and assess damage, if any, due to release of GM products
- DBT, MoA and various state governments support R&D in agricultural biotechnology through various research institutes and universities

In 2007, the Government of India (GOI) introduced a National Biotechnology Development Strategy to set up an independent and autonomous regulatory authority that would provide a single window mechanism for biosafety clearance of GM products and processes. In 2013, "Biotechnology Regulatory Authority of India Bill 2012" (BRAI) was submitted to the Parliament of India.

3.11.1 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.

3.11.2 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:

- Sale, storage and handling
- Exportation and importation of genetically engineered cells or organisms
- Production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of genetically engineered products that make use of genetically engineered microorganisms in any way

3.11.3 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.

3.11.4 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.

3.11.5 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.

3.11.6 Foreign Trade (Development Regulation) Act, 1992 (2006 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 amendment in the foreign trade policy, making labelling of imported GM products mandatory.

3.11.7 Guidelines and Standard Operating Procedures for the Conduct of Confined Field Trials (2008)

The Guidelines summarize the information requirements and procedures used by the two regulatory committees, the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Approval Committee (GMAC), that are responsible for evaluating and approving applications for confined field trials. The information provided in this document does not preclude additional regulatory requirements on case to case basis either from RCGM or GMAC or any other Ministries/ regulatory bodies.

These Guidelines supplement the biosafety measures for field trials given in section 7 of the "Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998" published by DBT.

3.11.8 Guidelines for Safety Assessment of Foods derived from Genetically Engineered Plants (2008)

These Guidelines are applicable to all whole foods, food products, and foods used as ingredients that are derived from GM plant Source. These guidelines are intended to provide guidance to both applicants and reviewers for regulatory purposes.

They are not intended to explicitly define all the data that might be required in the course of a safety assessment as further data requirements may be identified during the safety assessment process.

3.11.9 Protocols for Food and Feed Safety Assessment of GM crops (2008)

A series of protocols developed by the Department of Biotechnology (DBT) as guidance to applicants seeking approval for the environmental release of genetically engineered (GM) plants in India under "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous microorganisms/ Genetically Engineered Organisms or Cells 1989" (Rules, 1989) notified under the Environment

(Protection) Act, 1986. These address key elements of the safety assessment of foods and/or livestock feeds that may be derived from GM crops and are based on international best practices, including guidance and peer reviewed publications available from the Codex Alimentarius Commission, the Food and Agriculture Organization, the World Health Organization, the Organization for Economic Cooperation and Development, and the International Life Sciences Institute.

Till date, DBT has prepared five protocols.

- Acute Oral Safety Limit Study in Rats or Mice
- Sub-chronic Feeding Study in Rodents
- Protein Thermal Stability
- Pepsin Digestibility Assay
- Livestock Feeding Study

3.11.10 Biotechnology Regulatory Authority of India Bill 2012 (draft)

The Biotechnology Regulatory Authority of India Bill 2012" (BRAI), which has been submitted to the Parliament of India for approval, would provide a single window mechanism for biosafety clearance. Pending parliamentary approval of the BRAI, India's regulatory mechanisms continues to be governed by the EP Act 1986 and the Rules of 1989.

Other Related Regulations

3.11.11 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.

3.11.12 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.

The Act consolidates the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

3.11.13 The Seed Bill (2010) (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.

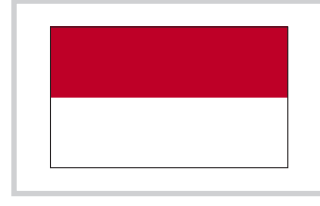
3.11.14 Agricultural Biosecurity Bill (2013) draft

The Bill provides for establishment of an Authority for prevention, control, eradication and management of pests and diseases of plants and animals and unwanted organisms for ensuring agricultural biosecurity and to meet international obligations of India for facilitating imports and exports of plants, plant products, animals, animal products, aquatic organisms and regulation of agriculturally important microorganisms and for matters connected therewith or incidental thereto.

Source:

1. http://agricoop.nic.in/seeds/seeds_bill.htm; accessed on October 16, 2013.
2. http://dbtindia.nic.in/uniquepage.asp?id_pk=65; accessed on July 3, 2014.
3. http://envfor.nic.in/divisions/csurv/biosafety/Files/Biologicals.PDF; accessed on September 27, 2013.
4. http://envfor.nic.in/legis/env/env1.html; accessed on July 7, 2014.
5. http://envfor.nic.in/legis/hsm/hsm3.html; accessed on September 27, 2012.
6. http://exim.indiamart.com/act-regulations/ftrd.html; accessed on October 27, 2013.
7. http://fda.up.nic.in/2011.htm; accessed on July 7, 2014.
8. http://igmoris.nic.in/status_gmo_products.asp; accessed on June 12, 2014.
9. http://plantquarantineindia.org/pdffiles/Consolidated_Version_PQ_Order_2003-upto_4th_amendment_2008.pdf; accessed on September 27, 2013.
10. http://www.envfor.nic.in/divisions/csurv/geac/annex-6.pdf; accessed on September 27, 2013.
11. http://www.envfor.nic.in/divisions/csurv/geac/groundrules.htm; accessed on October 27, 2013.
12. Manoranjan Hota, Ministry of Environment and Forests, Govt. of India, New Delhi, India, 110 003, email: hota@nic.in, (Personal Communication in 2007).
13. USDA (2013) Foreign Agricultural Service, GAIN Report IN3083 India Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_New%20Delhi_India_7-15-2013.pdf; accessed on June 17, 2014.

3.12 Indonesia (Republic of)



Indonesia has approved GM soybean and maize for food. In addition, three GM sugarcane varieties for drought tolerance have been approved for environmental release. However, the Ministry of Agriculture's approval for commercial cultivation is yet to be granted.

Indonesia signed the Protocol in 2000 and ratified it in May 2005. The NBF was developed in 2004 and in 2005 the government released Regulation No. 21 concerning biosafety of transgenic products. In 2008, the National Agency of Drug and Food Control (BPOM) published the Guidelines for Food Safety Assessment on Transgenic Products. An updated BPOM regulation was issued in March 2012, which further simplified the procedures for food safety approval. Labelling is also required for packaged and/

or retail food products containing transgenic ingredients, which includes a five per cent threshold level for transgenic ingredients (USDA, 2012).

3.12.1 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.

3.12.2 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 labelling.

3.12.3 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.

3.12.4 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:

- Carrying out an assessment of the current technological capacity to manage Biosafety issues, and the implications of this on the implementation of a NBF
- Strengthening national capacity to develop national regulatory biosafety frameworks

- Strengthening national capacity for competent decision making on notifications and requests related to LMOs, including the establishment of appropriate administrative systems
- Support regional and sub-regional collaboration, including harmonization of the implementation of national regulations
- 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
- Provide all stakeholders with an opportunity to be involved in the design and implementation of a NBF

3.12.5 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 a foreign country, procedures for risk assessment, release, and distribution and use and mechanism to control them.

3.12.6 Decree of Indonesian Ministry of Agriculture No. 61/2011 concerning the Procedures for Testing, Evaluating, Releasing, and withdrawing of Transgenic Crop Varieties (2011)

This Decree regulates the procedures on testing, evaluating, releasing, and withdrawing of crop varieties, as well as provides the crop varieties classifications, to include non-transgenic crops and transgenic crops.

The regulation expedites the licensing process, the environmental safety approval processes, and the field trials for transgenic products. Under this regulation, the limited field trial for the transgenic environmental safety assessment can be conducted in parallel with the adaptation trial for the plant variety release assessment. Thus, it can potentially save two crop planting cycles. In addition, if the transgenic product comes from a conventional hybrid that has already obtained the plant variety release approval, that product will not require multi-location field trials. It only needs a comparison trial data with the conventional one, and this comparison trial data is needed from only one location field trial from one planting period.

3.12.7 Decree of the Head of Drug and Food Control No. HK.03.1.23.03. 12.1563/2012 on the Guideline for Food Safety Assessment of Genetically Modified Products (2012)

The Decree simplifies the procedures of application for the safety assessment of transgenic products. The new regulation requires that applicants send the food safety assessment application only to the Head of National Agency for Drug and Food Control (BPOM) regardless the transgenic material's origins, to include material from transgenic animal, fish, plant, or microorganisms.

In addition, the new regulation requires local producers, as well as importers of transgenic products must submit their applications exclusively to the Head of BPOM.

The regulation also states that the final decision on food safety for any transgenic products, regardless of whether the product is fresh or processed, will be regulated by BPOM.

3.12.8 Decree of the Head of Drug and Food Control No. HK.03.1.23.03.12.1564/2012, on Food Labelling requirements for Transgenic Products (2012)

According to the regulation, the packaged food that contains at least 5 percent of transgenic product must be labelled and stated "Food Containing Genetically Modified Material" on the label.

3.12.9 Decree of Indonesian Ministry of Environment No. 25/2012 concerning Guideline of Document Compilation for Environmental Risk Analysis of Genetically Modified Products (2012)

This regulation is intended to provide guidance for every person who prepared the document a risk analysis environment of genetically engineered products (GMP) as one of the requirements to obtain a permit safe environment. The scopes of these guidelines include:

- Instructions for filing documents for environmental risk analysis of GM plants
- The information required includes GM plants, GM plant genetic trait, the potential impact on the environment, the management and monitoring of risk and environmental risk communication GM plants
- Forms to be completed by the applicant

Source:

1. 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 in 2007).
2. National Biosafety Framework of the Republic of Indonesia (2004) Available at: http://www.unep.org/biosafety/files/IDNBFrep.pdf; accessed on June 1, 2014.
3. Tri Joko Santoso, Plant Molecular Biology Division, Indonesian Center for Agricultural Biotechnology and Genetic Resource, Research and Development (ICABIOGRAD), Ministry of Agriculture, Jalan Tentara Pelajar 3A, Bogor, West Java, Indonesia 16111. Email: trijsant@yahoo.com (Personal Communication in 2014).
4. USDA (2012) Foreign Agricultural Service, GAIN Report ID1231 Hong Kong Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_10-15-2012.pdf; accessed on October 17, 2013.

3.13 Iran (Islamic Republic of)

Iran is engaged in research and development in GM crops. Insect resistant rice was approved some years back although it is not yet under cultivation. In August 2000, Iran established the National Biosafety Committee (NBC) as part of the Ministry of Science, Research and Technology. A ten-year National Biotechnology Strategy was developed and ratified by the government in May 2004. The Biotechnology Development Council (BDC) was established in 2005 with the objective to lead the biotechnology development, promote the private and the public sector, and raise public awareness about biotechnology.

Following the development of the NBF in 2006, a draft national biosafety law was developed which came into force on August 27, 2009. The law specifies all of the details and processes related to field trials, production, release, import and export, transport, purchase and sale, distribution, consumption and use of LMOs and their products. The Executive regulations were approved by NBC on April 7, 2012 and came into force on July 10, 2013.

3.13.1 National Biosafety Framework (2007)

The NBF includes the following features:

- The country's macro policy regarding modern biotechnology, agricultural products, health, environmental protection and sustainable development
- The laws, regulations and administrative systems
- 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
- The development of a system for the assessment and supervision of possible harmful effects of LMOs on the environment and human health
- The application of methods for informing, educating and involving interested individuals, institutes and the public regarding the development and the administration methods

3.13.2 Iran National Biosafety Act (2009)

The Act details on the provisions for all the issues related to the production, release, transport, export, import, sale, purchase, application and use of living modified organisms are permitted with the observance of the provisions of this act.

Based on Article 4 of the Biosafety law, handling issues related to modern biotechnology, with regards to regulating LMOs as referred to in the Protocol, fall under the responsibility of the competent national authorities bodies. These include:

- The Minister of Agriculture: issues related to production of LMOs in the agricultural sector and natural resource
- The Minister of Health and Medical Education: issues related to health and safety of food, cosmetics and medical materials
- The Environmental Protection Organization: issues related to wild life and evaluation of the environmental risk assessment based on scientific documents provided by an applicant.

Laboratory and green house research of living modified organisms and the issues related to pharmaceuticals and their derivatives for human consumption are not in the scope of this Act.

Other Related Regulations

3.13.3 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.

3.13.4 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.

3.13.5 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. National Biosafety Framework (2004) Department of Environment, Islamic Republic of Iran. Available at: http://www.unep.org/biosafety/files/IRNBFrep.pdf; accessed on March 2, 2013.
2. Esmailzadeh, N.S. (2013) A major milestone 2013: A new law will help Iran promote safety in the use of biotechnology in Biosafety Protocol News. July 2013 Issue 11: 21-23.
3. Esmailzadeh, N.S. BCH Focal Point, Islamic Republic of Iran, email: nasrin@nrcgeb.ac.ir. (Personal Communication in 2007 and 2014).

3.14 Japan

Research in biotechnology is being pursued in several institutions in Japan. GM crops in sugar beet, canola, soybean, maize among others have been approved for environmental release but there is no known cultivation of these crops in the country. On the other hand, Japan is one of the largest importers of GM crops approved for food and feed.

Japan ratified the Protocol in 2003 and in 2004, adopted the 'Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms' (http://www.bch.biodic.go.jp/download/en_law/en_regulation.doc), also called the "Cartagena Law".

In Japan, the commercialization of GM plant products requires food, feed and environmental approvals. Four ministries are involved in the regulatory framework: Ministry of Agriculture, Forestry and Fisheries (MAFF), Ministry of Health, Labor and Welfare (MHLW), The Ministry of Environment (MOE), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The Food Safety Commission (FSC), an independent risk assessment body, performs food and feed safety risk assessment for MHLW and MAFF. Labelling of GM foods is required in Japan, all GM and non-regulated products need to be labelled.

3.14.1 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:
  - Type 1 LMO – (the use of LMOs without preventive measures against their dispersal into environment)
  - 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:
  - Containment measures to be taken are stipulated by the ordinance of the competent ministries
  - Containment measures to be taken are not stipulated and measures to be taken as previously confirmed by the competent ministry

Other Related Regulations

3.14.2 Food Sanitation Law in Japan (Law No 233) (1947, last amended in 2011)

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.

3.14.3 Labelling 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 labelling and the format in which labelling 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 labelling (soybean including green soybeans and soybean sprouts, corn, potato, rapeseed and cotton seed). The list of products from these crops mandated for labelling is also given. The Standard also details the products not requiring any labelling.

Source:

1. http://www.bch.biodic.go.jp/english/law.html; accessed on October 3, 2012.
2. 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 October 16, 2013.
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 February 11, 2013.
4. Ryoko Sakuramata, Ministry of the Environment Japan, Tokyo. e-mail: bch@env.go.jp, (Personal Communication in 2007).
5. The Food Sanitation Law in Japan. Available at: http://www.jetro.go.jp/en/market/regulations/pdf/food-e.pdf; accessed on October 16, 2012.
6. USDA (2013) Foreign Agricultural Service, GAIN Report JA3027 Japan Agricultural Biotechnology Annual Japan's approval remains a key for commercial release of GM crops. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_8-27-2013.pdf; accessed on June 18, 2013.

3.15 Jordan (Hashemite Kingdom of)

No GM crops are cultivated in Jordan and the present plant variety protection laws prohibit registration of GM varieties. The country signed the Protocol on October 11, 2000 and ratified it on February 9, 2004. In the same year the NBF was drafted. The draft regulations entered into force in 2009.

In 2014, a new "draft" biosafety law regulating agricultural GM products was introduced (http://www.moenv.gov.jo).

The regulation covers trade in GMOs, mainly agricultural biotech products. Recently, the Ministry of Agriculture (MOA) established a new entity called the Phytosanitary and Biodiversity Department to handle biotechnology trade issues. Jordan's Food and Drug Administration (JFDA) will also likely play a role in implementing any GMO regulations (USDA, 2010).

While Jordan does not have a mandatory GM labelling law, the 2014 draft biosafety law includes the requirement of labelling.

3.15.1 National Biosafety Framework of Jordan (2004)

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

- Improve a regulatory system of biosafety
- 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

- Strengthen the scientific researches on biosafety
- Establish the system of biosafety monitoring which includes the operational mechanism of networking of biosafety monitoring, the risk monitoring tools and processing techniques
- Undertake publicity and education on the development of biosafety
- Undertake international cooperation

3.15.2 By-Law for Biosafety of Genetically Modified Organisms Issued in Accordance with Article No (23) of the Law of Environment No (1) for the Year (2009)

The regulation based on the Cartagena Protocol, covers trade in biotech organisms, including biotech products. The regulation covers trade in biotech organisms, including biotech products. Recently, Ministry of Agriculture (MoA) has established a new entity called Phytosanitary and Biodiversity Department to handle the biotechnology trade issues.

3.15.3 Biosafety Law (2014) (Draft)

The proposed draft biosafety law would replace the existing By-law for biosafety of GMOs. It covers trade in GMOs, mainly agricultural biotech products. Jordan's Food and Drug Administration (JFDA) and the Phytosanitary and Biodiversity Department are likely play a role in implementing any GMO regulations including biotech trade issues.

Other Related Regulations

3.15.4 Protecting Plant Varieties (PVP) law (2000) and PVP rules (2002)

The PVP Law and Rules provide for the establishment of an office to register new plant varieties at the Ministry of Agriculture (MoA) for registration of new varieties. A key component of the PVP is that seed producers are not allowed to export their products to countries that do not observe IPR for agricultural products. Not all seed importers are interested in PVP registering, since most are hybrid seeds, the first generation offspring of two different plants, have their own IPR self-protection. Jordan is a full member of World Intellectual Property Organization (WIPO) and of the Union for Protection of New Varieties of Plants (UPOV) since 2004.

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 March 29, 2012.
2. USDA (2010) Foreign Agricultural Service, GAIN Report J1005 JO1005Jordan Biotechnology - GM Plants and Animal: Enter a Descriptive Report Name. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GM%20Plants%20and%20Animals_Amman_Jordan_6-24-2010.pdf; accessed on February 26, 2013.
3. http://www.moenv.gov.jo; accessed on July 15, 2014.

3.16 Kazakhstan (Republic of)

Kazakhstan does not grow any GM crops. The county ratified the Protocol in 2008. The NBF was developed in 2004 and a draft regulation was also proposed in 2004. Kazakhstan's draft "Law on State Regulation of Genetic Engineering Activities" which is in the Parliament since 2011 is being reviewed by a Parliamentary Committee, and is expected to come up again for discussion in 2014. According to Customs Union Regulations, up to 0.9 percent of unapproved GM events are allowed (USDA, 2013).

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

The NBF 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.

3.16.2 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:

- Reception, duplication, test and use of GMOs in the closed systems for various purposes, with application of methods of genetic engineering
- Deliberate release of GMOs, including any living structures capable of reproduction like seeds, tubers, cuttings, pollen, spores, etc. into the environment
- In-deliberate release of GMOs into the environment
- Any kind of research on GMOs, including laboratory, clinical, field trial, industrial tests
- Illegal transboundary movement of GMOs
- Storage, disposal and destruction of GMOs

3.16.3 Law on State Regulation of Genetic Engineering Activities (2011) (draft)

This draft law on state regulation of genetic engineering activity specifies separate roles for different government bodies on the regulation of agricultural biotechnology.

The provisions of this Law apply to the following types of genetic engineering: 1) to establish and (or) testing of LMOs/ GMOs; 2) the use of LMOs/ GMOs in closed systems; 3) release into the environment, the use of LMOs/ GMOs in open systems; 4) The transboundary movement, transit, import and export of LMOs/ GMOs. Article 17 of the law specifies the requirements for LMOs/ GMOs and the processes of their life cycle (including design, manufacturing, maintenance, storage, transportation, disposal and recycling) shall be established by technical regulations. Transit of LMOs through the territory of Kazakhstan is also covered.

3.16.4 Customs Union Technical Regulation on Labelling (2013)

Imports of GM crops or products are allowed into Kazakhstan, but must abide by Customs Union regulations which cover the entire Customs Union of Belarus, Russia, and Kazakhstan.

Other Related Regulations

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

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

3.16.6 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.

3.16.7 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.

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 March 1, 2012.
2. Sativaldi Jatayev, Assistant to BCH NFP-Kazakhstan, Chief of the International Cooperation Division, National Center for Biotechnology, Republic of Kazakhstan, 13/1, Valikhanova Str. 010000, Astana, Kazakhstan. Email: jatayev@biocenter.kz (Personal Communication in 2014).
3. USDA (2013) Foreign Agricultural Service, GAIN Report Kazakhstan - Republic of Agricultural Biotechnology Annual Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Astana_Kazakhstan%20-%20Republic%20of_7-12-2013.pdf; accessed on June 24, 2014.

3.17 Kiribati (Republic of)

Kiribati ratified the Protocol on July 19, 2004 and developed its NBF in 2007. There is limited research and development activity in biotechnology.

3.17.1 Environment Act (1999) (as amended in 2007; section 5.2)

The Act provided for: the general environmental principles of sustainable development (6.1.b), environmental management and conservation of biological diversity (6.2.b), the precautionary principle (6.2.a), environmental inspectors (10), development

control (13-17), review assessment (26-27) and monitoring (28). The Act also provided for a Schedule of prescribed developments (13.1) to comply with a comprehensive system of control of development activities, mainly using environmental impact assessment. The GMOs were included as one of the prescribed activities in the Schedule.

3.17.2 Biosafety Regulations (Appendix A; section 5.3) (2005) (draft)

The draft regulation for Kiribati to be operational under the Environment Act 1999 (as amended), would be the main regulatory regime for biosafety.

The Biosafety Regulations specifically provides for the regulation of the transboundary movements of LMOs and the applications of modern biotechnology, in accordance with the provisions of the Protocol.

The proposed Regulations set up the administrative arm for biosafety management particularly in the establishment of a National Focal Point (NFP) and a National Competent Authority (NCA). The Regulations provides for procedures including the Advanced Informed Agreement (AIA) procedure prescribed in the Protocol, for an application for the first transboundary movement of an LMO.

The Regulations also prescribes measures for LMOs to be used in containment, in transit, and those destined for unintentional and illegal releases.

3.17.3 National Biosafety Framework (2007)

This NBF contains five key elements: a biosafety policy; a regulatory regime; system to handle applications for permits/ licenses; systems for Follow up actions; and mechanisms for public awareness and participation. The proposed biosafety regulations and consideration of capacity building and strengthening requirements for biosafety management provide important steps towards protection of Kiribati's biodiversity and also human health from risks of LMOs and applications of modern biotechnology, and for the Government of Kiribati in meeting its obligations, as a party to the Protocol.

Source:

1. Biosafety (Living Modified Organisms) Regulations, Republic of Kiribati (2005) Available at http://en.biosafetyscanner.org/pdf/doc/89_allegato.pdf; accessed on May 20, 2014.
2. National Biosafety Framework Kiribati (2007) Environment and Conservation Division, Ministry of Environment, Lands and Agriculture Development. 99p. Available at: http://bch.cbd.int/database/record.shtml?documentid=101776; accessed on February 26, 2013.

3.18 Korea (Democratic People's Republic of)

DPR Korea signed the Protocol on April 20, 2001 and ratified it on July 29, 2003. The country initiated the development of NBF from February 2002 and completed it in 2004 when draft regulations were also formulated. However, no further information is available on the status of the regulations.

3.18.1 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.

3.18.2 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, DPR of Korea. P 55. Available at: http://www.unep.org/biosafety/files/KPNBFrep.pdf; accessed on February 25, 2013.

3.19 Korea (Republic of)

At present no GM crops are commercially cultivated in Korea. However, research and development on genetic modification remains focused on the country's main crops, such as rice, Chinese cabbage, hot pepper, potato, and soybean.

Korea ratified the Protocol on October 2, 2007. On January 1, 2008, Korea implemented the LMO Act, which is the implementing legislation for the Protocol and the overarching law governing the country's biotechnology related rules and regulations. The Government of Korea started drafting the biosafety regulations in 2001 and the LMO Act was ready in September 2005, while the regulations were finalized in March 2006 (USDA, 2007). However, the regulations were implemented only after January 1, 2008. The LMO Act was revised in December 2012 with modifications including a revised definition of stacked events. The revised Act is effective from December 12, 2013.

All GM plants used as food or food ingredients, feed, fibre, and fuel are required to undergo a food safety and environmental risk assessments. Several different agencies are involved in the overall assessment process. Korea has three categories of approval: full approval and two types of conditional approval. Full approval is given to GM crops that are commercially produced and imported for human consumption. Conditional approval applies to those crops that have been discontinued or are not grown commercially for human consumption. The assessments are conducted by the Korea Food and Drug Administration (KFDA) for food and by the Rural Development Administration (RDA) for feed.

GM food labelling in Korea is regulated mainly on the basis of the Food Sanitation Act and Agricultural Products Quality Management Act. Currently, 3 percent for GM event approved in Korea is observed as GMO threshold for unintended contamination, but none of the unapproved GMOs can be marketed (USDA, 2013).

3.19.1 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.

3.19.2 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.

3.19.3 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.

3.19.4 Mandatory Labelling of GM Agricultural Products and GM Foods (2000)

The Regulation provides details of identification items, identification standards and the methods of labelling of LMOs.

3.19.5 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.

3.19.6 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.

3.19.7 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.

3.19.8 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.

3.19.9 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.

3.19.10 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.

3.19.11 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.

3.19.12 The Act on Transboundary Movements of Living Modified Organisms (2003) revised in 2013

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.

3.19.13 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.

3.19.14 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.

3.19.15 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms (2008)

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.

Source:

1. National Biosafety Framework 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 April 3, 2012.
2. USDA (2007) Foreign Agricultural Service, GAIN Report No. KS7050 Republic of Korea Biotechnology, Agricultural Biotechnology Report. Available at: http://www.fas.usda.gov/gainfiles /200707/146291775.pdf; accessed on October 3, 2012.
3. USDA (2013) Foreign Agricultural Service, GAIN Report No KS1336 Republic of Korea-Agricultural Biotechnology Annual. Available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Seoul_Korea%20-%20Republic%20of_7-17-2013.pdf; accessed on May 3, 2014.

3.20 Kyrgyz Republic

Kyrgyzstan has ratified the Protocol in 2005. The competent state authority for the fulfillment of Kyrgyz Republic obligations under the CBD and the Protocol is the State Agency on Environment and Forestry. The country's biosafety framework was developed under the UNEP- GEF Project in 2005 and a draft law of the Kyrgyz Republic on Biosafety was elaborated. These were subsequently approved by the government in 2006 and submitted to the Parliament in 2008 for consideration. This draft law was returned to the government for reconsideration and from 2009 to 2010 it was reconsidered by the State Agency on Environmental Protection and Forestry together with other experts. Currently, the consideration of the draft law "On Biological Safety" has been postponed (http://centralasiaonline.com/en_GB/articles/caii/features/main/2014/04/01/feature-01).

3.20.1 National Biosafety Framework (2005)

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.

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

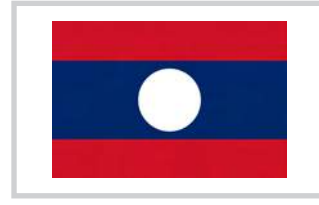
The draft law regulates types of activities related to safe creation of LMOs/GMOs by genetic engineering methods, their testing, usage in closed systems and introduction into the environment,

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. http://centralasiaonline.com/en_GB/articles/caii/features/main/2014/04/01/feature-01; accessed on July 16, 2014.
2. National Biosafety Framework (2005) Ministry of Ecology and Emergencies of the Kyrgyz Republic, p91. Available at: http://www.unep.org/biosafety/files/KGNBFrep.pdf; accessed on March 3, 2013.

3.21 Lao People's Democratic Republic



Modern biotechnology is still in infancy in Laos. Laos ratified the Protocol on November 1, 2004 and the National Policy on Biotechnology and Biosafety was established to promote biotechnology R&D in accordance with the CBD and the CPB on biosafety regulation, risk assessment and management, notification, movement and management of GM products, public awareness, education and participation. The NBF was developed in 2004. The Science, Technology and Environment Agency (STEA) is the national competent authority (http://www.fao.org/fileadmin/templates/abdc/documents/asean.pdf).

3.21.1 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 programme to implement the Protocol and the priorities of the government to implement the Biosafety Framework.

3.21.2 Biotechnology Safety Law (2014)

This law defines the principles, regulations and measures on management and monitoring of biotechnology safety to ensure safety in research, development, handling, movement, and the use of GMOs resulting from the use of biotechnology, which may result in having negative impacts on conservation and sustainable use of biodiversity, with a focus on the limitation and reduction of risks to the life and health of human beings, animals, plants and the environment that can be linked at the regional and international levels, and which contribute to national socio-economic development.

Other Related Regulations

3.21.3 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 resource and biodiversity, and to ensure the sustainable socio-economic development of the nation.

Source:

1. Biotechnology Safety Law (2014) Available at: http://bch.cbd.int/database/record.shtml?documentid =105658; accessed on July 16, 2014.
2. http://www.fao.org/fileadmin/templates/abdc/documents/asean.pdf; accessed on July 16, 2014.
3. 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 March 28, 2012.

3.22 Lebanese Republic

Presently, there is no official policy or strategy for biotechnology in Lebanon. However, biotechnology has been included in the structure and agenda of agricultural research institutions. Lebanon is not yet a producer of GMOs, even if there is evidence that work with GMOs is being conducted at various academic and research institutions in the country(http://www.fao.org/docrep/012/al310e/al310e03.pdf).

Lebanon ratified the Protocol on February 6, 2013. Although the country has developed its NBF under the provisions specified in the Protocol since July 2005, the draft decree to implement the provisions of the Protocol in Lebanon developed under it is not endorsed yet. The Sanitary and Phytosanitary Measures Law (2006) has imposed a ban on the import of GM Plants owing to the quarantine and health risks (http://www.bbic-network.org/Uploads/Document/Genetically%20Modified%20Organisms%20(GMOs)%20and%20Biosafety%20Current%20Status%20in%20Lebanon.pdf). Presently, there are no laws or decrees against the consumption of food or feed containing GMOs.

3.22.1 Biosafety Lebanon – National Biosafety Framework (2005)

The NBF aims to:

- 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
- Establish an administrative system for the management of biosafety related issues
- 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
- Establish systems for the monitoring and enforcement of biosafety measures
- Capacity building for biosafety management by promoting and facilitating public awareness, education and participation and human resource development

Other Related Regulations

3.22.2 Law 256 (1994)

The Law is in compliance to the Framework Convention on Climate Change and is prepared by the Ministry of the Environment with the objective of promoting in situ conservation of crop wild relatives.

3.22.3 Law 260 (1995)

The Law is in compliance to the Convention on Biological Diversity and is prepared by the Ministry of the Environment with the objective of developing monitoring and early warning systems for loss of diversity.

3.22.4 Law 444 (2002)

The Law aims at protection of the environment and is prepared by Ministry of the Environment for conservation and sustainable use of biodiversity through the protection of its natural resource.

3.22.5 Sanitary and Phytosanitary Measures Law 778 (2006)

This Law intended to meet the requirements set by the WTO in an attempt to facilitate Lebanon's accession. Article 14 in this law bans the importation of GM plants that may introduce new diseases and toxins into the country.

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 March 2, 2013.
2. GMOs and Biosafety: Current status in Lebanon: Available at http://www.bbic-network.org/Uploads/Document/Genetically%20Modified%20Organisms%20(GMOs)%20and%20Biosafety%20Current%20Status%20in%20Lebanon.pdf; accessed on May 7, 2014.
3. Lebanon. Available at: http://www.fao.org/docrep/012/al310e/al310e03.pdf; accessed on May 12, 2014.

3.23 Malaysia

Malaysia does not grow any GM crops although the country has approved GM maize and soybean for food and feed. GM research is being undertaken in a number of crops including oil palm. Malaysia signed the Protocol in 2000 and the Biosafety Bill was passed in 2007, and the Biosafety Act was enforced in 2009.

The National Biosafety Board (NBB) and the Department of Biosafety (JBK) were established in 2010. Consequent to this, the "Guidelines for Contained Use Activity of LMO" was published and the biosafety regulations were enforced.

In April 2013, the Ministry of Health published the GM food and ingredient labelling guidelines (USDA, 2013).

3.23.1 Biosafety Act (2007)

The Biosafety Act 2007 (Act) was passed in the Malaysian Parliament on the July 11, 2007 and is in force effective December 1, 2009. The objective of the Act is to establish a National Biosafety Board (NBB) 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.

Under this Act, there are two different scopes of activities dealing with LMOs. Part III deals with release activities and importation of LMOs while Part IV mainly concerns itself with LMOs used for contained use and exportation. The application for approval for any release activities and importation under Part III must be submitted to the NBB and shall be accompanied with a risk assessment and a risk management report, an emergency response plan and other information specified by the NBB. In order to commence the activities outlined under Part IV, the applicants should merely inform the NBB of their intentions through a notification form. Notification forms must be submitted and accompanied by an emergency response plan, specific measure for contained use activity and such other information as may be specified by the NBB.

3.23.2 Biosafety (Approval and Notification) Regulations (2010)

The Biosafety (Approval and Notification) Regulations 2010 (the Regulations) was finalized and came into force on 1 November 2010. The Regulations set out the details on: the different criteria to apply for different activities; the procedure and content of the applications; the time lines, the incurred fees, the details required for the risk assessment and management reports as well as the emergency response plan, the decision-making criteria and the procedure for appeals.

3.23.3 Guidelines for Institutional Biosafety Committees (IBCs): Use of Living Modified Organisms and Related Materials (2010)

The IBC is a formal expert committee of an organisation, chaired by the head of the organisation or his designate (a suitable senior officer). In the Biosafety (Approval and Notification) Regulations 2010, any organisation (both public and private), which undertakes modern biotechnology research and development, shall establish an IBC which must be registered with the NBB. This Guideline outlines the setting up of IBCs, role of IBCs and the processes that must be followed when obtaining, using, storing, transferring, or destroying LMO/rDNA materials. It also provides explanations of the relevant regulatory requirements and procedures.

3.23.4 Biosafety Guidelines for Contained Use Activity of LMOs (2010)

This Guideline gives details on the Biosafety Levels (BSL) for containment as well as the safe practices for working with LMOs and products of these organisms. Adoption of this guideline is essential for all public and private organisations working on modern biotechnology so as to safely handle, store and transfer LMOs as well as products of such organisms without endangering individuals, the public, biodiversity and the environment. This Guideline should be used in addition to relevant legislations, guidelines and references that involve containment facilities. Organisations intending to carry out contained use activities involving LMOs and related materials are required to use this guideline to determine the BSL and facility type required. The principles of risk assessment for the activity conducted and also the classification of risk groups for microorganisms are given so that the BSL will be appropriate for the type of activity conducted.

3.23.5 Biosafety Guidelines: Risk Assessment of Genetically Modified Microorganisms (2012)

This Guideline is essential for all public and private organizations, working on modern biotechnology, specifically involving genetically modified microorganism (GMM) so as to conduct a proper risk assessment that will enable safely handling and ensure protection of human, plant and animal health, the environment and biological diversity. It is divided into two parts and provides elaborate instructions on how to conduct a risk assessment for (a) GMM not associated with plants and (b) GMM associated with plants.

3.23.6 Biosafety Guidelines: Environmental Risk Assessment of Genetically Modified Plants in Malaysia (2012)

This document provides guidelines for the environmental risk assessment (ERA) of GM plants in Malaysia. It covers ERA of applications for the cultivation of GM plants, as well as for the import of food and feed containing or consisting of GM plants, or produced from GM plants. The objective of ERA, on a case-by-case basis, is to identify and evaluate potential adverse effects of the GM plant, direct and indirect, immediate or delayed (including cumulative long-term effects) on the receiving environment(s) where the GM plant would be released.

3.23.7 Biosafety Guidelines: Confined Field Trial of Living Modified Plants in Malaysia (2012)

The objective of this Guideline is to provide researchers with the necessary practices when conducting confined field trial of living modified plants or crops to fulfill biosafety regulatory compliance. It also gives guidance on practices that will prevent pollen or seed dissemination into and within the environment, persistence of the LM plant or any of its parts and its progeny in the environment, and to prevent entry of the LM plant or plant products into the human food or animal feed chain.

3.23.8 Guidelines on Labelling of Foods and Food Ingredients obtained through Modern Biotechnology (2013) (draft)

The MOH will begin enforcing the guidelines on 8 July, 2014. Some key elements of the labelling guidelines include the following:

- If the GM content is not more than three per cent, labelling is not required, "provided that this presence is adventitious or technically unavoidable"
- For single ingredient foods, the words "genetically modified (name of the ingredient)" must appear in the main display panel
- For multi-ingredient foods, the words "produced from genetically modified (name of the ingredient)" should appear in list of ingredients and "contains genetically modified ingredient" must be stated on the main display panel
- Highly refined foods, defined as those where processing has removed all novel DNA and protein are exempt from the labelling requirement (e.g.: vegetable oils, corn syrup, acidic foods, and salty foods)
- Meat from animals fed with GM grains does not need to be labelled
- Only GM crops that have been approved by NBB can be used for foods and food ingredients

Source:

1. Biosafety (Approval and Regulations) (2010) Available at http://www.biosafety.nre.gov.my/; accessed on July 5, 2014.
2. Biosafety Guidelines for Contained Use Activity of LMOs (2010) Available at http://www.biosafety.nre.gov.my/; accessed on July 5, 2014.
3. Biosafety Guidelines: Confined Field Trial of Living Modified Plants in Malaysia (2012) Available at http://www.biosafety.nre.gov.my/; accessed on June 23, 2014.
4. Biosafety Guidelines: Environmental Risk Assessment of Genetically Modified Plants in Malaysia (2012) Available at http://www.biosafety.nre.gov.my/; accessed on July 5, 2014.
5. Biosafety Guidelines: Risk Assessment of Genetically Modified Microorganisms (2012) Available at http://www.biosafety.nre.gov.my/; accessed on July 5, 2014.
6. Guidelines for Institutional Biosafety Committees (IBC): Use of Living Modified Organisms and Related Materials (2010) Available at http://www.biosafety.nre.gov.my/; accessed on July 5, 2014.
7. Guidelines on Labelling of Foods and Food Ingredients obtained through Modern Biotechnology. Available at: http://fsq.moh.gov.my/v4/images/filepicker_users/5ec35272cb-78/Perundangan/Garispanduan/Pelabelan/GUIDELINES-ON-LABELLING-OF-FOODS-AND-FOOD-INGREDIENTS-PRODUCED-FROM-MODERN-BIOTECHNOLOGY_%2012042013-p.pdf; accessed on June 25, 2014.
8. Kangayatkarasu Nagulendran, CBD National Focal Point, Ministry of Natural Resources and Environment Level 12, Tower Block 4G3, Precinct 4, Putrajaya, Malaysia. Email: biodiversity@nre.gov.my (Personal Communication in 2007).
9. Johnny Andrew, Department of Biosafety, Ministry of Natural Resource and Environment, Malaysia. Email: johnny@nre.gov.my, biosafety@nre.gov.my (Personal Communication in 2014).
10. Malaysia Biosafety Act (2007) Available at http://www.biosafety.nre.gov.my/; accessed on July 5, 2014.
11. USDA (2013) Foreign Agricultural Service, GAIN Report Malaysia Agricultural Biotechnology Annual. Available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Kuala%20Lumpur_Malaysia_7-24-2013.pdf; accessed on July 5, 2014.

3.24 Maldives (Republic of)

The National Biodiversity Strategy and Action Plan (NBSAP) of Maldives has identified biotechnology as a major thrust area in priority setting and strategic planning in crop improvement. It has also identified the need for regulatory mechanisms in areas of biosafety. Maldives ratified the Protocol on September 11, 2003. Trade in GM products is not regulated at present and there is no systematic approach to biotechnology and biosafety policy and regulation (http://www.unep.org/chinese/biosafety/files/MVNBFrep.pdf).

3.24.1 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.

3.24.2 National Biosafety Regulation (2006) (draft)

The proposed Biosafety Regulations of Maldives apply to all stages of research and development, import and export, contained use, deliberate release, direct use as food, feed or for processing, and any other type of use of GMOs and GMO products for any purpose.

3.24.3 Guidelines for Implementing the National Biosafety Regulations (2006) (draft)

The main objectives of these Guidelines are to provide the basis for implementing an appropriate national regulatory framework for

- Biosafety by supplementing existing laws, regulations and procedures related to agricultural, environmental, food and pharmaceutical products and the principles governing methods and standards of practice for research and development, risk assessment, import and export, deliberate release, and marketing of GMOs and GMO products
- Promote the development and safe and responsible use of modern biotechnology, at the same time ensuring public health and environmental safety
- Promote public awareness of and participation in decision-making related to the use of GMOs and GMO products
- Promote co-operation and consultation with international, regional and other national agencies to ensure safe and responsible use of modern biotechnology, GMOs and GMO products

Source:

1. Muhusina Abdul Rahman, Department/ Biodiversity Conservation Unit, Ministry of Environment and Energy, Ameenee Magu, Maafannu, 20392 Male' Kaafu Atoll Maldives. Email muhsina.abdulrahman@gmail.com (Personal Communication in 2014).
2. National Biosafety Framework for the Republic of Maldives (2006) Ministry of Environment, Energy and Water. P 75. Available at: http://www.unep.org/biosafety/files/MVNBFrep.pdf; accessed on March 2, 2013.

3.25 Marshall Islands (Republic of the)

Marshall Islands ratified the Protocol on January 27, 2003 and developed its NBF in 2009.

3.25.1 National Biosafety Framework for the Marshall Islands (2009)

The Framework covers the areas of, and provides proposals on policy, a regulatory regime including monitoring and enforcement, and system to handle applications, systems for risk assessment, and mechanisms for public awareness and participation.

Source:

1. National Biosafety Framework for the Marshall Islands (2009). Available at: http://www.unep.org/biosafety/files/Draft%20NBF.pdf; accessed on July, 7, 2014.

3.26 Micronesia (Federated States of)

Till date, the Federated States of Micronesia has not signed, nor ratified the Protocol. The country has developed its draft NBF followed by the Biotechnology and Biosafety Act in 2007.

3.26.1 National Biosafety Framework (2007) (draft)

The Framework covers the five broad areas on policy, a regulatory regime including monitoring and enforcement, and system to handle applications, systems for risk assessment, and mechanisms for public awareness and participation through the draft legislation on biotechnology and biosafety.

3.26.2 Biotechnology and Biosafety Act (2007) (draft)

The act is meant to facilitate the beneficial uses of LMOs and application of modern biotechnology, after appropriate scientific assessment and analysis, to fulfil the Federated States of Micronesia's obligations under the Cartagena Protocol.

Source:

1. Draft National Biosafety Framework of the Federated States of Micronesia. Available at: http://www.unep.org/biosafety/files/MicronesiaDraftNBF040707.pdf; accessed on July 4, 2014.

3.27 Mongolia

Mongolia ratified the Protocol on November 7, 2002. The NBF was developed in 2005 and the Law on LMOs enforced in 2007.

The UNEP-GEF project on 'Capacity Building for Biosafety Implementation for Mongolia' is operational since 2011 to develop biosafety regime and strengthen capacity for implementation of biosafety requirements.

3.27.1 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 resource in biotechnology development and its safety issues.

3.27.2 Law on LMOs (2007)

Mongolian Law on LMOs has been adopted in June 28, 2007 by Mongolian Parliament. The objective of this Law on LMOs is to contribute to ensuring an adequate level of protection in the field of the safe transboundary movements, transfer, handling and use of LMOs resulting from modern biotechnology.

Source:

1. Biosafety Clearing House Mongolia. Available at: www.biosafety.mn; accessed on June 29, 2014.
2. National Biosafety Framework (2005) Available at: http://hqweb.unep.org/chinese/biosafety/files/MNNBFrep.pdf; accessed on June 29, 2014.
3. S. Bayarkhuu, General Secretary, National Biosafety Committee, Mongolia, bayarkhuu@mne.gov.mn (Personal Communication in 2014).

3.28 Myanmar (Union of)

One GM crop insect resistant Bt cotton variety "Ngwe chi 6"is under commercial cultivation in Myanmar.

Myanmar signed the Protocol on May 11, 2001 and ratified it on February 13, 2008. The NBF was initiated in 2001 and implemented in 2006. However, the Myanmar Biosafety Law is still at draft stage.

3.28.1 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.

3.28.2 Myanmar Biosafety Law (Draft) (2006)

The Law is applicable to development, contained use, field test, fermentation, intentional introduction into the environment, and import and export of GMO that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health. It also covers the activities such as procedures and mechanism for receiving applications for activities involving GMOs; process for transparent decision making; mechanism for protecting commercially sensitive information through measures to protect confidential information; measures to deal with non-compliance, including monitoring, enforcement, liability, and penalties and procedures to deal with emergencies.

Other Related Regulations

3.28.3 The Forest Law (1992)

The law allows the Minister of Forestry, with the approval of Cabinet, to constitute the Watershed or Catchments Protection Reserved Forests and the Environment and Bio-diversity Conservation Reserved Forests, among others, on land at the disposal of the Government, in order to conserve the environmental factors.

3.28.4 The Plant Pest Quarantine Law (1993)

This law is aimed to prevent quarantine pests entering the country.

3.28.5 The Protection of Wildlife Wild Plants and Conservation of Natural Areas Law (1994)

This law has the objective to protect the wildlife of the State; implement the policy of conserving the protected areas; carry out protection of wild species flora and fauna and representative ecosystems; protect endangered species and their habitats; and establish zoological and botanical gardens.

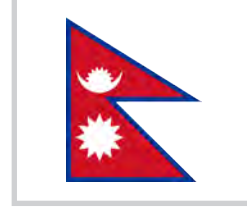
3.28.6 The Seed Law (2011) (enforced on August 2013)

The law is aimed to maintain quality and supply of seed. It specifies the minimum seed quality control to be achieved through field inspection, sampling, testing and certification of seeds to be supplied to farmers. The law also sets up a procedure for registration of new variety of seeds and promotes public-private partnerships in seed multiplication and hybrid seed production.

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 March 2, 2013.

3.29 Nepal (Federal Democratic Republic of)



Nepal is at an early stage in GM crop testing, quality control and development of legislation. GM research can be done with the permission from authorized agency but government can ban import and research on any GMOs with potential risk to alter diversity and have negative impact on health and environment (Thapa, 2013). Till date, there is no GM crop or seeds registered, introduced or grown in Nepal.

As a signatory to the Protocol, Nepal has made provision of National Focal Point of CBD and BCH under its Ministry of Forest and Soil Conservation. Nepal signed the Protocol in 2001 but is yet to ratify it. In addition, government of Nepal also formed National Biodiversity Coordination Committee, National Biosafety Committee/ National Competent Authority and established six sectoral Competent Authorities for effective monitoring and regulation of GM products.

3.29.1 National Biosafety Framework (2007) (draft)

The NBF 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:

- The existing or potential use of GMOs in laboratory or in an open space
- Human health, biodiversity, natural environment, agricultural products, foods and drinking products, animal feed and areas of sewerage management
- Regulation of experiment, flow of information, review, assessment of risks including socioeconomic and ethical effects

- Monitoring of import and export, laboratory and field test
- Research and development in academic and industrial sectors
- Safety of the place where functions relating to GMOs are carried out
- 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.

3.29.2 Biosafety Bill (2007) (draft)

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

Other Related Regulations

3.29.3 Plant Protection Act (2002)

The present Law repeals the former one, Act No. 2029 (1972), and institutes the Plant Quarantine Check Post, whose powers and areas of influence are determined by the Government through notification in the Nepal Gazette. All import and export of plants, seeds and related items must be licensed by the Plant Quarantine Check Post and fees paid accordingly. Under this Act, the National Plant Quarantine Committee has been instituted; whose functions and tasks shall be the protection of plants from whatever harmful occurrence (pests, diseases, infections). It specifies the prohibitions and restrictions regarding the import of plants or plant products

3.29.4 Seeds Act (2010)

The main objective of the Act is to maintain the convenience and economic interest of the general public by providing the Seeds of quality-standards in a well-planned manner upon producing, processing and testing the Seeds of high quality-standards to have the production of different crops increased. The Act was first issued in October 26, 1988 and last amended January 21, 2010.

Source:

1. Ananta V. Parajuli, Chief, Environment Division, Ministry of Forests and Soil Conservation, Singha Durbar, Kathmandu, Nepal, email: mfsced@wlink.com.np (Personal Communication in 2007).
2. 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 on September 27, 2013.
3. Sagar Rimal, Chief of Biodiversity section, Ministry of Forest and Soil Conservation Kathmandu Nepal. Email: rimalsagar@yahoo.com. (Personal Communication in 2014).
4. Thapa, M. (2013) Regulatory framework of GMOs and hybrid seeds in Nepal. *Agronomy J. Nepal.* **3:** 128-137.

3.30 New Zealand

No GM crops are currently grown in New Zealand although a number of crops and events are approved for food and feed. The country ratified the Protocol in February 2005. GM products are regulated under the 1996 Hazardous Substances and New Organisms (HSNO) Act and administered by the Environmental Protection Agency (EPA) (USDA, 2013). The Ministry of Primary Industries is responsible for enforcing the EPA conditions on approved field tests and released organisms. It also inspects containment facilities and administers standards for safety, labelling, and food composition including imported food and foods produced using GMOs.

Food Standards Australia New Zealand (FSANZ) is a bi-national independent statutory authority operating under the Food Standards Australia New Zealand Act 1991. The standards cover composition, labelling, and contaminants, including microbiological limits. They apply to all food produced or imported for sale in Australia and New Zealand, including food products that are or contain products derived from GMOs.

3.30.1 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.

3.30.2 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.

3.30.3 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 October 29, 2001 to the close of October 29, 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.

3.30.4 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.

3.30.5 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.

3.30.6 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 Order, separate consents are required for exportation of LMO that falls into more than one category of exportation.

Other Related Regulations

3.30.7 Biosecurity Act (1993)

Biosecurity Amendment Act (1993)
Biosecurity Amendment Act (1994)
Biosecurity Amendment Act (1996)
Biosecurity Amendment Act (1997)
Biosecurity Amendment Act (1999)
Biosecurity Amendment Act (2003)
Biosecurity Amendment Act (2004)
Biosecurity Amendment Act (2005)
Biosecurity Act (2012) Amendment

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. Biosecurity Act (1993) Available at: http://www.legislation.govt.nz/act/public/1993/0095/latest/DLM314623.html; accessed on March 5, 2013.
2. 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 October 6, 2013.
3. 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/resource/publications/pdfs/ER-PR2-03-9.Pdf; accessed on October 6, 2013.
4. Kirsty Allen, Senior Advisor, New Organisms, Environmental Protection Authority, Level 10, 215 Lambton Quay, Private Bag 63002, Wellington 6140, New Zealand. Email: Kirsty.allen@epa.govt.nz (Personal Communication in 2014).
5. Law changes for new and genetically modified organisms. Available at: http://www.mfe.govt.nz/issues/organisms/law-changes/index.html; accessed on October 5, 2013.
6. USDA (2013) Foreign Agricultural Service, GAIN Report NZ1310 Agricultural Biotechnology Annual New Zealand. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Wellington_New%20Zealand_7-15-2013.pdf; accessed on July 4, 2014.
7. 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 July 5, 2014.

3.31 Niue

There is no reported crop cultivation or importation of GMOs in Niue. The country ratified the Protocol in July 2002. The NBF was developed in 2006 when the biosafety regulation was also put in place.

3.31.1 Niue's 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.

3.31.2 Biosafety (Genetically Modified Organisms) Regulation (2006)

The 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.

Other Related Regulations

3.31.3 Agriculture Quarantine Act (1984)

The Agriculture Quarantine Act 1984 and its regulations make provision for the protection of plants and animals through import, export and disease controls. The Act applies to genetically modified forms of organisms (through its definitions). Wide enforcement powers are given to quarantine officers.

3.31.4 Environment Act (2003)

The Environment Act 2003 is the principal environment law in Niue. It provides the legal foundation for the Environment Department and makes provision for the administration of environment related matters, the enactment of a range of environment regulations and the enforcement of environment laws in Niue. The Act provides a range of factors that must be taken into account in its application including: sustainable development; protection of indigenous flora and fauna, coastal zones and historic areas; preservation of culture and traditions; conservation and sustainable use of biological resource; and compliance with multilateral agreements.

3.31.5 Environment (Amendment) Bill (2006)

The Draft Environment (Amendment) Bill 2006 (Draft Bill) proposes to make amendments to the Environment Act 2003 (the Act). These amendments ensure that the Draft Regulations are fully supported by the Act and facilitate the operation of the biosafety regulatory regime.

The Draft Bill inserts a new provision to make clear the Environment Department has responsibilities relating to the implementation of international conventions relating to the environment. The Draft Bill also clarifies the range of penalties for breaches of the Act and Regulations.

3.31.6 Biosecurity Bill (2006)

The Draft Biosecurity Bill aims to protect the health, environment and agriculture of Niue and to facilitate trade in its animal and plant products. This Bill is part of a regional project undertaken by the Secretariat of the Pacific Community that seeks to harmonize biosecurity laws in the Pacific. Its purposes are to: control the introduction and spread of new pests and diseases affecting plants and animals; control those pests and diseases affecting plants and animals that are already present in Niue; provide for the safe import and export of animals, plants and their products; and facilitate cooperation in the prevention of the international movement of pests and diseases affecting plants and animals.

The Draft Bill creates a comprehensive regime to control the import and export of plants and animals, as well as internal control of pests. Articles, pests and diseases that are an unacceptable biosecurity risk to Niue may be declared prohibited. Some exemptions apply, including for goods in transit. Duties are placed on importers and exporters to declare goods and make them available for inspection. The Draft Bill restricts the disposal of garbage and ballast at sea.

Source:

1. Draft National Biosafety Framework- Tokaga Motu (2006) Government of Niue. Available at: http://www.unep.org/biosafety/files/NUNBFrep.pdf; accessed on March 2, 2013.

3.32 Pakistan (Islamic Republic of)

Bt cotton is the only GM crop approved for commercial cultivation in Pakistan. Bt varieties so far released are true breeding and, hence, the seed can be the utilized for the next season's planting.

Pakistan ratified the Protocol on March 2, 2009. Under the Pakistan's Environmental Protection Act of 1997, the country adopted the National Biosafety Rules in April of 2005. The National Biosafety Committee (NBC) is the apex body responsible to review and approve laboratory work, field trials, trade, and commercialization of GM products. NBC is supported by the Technical Advisory Committee (TAC), which reviews the GM events, laboratory and field work, and commercialization of crops, and the Institutional Biosafety Committee (IBC) which undertakes the risk assessment, monitoring and inspection of all regulated activities. The findings of IBC are reviewed in TAC for approval in NBC.

There are no labelling requirements for GM products.

3.32.1 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.

3.32.2 Pakistan Biosafety Rules (2005)

These Rules are applicable to the:

- 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

- All work involved in the field trial of genetically manipulated plants, animals (including poultry and marine life), microorganisms and cells
- 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 February 3, 2013.
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 February 3, 2013.

3.33 Palau (Republic of)

The country signed the Protocol on May 29, 2001 and ratified it on June 13, 2003.

3.33.1 Plant and Animal Quarantine-Biosafety Regulations (2004) (draft)

These regulations apply to all implications relating to the Protocol, with the focus on the transboundary movement, handling, and use, of any LMO. These regulations do not apply to the movement of LMO's within Palau nor do they apply to the transboundary movement of human or veterinary pharmacological LMOs that are addressed by other international agreements or organizations.

Source:

1. http://www.unep.org/biosafety/files/Palau_lmo_reg_finaldraft.pdf; accessed on July 7, 2014.

3.34 Papua New Guinea

Papua New Guinea (PNG) ratified the Protocol on October 14, 2005. PNG drafted a bill under the UNEP-GEF project (Biosafety and Biotechnology Bill), and it was submitted to UNEP on October 20, 2005, following the endorsement by the Minister for Environment and Conservation. However, the Bill is still in the process of being endorsed by the Cabinet. Currently, existing laws are being used to address cases concerning biosafety in PNG. The lack of specific laws that regulate the movement and use of GMOs pose serious concerns. Hence, there could be unregulated inflow of GMOs and materials derived from GMOs without the knowledge of any government authority (Shigaki, 2013).

3.34.1 Papua New Guinea's National Biosafety Framework (2005)

The draft NBF 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:

- Increase awareness on biosafety and biotechnology
- Conduct an inventory to establish number of GMOs in the country either as food, feed, food processes or pharmaceuticals
- Develop an institutional framework for the assessment of GMOs
- Develop regulations and guidelines for the safe assessment, handling, use, management and transfer of a GMOs
- Strengthen and improve human and institutional capacities for the identification and assessing risks related to GMOs
- Formulate policy and regulatory framework on biosafety and biotechnology
- Strengthen and promote the precautionary approach
- Strengthen and promote community participation in assessment, use, management and transfer of a GMO
- Strengthen institutional networking and coordination

3.34.2 Biosafety and Biotechnology Bill (2005) (draft)

The main objectives of the bill are:

- 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
- 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
- Protect and sustain the potential of natural and physical resource against threats posed by GMOs to meet the foreseeable needs of future generations and safeguard eco-systems
- Avoid or mitigate any adverse effects of activities on the environment by regulating the activities related to GMOs
- 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: http://www.unep.org/biosafety/files/PGNBFrep.pdf; accessed on March 2, 2013.
2. Shigaki, T (2013) Biotechnology and Biosafety in Papua New Guinea. In: Stakeholders' Dialogue on Biosafety Regulations in the Asia-Pacific Region- Proceedings and Recommendations, Bangkok April 16-17, 2013. Available at http://www.apcoab.org/uploads/files/1382679434pro_SD_BRAPR.pdf; accessed on June 27, 2014.

3.35 Philippines (Republic of the)

The Philippines has been growing GM corn since 2003. Bt eggplant and Golden rice have completed most of the biosafety tests but these are yet to be approved for commercial release. The country has approved import of GM or GM derived food and feed. Currently, there are no labelling requirements for GM food products, although labelling guidelines have been drafted.

Philippines signed the Protocol on May 24, 2000 and ratified it on October 5, 2006. The biotechnology regulatory regime is embodied in the Department of Agriculture's Administrative Order No. 8 (DA-AO8) issued in April 2002 which derives its legal basis from the Philippine Plant Quarantine Law of 1978, the Agricultural and Fisheries Modernization Act of 1997. Executive Order No. 340 of 1990 creates the National Committee on Biosafety of the Philippines (NCBP). The Bureau of Animal Industry (BAI) evaluates feed safety while the Bureau of Agricultural and Fishery Products Standards handles food safety concerns. Quarantine and environmental issues fall under the responsibility of the Bureau of Plant Industry (BPI) while the Fertilizer and Pesticide Authority handles applications of pest protected plants. A unique feature of Philippine regulations is the conduct of a parallel review by the Scientific and Technical Review Panel (STRP), an independent body of experts from academia and the local scientific community (USDA, 2013).

3.35.1 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.

The Guidelines spells out the national policies on biosafety; organizational structure of biosafety committees; Institutional Biosafety Committees (IBCs), 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, as well as packaging and transport requirement and procedures.

The Guidelines was adopted by the Department of Science and Technology-Biosafety Committee (DOST-BC) in its conduct of risk assessment of GMOs intended for contained use. The DOST-BC was established pursuant to Executive Order No. 514, issued on March 27, 2006 to handle applications on GMOs under contained use and monitor on-going projects for biosafety compliance.

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

The Guidelines establishes 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 (NCBP) 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.

The Guidelines was adopted by the DOST-Biosafety Committee in 2009 in the conduct of risk assessment for confined tests of GMOs – activities that are carried out outside the physical containment facility and subject to appropriate isolation requirements and material management. Under these Guidelines, crops that are eligible under confined test are the following:

- GM crops whose size & growth habits require areas not afforded by standard screen house
- GM crops already commercially available in the country where they were developed, but not yet approved in the Philippines, with sufficient information needed for risk assessment
- Locally developed GM crops with sufficient information generated in the laboratory/screen house – data on which is sufficient for risk assessment
- Other crops and events that warrant limited release under contained/confined conditions as determined by the DOST-Biosafety Committee

Starting July 30, 2001, the Guidelines excluded potentially harmful exotic species in its scope since these are already addressed in the Wildlife Act 9147 being implemented by the Department of Environment and Natural Resource (DENR).

3.35.3 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:

- 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
- 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

The Order provides for the conduct of a science-based risk assessment required for all regulated articles prior to contained use, field testing, propagation or commercialization, importation for direct use as food or feed or for processing, and delisting. 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 the DOST-Biosafety Committee. It likewise states that no regulated article shall be released into the environment for field testing unless it has been tested under contained conditions in the Philippines under the supervision of the DOST-BC. Moreover, it provides that no regulated

article shall be released for propagation, unless it is determined that based on the field testing conducted under local condition, the regulated article will not pose any significant risks to human and animal health and to the environment. The Order allows the importation for direct use as food and feed or for processing provided that the regulated articles pose no risks to human and animal health.

3.35.4 National Biosafety Framework for the Philippines (2006)

By virtue of Executive Order No. 514 series of 2006, the NBF was established to cover 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 aims to strengthen the existing science-based determination of biosafety to ensure safe and responsible use of modern biotechnology so that the Philippines and its citizens can benefit from its application while avoiding or minimizing the risks associated with it. It also aims to enhance the decision-making process on the application of products of modern biotechnology to make it more efficient, predictable, effective, balanced, culturally-appropriate, ethical, transparent and participatory. It is intended to serve as guidelines to implement the country's international obligations on biosafety.

The key features of the NBF are the delineation of responsibilities among government agencies involved in biosafety regulation of GMO in anticipation of the expanded coverage to include, not only agricultural crops but other GMOs as well. The biosafety policies and guidelines issued by the NCBP are implemented by the Competent National Authorities (CNAs): the Department of Science and Technology (DOST) Department of Agriculture (DA), Department of Environment and Natural Resource (DENR) and Department of Health (DOH.

3.35.5 Administrative Order No.22 Series of 2007- Amending Specific Sections of Part V of D.A. Administrative Order No. 8, s. 2002, "Approval Process for the Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing"

The Administrative order amended some of the provisions found in Part V of DA Administrative Order No 8, s. 2002 clarifying further the approval process of regulated articles for direct use as food and feed or for processing.

3.35.6 Administrative Order No 31 Series of 2008-Adopting the Codex Principles for the Risk Analysis for Food derived from Modern Biotechnology and the Codex Guideline for the conduct of Food Safety Assessment of Food derived from Recombinant DNA Plants

The Administrative order provides for the adoption of the Codex Principles for the Risk Analysis of Food Derived from Modern Biotechnology (CAC/GL44-2003) and the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants or otherwise known as the Codex Plant Guideline (CAC/GL 45-2003) with a view to harmonize the regulation with the Codex Guidelines.

3.35.7 Administrative Order no. 1 series of 2009 Food Safety Assessment in situations of Low-level presence of Recombinant- DNA Plant Materials in Food and Feed

This Administrative order utilizes the Annex 3 to the Codex Plant Guidance, "Food Safety Assessment in Situations of Low level presence of Recombinant- DNA Plant material in food" for the conduct of food safety assessment in situations of low level presence of recombinant-DNA plant materials in food and feed.

Source:

1. 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: zen0555@yahoo.com (Personal Communication in 2007 and 2014).
2. The National Biosafety Framework for the Philippines (2004) Department of Environment and Natural Resource-Protected Areas and Wildlife Bureau. 2004. Quezon City, Philippines. p 77. Available at: http://www.unep.org/Biosafety/files/PHNBFrep.doc; accessed on May 14, 2012.
3. USDA (2013) Foreign Agricultural Service, GAIN Report: Agricultural Biotechnology Annual-Philippine Biotechnology Situation and Outlook. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Manila_Philippines_7-17-2013.pdf; accessed on July 18, 2014.

3.36 Samoa (Independent State of)

Samoa signed the Protocol on May 24, 2000 and ratified it on May 30, 2002. The country drafted its NBF in 2004. The draft Biodiversity Bill, Biosafety (LMOs) Regulations (draft) and National Biodiversity Policy (draft) have been prepared following an inclusive process and is currently with the Attorney General's Office for final drafting and subsequent submission to Parliament for enactment (http://bch.cbd.int/database/record.shtml?documentid=102954).

3.36.1 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.

3.36.2 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:

- Manage importation, development, field testing, fermentation, release, or export of GMOs
- Protect Samoa's biodiversity, environment, and people from adverse effects from GMOs
- Manage import and release of organisms that are not GMOs and are also not found in Samoa

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

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

Other Related Regulations

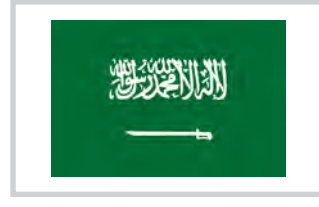
3.36.4 Biosecurity Act (2005)

The Act regulates all movement of live animals and plants including cultures, in and out of the country and has guidelines in place for screening and risk assessment. The quarantine functions directly related to regulating the entry of all living organisms including germplasm into the country are also performed under this Act. Living plants and animal germplasm in transit and or for contained use are regulated and treated consistent with existing guidelines of the Biosecurity Act 2005.

Source:

1. http://bch.cbd.int/database/record.shtml?documentid=102954; accessed on July 3, 2014.
2. Samoa's National Biosafety Framework (2004) Minister of Natural Resource and Environment, P 140. Available at: http://www.unep.org/biosafety/files/WSNBFrep.pdf; accessed on March 29, 2013.

3.37 Saudi Arabia (Kingdom of)



Saudi Arabia does not grow any GM crops nor is there any report of development of GM crops in the country. However, GM grains such as corn and soybean meal are being imported for feed. Saudi Arabia ratified the Protocol in August, 2007. National Biosafety Committee (NBC) has been established which has drafted the National Biosafety Rules. Saudi Arabia is a member of Gulf Standardization Organization (GSO) which issued two agricultural biotechnology related regulations in 2011 dealing with genetically modified unprocessed agricultural and processed agricultural products. The country has also implemented labelling regulations for GM processed food (USDA, 2013).

3.37.1 Saudi Arabia Biotech Labelling Decree (2001) (revised in 2004)

The decree requires positive biotech labelling for processed foodstuffs if a product contains more than 0.9 percent genetically modified vegetable (plant) ingredients.

In 2004, the government implemented a comparable biotech-labelling requirement on animal feed, fruit and vegetables while banning imports of GM seeds.

3.37.2 Saudi Arabia Gulf Cooperation Council (GCC) Biotech Standards (2011)

The following two agricultural biotech standards were approved and adopted:

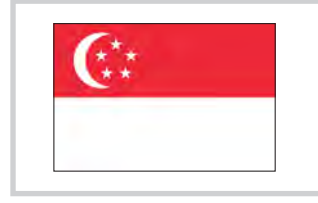
- GSO 2141/2011 General Requirements for Genetically Modified Unprocessed Agricultural Products
- GSO 2142/2011 General Requirements for Genetically Modified Processed Agricultural Products

The GSO 2141/2011 deals with the general requirements for genetically modified unprocessed agricultural products, while the GSO 2412/2011 specifies the general requirements for genetically modified processed food and feed products. The two technical regulations require positive biotech labelling if unprocessed agricultural products, processed food product, feed products or seeds contains more than one percent of GM ingredients.

Source:

1. USDA (2013) Foreign Agricultural Service, GAIN Report SA1309: Saudi Arabia Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Riyadh_Saudi%20Arabia_8-26-2013.pdf; accessed on June 24, 2014.

3.38 Singapore (Republic of)



Singapore imports most of its agricultural and food products and does not grow any GM crops. Singapore has not signed the Protocol but has a Genetic Modification Advisory Committee (GMAC) which is responsible for overseeing GM research, production, use, handling and release. GMAC implements the regulatory and administrative framework for approving GMOs, and coordinates with international agencies to harmonize its guidelines. The country has approved the import of Bt corn, cotton, canola, sugar beet and soybean for food and feed.

Singapore Biosafety Guidelines published in 2006 and revised in 2013 cover the release of GMOs. Prior to the import and distribution of GMOs into the Singapore market, applicants have to seek approval from the GMAC. Currently, Singapore does not require labelling to identify GM content (USDA, 2013).

3.38.1 Singapore Guidelines on the Release of Agriculture-related Genetically Modified Organisms (1999)

Established to ensure safe movement and use of agriculture-related GMOs in Singapore, the Singapore Guidelines on the Release of Agriculture-related GMOs provide a common framework for the risk assessment of agriculture-related GMOs to human health and the environment. It covers agriculture-related organisms with genetic material that has been altered in a way that is unlikely to occur naturally by mating or natural recombination, which include animals (including fish and invertebrates), plants, microorganisms and vaccines used in cultivation, farming, agronomy, husbandry and horticulture or as food.

The Guidelines address issues related to food safety based on the concept of substantial equivalence.

3.38.2 Singapore Biosafety Guidelines for Research on GMOs 2006 (revised in 2013)

In ensuring safe containment, handling and transport of GMOs used in research, the Singapore Biosafety Guidelines for Research on GMOs were drawn to address biosafety concerns regarding research work involving GMOs.

The Guidelines provide a common framework for the assessment and notification of research work on GMOs. It covers 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. Experiments are classified based on the risk levels accorded to the various experimental work involved in contained research studies.

Source:

1. Marcus Ong, Senior Executive Manager, International Relations Agri-Food & Veterinary Authority of Singapore. Email: Marcus_ONG@ava.gov.sg (Personal Communication in 2014).
2. Singapore Biosafety Guidelines (2013) available at http://www.gmac.gov.sg/pdf/Singapore%20Biosafety%20Guidelines%20for%20GMO%20Research_Final%20Draft%20-%20Jan%202013.pdf; accessed on January 26, 2014.
3. USDA (2013) Foreign Agricultural Service, GAIN Report Singapore Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Singapore_Singapore_7-17-2013.pdf; accessed on July 18, 2014.

3.39 Solomon Islands

The Solomon Islands ratified the Protocol on July 28, 2004 and drafted its NBF in 2012.

3.39.1 Solomon Islands National Biosafety Framework (2012)

The components of the NBF include the regulatory framework, administrative structure and the decision making procedures as well as mechanisms for public participation and information.

Source:

1. Solomon Islands National Biosafety Framework (2012) Available at: http://www.unep.org/biosafety/files/Solomon%20Islands%20_%20NBF_Final%20_May%2023%202012.pdf; accessed on July 6, 2014.

3.40 Sri Lanka (Democratic Socialist Republic of)

In Sri Lanka, research and development in the production of GMOs intended for food, feed or processing (GMO/FFPs) has not gone beyond the laboratory stage as scientists are awaiting the proposed Biosafety Act to be implemented (Perera, 2013). Sri Lanka signed the Cartagena Protocol on May 24, 2000 and ratified it on April 28, 2004. The National Biosafety Framework was developed in 2005 and the Ministry of Environment is the National Focal Point for biosafety matters.

3.40.1 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.

3.40.2 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".

3.40.3 National Biosafety Framework of Sri Lanka (2005)

The NBF 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.

3.40.4 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.

3.40.5 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

3.40.6 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.

3.40.7 Food (Labelling & Advertising) Regulation (2005)

The Regulation covers labelling of packaged food for consumer awareness, health, safety, and nutrition reasons. Labelling and control of GM products was introduced in the Regulation in 2007.

Source:

1. B.M.U.D. Basnayake, Secretary, Ministry of Environment, 82, Sampathpaya Rajamalwatta Road, Battaramulla, Sri Lanka. Email: iresha.rajapakse@gmail.com, secoffice@menr.lk (Personal Communication in 2014).
2. National Biosafety Framework of Sri Lanka (2005) Ministry of Environment and Natural Resource, Colombo, Sri Lanka. Available at: http://www.unep.org/biosafety/files/LKNBFrep.pdf; accessed on February 1, 2013).

3. Perera, A. (2013) Biosafety Regulations in Sri Lanka: A Status Update. In: South Asia Biosafety Conference and workshops, September 18-20, 2013, New Delhi. South Asia Biosafety Program, Biotech Consortium India Limited, the Bangladesh Academy of Science and the Centre for Environmental Risk Assessment, pp 19-20.

4. USDA (2007) Foreign Agricultural Service, GAIN Report CE7003 Sri Lanka Biotechnology Annual. Available at: http://www.fas.usda.gov/gainfiles/200707/146291816.pdf; accessed on October 17, 2012).

3.41 Syrian Arab Republic

Syria does not produce any GM crops or products. The country signed and ratified the Protocol on January 29, 2004 and established the NBF in 2006. The Biosafety Committee is responsible for taking any necessary actions to ensure compliance with the Protocol. http://bch.cbd.int/database/record.shtml?documentid=102502).

3.41.1 Biosafety Guidelines in Syria (2001)

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

3.41.2 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.

3.41.3 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. Belal Alhayek, Director of Biodiversity, Lands & Protected Areas, National Focal Point of Convention Biological Diversity, Cartagena Protocol on Biosafety and Biosafety Clearing House, Damascus, Syrian Arab Republic bilalalhayk@yahoo.com, blalhayek75@gmail.com (Personal Communication in 2014).

2. http://bch.cbd.int/database/record.shtml?documentid=102502 accessed on June 25, 2014.

3. 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 March 29, 2012.

3.42 Tajikistan (Republic of)

Tajikistan ratified the Protocol on February 12, 2004. The NBF was developed in 2004.

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

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

- Adopting the Law on Biosafety
- Development and introducing amendments into the acting legislation
- Development and adopting of relevant legislative documents on realization of Law on Biosafety to ensure implementation of the legislation developed
- Preparation of guidelines for the national competent institution and authorized agencies
- Development of inter-institutional guidelines on cooperation in the process of decision making
- Development of instructive documents on inter-institutional procedures of biosafety regulation
- Development of marking system or 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.

3.42.2 Republic of Tajikistan Law on Biological Safety (2005)

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:

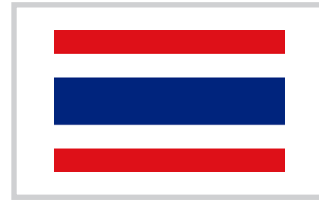
- Production, reproduction, import, export, testing and contained use of microorganisms, plants and animals, GM with application of modern biotechnology
- Deliberate release into the environment and placing at market living organisms that were GM including any living organisms able to reproduce, that is seeds, cuttings, pollen, tubers, spores, etc.
- Non-deliberate release of GMOs into the environment
- 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
- Any type of investigation of GMOs including laboratory, clinic, field and production testing; (f) Non-deliberate or illegal transboundary movement of GMOs
- Storage, burial, elimination of GMOs and/or their products, waste utilization being the result of modern biotechnology methods
- 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 March 2, 2013.
2. Republic of Tajikistan Biological Safety Law (available at http://bch.cbd.int/database/attachedfile.aspx?id=802; accessed on February 27, 2013.

3.43 Thailand (Kingdom of)



Currently, no GM crops are commercially grown in Thailand. However, field trials were conducted in a number of crops, viz. Flavr Savr tomato, Bt corn, Bt cotton and ring spot virus resistant papaya among others. In 2003, the government imposed a ban on field trials due to environmental and health concerns which continues to this day. However, Biosafety Law and Guidelines are being drafted to develop a sound system of field trials and their monitoring.

Thailand became a member of the Protocol in February 2006 and officially stated that government follows the principles and rules of the CBD. The policy includes eight elements: 1) public awareness, education and participation; 2) sustainability; 3) risk assessment and management; 4) risk characterization; 5) risk communication; 6) precautionary principle; 7) freedom of choice; and 8) capacity building. Thailand signed the Supplementary Protocol in March 2012.

Thailand allows the import of transgenic plants as processed foods and soybeans and corn for feed and industrial use.

As for processed food containing GM plant materials, when the contents exceed the five percent tolerance threshold labelling is required (USDA, 2013).

3.43.1 Plant Quarantine Act B.E 2507 (1964) Amended by Plant Quarantine Act (No.2) B.E. 2542 (1999) and Plant Quarantine Act (No.3) B.E. 2551(2008)

According to the Act, GM plants are prohibited materials and must be approved for importation into the country (for research and experiments only) regarding relevant regulations, notifications and orders. Lists of prohibited GM plant materials including terms, conditions and guidelines on import permission request are provided by the Department of Agriculture's notifications issued under the Act.

3.43.2 Ministerial Notification No. 251, B.E. 2545 (2002)

Soybean and soybean products, corn and corn products, which obtained through certain techniques of genetic modification/ genetic engineering, shall be subjected to labelling. GMO labelling is

required for any processed product containing recombinant DNA or protein resulting from gene technology over 5 per cent of each top three main ingredients by weight, and each ingredient constitutes over 5 per cent of the total product weight.

3.43.3 National Biosafety Framework (2006)

National Biosafety Frameworks (NBF) of Thailand provides details of various national frameworks in accordance with the context of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It brings together five key national biosafety frameworks consisting of

- National Biosafety Policy Framework
- National Biosafety Legal and Regulatory Framework
- National Biosafety Institutional Framework
- National Biosafety Handling Framework
- National Biosafety Technical Guidelines Framework

It also includes a chapter on public participation on biosafety matters. The main objective of NBF is to bring together various agencies and institutions, their authority, responsibility and scattered information relevant and applicable to biosafety of modern biotechnology and to consolidate and integrate them systematically into a single and unique biosafety framework.

The secondary objective of NBF is to further envisage that the national biosafety framework herein developed will provide a solid platform for proper and efficient coordination of the key pertinent biosafety issues, taking into consideration their accountability, clarity, transparency and guidance for all participating stakeholders, governmental, public and private sectors alike, in order to overcome the debate on GMOs and to help alleviate the conflicts of interest, misunderstanding and misperception of the genetically modifies products and entities derived from genetic engineering or modern biotechnology. This is to be undertaken within the context of science-based precautionary approach and principle up to a certain extent that could lead to the knowledge management and the exploitation of modern biotechnology to help develop the national socio-economic status in the future.

3.43.4 Biosafety Guidelines for Contained Use of Genetically Modified Microorganisms at Pilot and Industrial Scale (2011)

The objective of this document is to provide guidelines for contained use of GMMs in pilot and industrial scales to ensure safety for the operators, the public, and the environment. The scopes and principles of the guidelines are as follows:

- Genetically Modified Microorganisms (GMMs) activities in pilot and industrial scales were classified according to degree of safety and level of risk from the use of GMMs. There are four categories:
  - GILSP Work is the work using GMMs that has been classified as safe and capable of implementing good industrial large scale practice
  - Category 1 Work is the work using GMMs that has been classified as safe but does not fulfill GILSP conditions
  - Category 2 Work is the work using GMMs that may pose low risks to the operator, community and environment

  - Category 3 Work is the work using GMMs that may pose risks to the operator, community and environment

- Four containment levels are identified according to degree of safety and risks of GMMs and other criteria such as the amount of GMMs in production process, purification of product, etc. which may alter levels of containment

3.43.5 Draft Act on Biosafety B.E. (2012)

The principle of the draft Act on the Biosafety B.E. is to control and monitor the utilizations of living modified organisms (LMOs), including its safe direct use LMOs for food or feed or processing, both from abroad or domestically, in appropriate manner and in accordance with international implementation, for protection and conservation of biological diversity, taking into account of human and animal health and also consumer protection. There are 8 chapters with 73 articles which includes the operational provisions on: import, export and transit of LMOs; contained use of LMOs; use in confined field trial; intentional release of LMOs to the environment; handling, transport, packaging and identification; liability and redress and penalties.

3.43.6 Biosafety Guidelines for Work Related to Modern Biotechnology or Genetic Engineering (2013)

The Guidelines embrace all research 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:

- 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

- 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

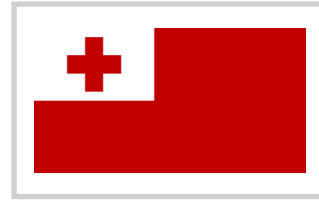
Source:

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, 2013.
2. Dalad Senthong, Biodiversity Division, Office of Natural Resource and Environmental Policy and Planning, 60/1 Soi Phibun Wattana 7, Phayathai Rama 6 10400, Bangkok, Thailand. E-Mail: D_senthong@hotmail.com (Personal Communication in 2014).
3. http://bch-thai.onep.go.th/law_e.html; accessed on October 7, 2013.
4. 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 August 26, 2013.
5. USDA (2012) Foreign Agricultural Service, GAIN Report Number TH7090: Thailand

Biotechnology Agricultural Biotechnology Report. Available at: http://www.fas.usda.gov/gainfiles/200707/146291754.pdf; accessed on February 12, 2013.

6. USDA (2013) Foreign Agricultural Service, GAIN Report Number TH7090: Thailand Biotechnology Agricultural Biotechnology Report. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Bangkok_Thailand_7-18-2011.pdf; accessed on February 28, 2013.

3.44 Tonga (Kingdom of)



Tonga signed the Protocol on September 18, 2003 and developed its draft NBF in 2004.

3.44.1 Tonga National Biosafety Framework (2004) (draft)

The NBF targets the following:

- Protection of natural plants and animals of Tonga from accidental escape of the LMO's novel engineered gene into the wild or domesticated relative
- Minimizing the risk to biodiversity and human health from LMOs in trade
- Development of effective and efficient pest risk assessment for LMOs
- Facilitation of trade while protecting the interest of the country pertaining to LMOs through effective boarder management
- Minimizing the incidence of food borne diseases due to LMO-FFP
- Monitoring aquatic LMOs to minimize effect on biodiversity from aquaculture practices
- Monitoring of LMOs to minimize effect on biodiversity
- Promotion of public awareness and participation through the media, and village meeting such as faikava and fono
- Development, implementation and enforcement of biosafety regulatory regime

3.44.2 The Biosafety Law (2009)

The law empowers an inter-ministerial Committee "National Biosafety Advisory Committee" to undertake risk assessments and communicate decisions made under this Act. The Committee is responsible for:

- Arranging and facilitating the review of risk assessments undertaken
- Establishing and maintaining appropriate mechanisms, measures and strategies for the regulation, management and control of risks associated with living modified organisms and the application of modern biotechnology within the Kingdom
- Implementing measures to control and prevent unintentional and illegal transboundary movements of living modified organisms, and to respond to such movements, including the taking of necessary emergency responses
- Ensuring that living modified organisms which are subject to transboundary movement are handled, packaged and transported under conditions of safety, and that relevant international standards and rules are applied in this regard

- Liaising with and providing assistance to other Ministries and agencies to ensure that living modified organisms within the Kingdom, or proposed to be imported into the Kingdom, are used, handled, stored and transported in accordance with the requirements of this Act and the Cartagena Protocol, and that –and in accordance with the Cartagena Protocol, and provide information and reports required by it
- Arranging the monitoring and reporting of the effects to the environment arising from living modified organisms and the application of modern biotechnology within the Kingdom
- Approval of any appropriate programme of public information and education concerning living modified organisms and the implementation of the Cartagena Protocol
- Doing any other act or thing necessary to:
  - I. manage the risks associated with living modified organisms and the application of modern biotechnology within the Kingdom
  - II. ensure that the Ministry fulfils its role as focal point under Article 19 of the Cartagena Protocol
  - III. effectively liaise with the BCH and the Secretariat and Conference of the Parties to the Convention

Source:

1. The Biosafety Act. Available at http://bch.cbd.int/database/record.shtml?documentid=101997; accessed on February 28, 2013.
2. Tonga National Biosafety Frameworks. 2004. Available at: http://www.unep.org/biosafety/files/TONBFrep.pdf; accessed on April 12, 2013.

3.45 Tuvalu

Tuvalu signed the Protocol in December 2002 and developed its NBF in 2008.

3.45.1 National Biosafety Framework of Tuvalu (draft) (2008)

This draft NBF contains the five key elements of a National Biosafety Framework for setting up functional systems for risk assessment, management and decision-making for GMOs.

- A national policy on biotechnology and biosafety – as there is no Government policy that could apply to biosafety and biotechnology, it was decided to develop a new draft policy that covers both the potential benefits from the application of biotechnology to achieve the overall aims of Te Kakeega, and the importance of biosafety in order to ensure the safe use of biotechnology
- A regulatory regime for biosafety based on a regulation under the EPA 2008
- A system to handle applications (administrative, risk assessment, risk management and decision making processes)
- Follow up actions (monitoring, inspections and enforcement)

- Systems for public awareness and participation in order to ensure that all stakeholders are able to take part effectively in decision-making on GMOs

3.45.2 Environment Protection Act 2008

This Act is administered by the Department of Environment and has the main objective to make provisions for the protection and management of environment in Tuvalu. Specific provision were made in relation to the implementation of international environment related Conventions (including the CBD and the Protocol).

Other Related Regulations

3.45.3 Quarantine Act 1929

The main objective of the Act is to make comprehensive provision in relation to quarantine. The effective imposition of quarantine arrangements and requirements are an important aspect of environment protection. It is also relevant in the context of trans-boundary movements.

3.45.4 Plants Act 1976

The Act provides for the protection of plants and the imposition of quarantine arrangements to control the importation of plants, and to prevent the introduction and spread of plant diseases. This has particular relevance to the controls that may be exercised over trans-boundary movements into Tuvalu.

3.45.5 Food Safety Act (2006)

The Act promotes public health and safety with regard to food, regulates the preparation, sale and use of food, assists consumers to make informed choices on food and to promote fair trading practices in relation to food. This law has important implications for human health and for the rights of consumers.

3.45.6 Biosecurity Bill (2007) (draft)

The legislation is aimed to protect the health, environment and agriculture of Tuvalu and to facilitate trade in its animal and plant products. This draft law seeks to make comprehensive provision for biosecurity related issues and processes, and to harmonize these in the region for controlling the introduction and spread of new pests and diseases affecting plants and animals; controlling those pests and diseases affecting plants and animals that are already present in Tuvalu; providing for the safe import and export of animals and animal products and plants and plant products and facilitating cooperation in the prevention of the international movement of pests and diseases affecting plants and animals.

Source:

1. The Draft National Biosafety Framework of Tuvalu (2008) Available at: http://www.unep.org/biosafety/files/TV-NBFdraft14Aug08.pdf; accessed on July 7, 2014.

3.46 Vanuatu (Republic of)

Vanuatu still needs to sign the Protocol; however, it has developed its NBF in 2005.

3.46.1 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:

- Risk analysis and decision making framework
- Control introduction, release and establishment of new species or varieties of organisms (including monitoring, reporting and containment)
- Border control, surveillance and emergency response for the exclusion and eradication of unwanted organisms and associated pathogens
- Information, education and awareness to allow informed use of organisms with potential to cause harm (including labelling of foods and animal feeds) and to facilitate community responsibility
- A precautionary approach with respect to new organisms, including GMOs and their derivatives and processed products
- A system for liability and redress

Source:

1. http://hqweb.unep.org/chinese/biosafety/files/VUNBFrep.pdf; accessed on March 30, 2014.
2. National Biosafety Framework (2005) Department of Vanuatu Quarantine and Inspection Services, P71. Available at: http://www.unep.org/biosafety/files/VUNBFrep.pdf; accessed on March 2, 2013.

3.47 Viet Nam (Socialist Republic of)

Vietnam has so far not approved any GM crop for commercial cultivation nor allowed any import of GM seeds. Field trials on GM corn, cotton and soybean have been approved though not all are actually under trial. The country ratified the Protocol January 21, 2004. The Ministry of Natural Resource and Environment (MONRE) is the Cartagena Protocol Focal Point of Vietnam.

The Food Safety Law requires labelling only "high risk" GM foods while the Bio Safety Decree requires labelling of all GMOs and products with GM content greater than 5 percent. The two laws also lay out two different agencies to manage labelling requirements (USDA, 2013).

As of December 2013, Vietnam does not have a monitoring or testing regime in place to evaluate the biotech content in imported and exported of food products or food products domestically produced in Vietnam.

3.47.1 Biodiversity Law No.20/2008/QH12 (took into effect in 2009)

Besides General Provisions, the law covers biodiversity reservation planning, conservation and sustainable development of natural ecosystems, conservation and sustainable development of biological organisms, conservation and preservation of heritage resource, international cooperation on biodiversity, mechanism and for biodiversity conservation and sustainable development and implementation

Part 3 of Chapter 5 focuses on risk management of GMOs and specimens" impact on biodiversity. This section provides general requirements for risk assessment, risk management and biosafety certification for research, release, import or export of GMOs and genetically modified specimens. There are also requirements for organizations or individuals who perform research/ release into the environment or import/export of genetically modified organism or specimens to provide information on the level of risk and the measures for risk management. The Ministry of Natural Resource and Environment (MONRE) will maintain a database of GMOs and genetically modified specimens relevant to biodiversity

3.47.2 Decree of Government No: 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms (2010)

The Decree stipulates the biosafety management of the related activities on GMOs, genetic specimens, and products originating from GMOs.

The Decree applies to all domestic and foreign organizations and individuals who engage in the activities related to GMOs, genetic specimen, and products originating from GMOs in the territory of Socialist Republic of Vietnam.

In accordance with the Decree 69/2010/ND-CP:

- The Ministry of Natural Resource and Environment shall issue Biosafety Certificate, carry out unique state management of database and information on GMO, inspection of GMO-related activities
- The Ministry of Agrculture shall have respobisibilities to issue Field-trial permit, Feed certificate
- The Ministry of Health had issue Food Certificate which is amended by the Decree 108/2011/ ND-CP
- The Ministry of Science and Technology shall issue Lab Certificate for laboratories have qualification for doing GMO-related researches and manage the R&D of GMO

3.47.3 Law on Food Safety No.55/QH12/2010 (took into effect in 2011)

This Law details the provisions for

- Issuance and duration of validity of conformity declaration certificates for packaged, processed food, food additives, processing aids, packaging materials, and containers exposed directly to food
- Regulations on safety for human health and the environment of genetically modified food; labelling of genetically modified food

- Producing and trading entities exempt from food safety certification
- Exemptions from state food safety inspection for a number of imported foods; state inspection procedures in the country that will export to Vietnam under The International Treaties of which the Socialist Republic of Vietnam is a member
- Indication of expiry date on food labels
- Delegation of responsibilities for state management of food safety:
  - Responsibilities of state management of food safety, the Ministry of Health
  - Responsibilities of state management of food safety, the Ministry of Agriculture and Rural Development
  - Responsibilities of state management of food safety, the Ministry of Trade and Industry
  - Responsibilities of state management of food safety of the People's Committees at all levels

Coordination between Ministries and sectors in the implementation of state management functions on food safety.

3.47.4 Decree of Government No: 108/2011/ND-CP Amending some articles of the Decree No. 69/2010/ND-CP dated June 6th, 2010 of the Government on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms (2011)

The Decree amends some articles of the Decree No. 69/2010/ND-CP regarding the Ministry of Agriculture and Rural Development being the competent authority for issuance/ withdrawal of a certificate of GMOs for use as food.

The Ministry of Agriculture and Rural Development shall issue the List of GMOs that have been already granted certificates for to be used as food and publish the list on its website on biosafety.

3.47.5 Circular No. 09/2012/TT-BTNMT of the Ministry of Natural Resource and Environment on Provide and Exchange of Information and Data on Genetically Modified Organisms (2012)

The Circular requires all National Competence Authorities to provide information and database on GMO such as legal documents, decisions, the environmental risk assessment report to the Ministry of Natural Resource and Environment through the national Biosafety Clearing House websites and through official document.

3.47.6 The National Strategy on Biodiversity to 2020, Vision Towards 2030 (2013)

The National Strategy has just been approved by the Prime Minister at Decision 1250/QD-TTg dated 31 July 2013. The biosafety management of GMO has been integrated in the National Strategy as one of the major tasks:

- Enhance the cooperation and experience learning in order to strengthen capacity among agencies who have responsibilities for GMO management at all levels in Vietnam

- Promote investing in facilities, human and financial resource for monitoring risks caused by GMO to environment and biodiversity; develop the legal documents on liability and redress in biosafety management of GMO

3.47.7 The Circular 08/2013/TT-BTNMT on Procedure for Granting and Revoking Biosafety Certificate for GM Crops (2013)

This Circular prescribes the order and procedures for granting and revoking Biosafety Certificate of genetically modified crops. In Vietnam, the Biosafety Certificate is a permit for environmental release. In Article 3 of the Circular, the group of GMCs to be considered eligible for granting biosafety certificate includes:

- Single transformation event is created as a result of transferring one or more genes encoding a desired trait by transgenic technology
- Stacked transformation events are created as a result of one of the two following processes:
  - Simultaneously transfering genes encoding desired traits into traditional crops by using transgenic technology
  - Transfering genes or gene encoding a desired trait into a genetically modified crop

Source:

1. Circular 69/2009/TT-BNNPTNT on risk assessment of genetically modified crops to biodiversity and environment (2009) Available at http://bch.cbd.int/database/record.shtml?documentid=101823; accessed on February 28, 2013.
2. Decree 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms (2010) Available at http://bch.cbd.int/database/record.shtml?documentid=101822; accessed on February 28, 2013.
3. Nhan Thi Thanh Hoang, Deputy Director, Biodiversity Conservation Agency, Vietnam Environment Administration, No. 10 Ton That Thuyet, Cau Giay, 084 Hanoi Viet Nam. Email: hnhan@vea.gov.vn, hoangnhan.bca@gmail.com, takieuanh@gmail.com. (Personal Communication in 2014).
4. The National Action Plan for Implementation of the Cartagena Protocol on Biosafety (2004) Available at: http://www.unep.org/biosafety/files/VNNBFrep.pdf; accessed on March 29, 2008.
5. USDA (2009) GAIN Report Number VM9072 Vietnam Agricultural Biotechnology Annual. Available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Grain%20and%20Feed%20Annual_Hanoi_Vietnam_5-6-2011.pdf; accessed on February 28, 2013.
6. USDA (2013) GAIN Report Number VM3062 Vietnam Agricultural Biotechnology Annual. Available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Hanoi_Vietnam_11-13-2013.pdf; accessed on June 28, 2014.

3.48 Yemen (Republic of)

Yemen does not grow any GM crops. The country ratified the Protocol on December 1, 2005 and developed its NBF in 2005. (http://apps.fas.usda.gov/gainfiles/200508/146130589.pdf).

Yemen is a member of the Gulf Standardization Organization (GSO) a regional organization made up of seven national standards bodies of the Gulf countries. The GSO has issued two mandatory agricultural biotechnology regulations numbers GSO 2141/2011

(General Requirements for Genetically Modified Unprocessed Agricultural Products) and the GSO 2142/2011(General Requirements for Genetically Modified Processed Agricultural Products).

3.48.1 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.

- Part one gives background information about Yemen's commitment towards the Protocol
- Part two of the NBF deals with national policies and strategies in biosafety
- Part three deals with the draft national biosafety by-law intended to be ratified and issued
- 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 labelling and identification and facing emergency situations is also covered
- Part five highlights the issue of risk management with detailed analysis. It also covers monitoring and enforcement
- Part six deals with public awareness. Capacity building is also highlighted as a priority issue in public awareness

3.48.2 Gulf Cooperation Council (GCC) Biotech Standards (2011)

The following two agricultural biotech standards were approved and adopted:

- GSO 2141/2011 General Requirements for Genetically Modified Unprocessed Agricultural Products
- GSO 2142/2011 General Requirements for Genetically Modified Processed Agricultural Products

The GSO 2141/2011 deals with the general requirements for genetically modified unprocessed agricultural products, while the GSO 2412/2011 specifies the general requirements for genetically modified processed food and feed products. The two technical regulations require positive biotech labelling if unprocessed agricultural products, processed food product, feed.

Source:

1. http://apps.fas.usda.gov/gainfiles/200508/146130589.pdf; accessed on June 25, 2014.
2. 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 March 2, 2013.

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1. Gupta K., J.L. Karihaloo and R.K. Khetarpal (2008) *Biosafety Regulations of Asia-Pacific Countries.* Asia-Pacific Association of Agricultural Research Institutions, Bangkok; Asia-Pacific Consortium on Agricultural Biotechnology, New Delhi and Food and Agricultural Organization of United Nations, Rome, p. 106. Available at: http://www.apaari.org/wp-content/uploads/2009/05/biosafety_regulations_of_asia-pacific_countries.pdf; accessed on June 2, 2014.

2. McLean, M.A., R.J. Frederick, P. Traynor, J.I. Cohen and 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 May 6, 2014.
3. UNEP-GEF (2012) National Biosafety Frameworks (2008). Available at: http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx; accessed on March 2, 2013.
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Chapter 4

RISK ASSESSMENT FRAMEWORKS: SOME CASE STUDIES

Risk assessment for ensuring biosafety involves a scientific process to estimate the risks posed by GMOs to human life and health, as well as their impact on the environment. The prevention, reduction or elimination of these risks requires methods of risk management that are normally implemented as actions conforming to particular regulations. In most cases risk assessment is considered in a broader context, including its relationship to risk management and decision-making. For example, the entire process of risk assessment, combined with risk management (and risk communication in some cases), is referred to as risk analysis (OGTR, 2013). It is recommended that risk assessment and risk management be implemented along with risk communication, which involves all interested parties and allows for an iterative process of risk analyses (FAO, 2011).

Effective risk assessment and monitoring mechanisms are the basic prerequisites to adequately address the perceived risks and watch out for new risks (Domingo and Bordonaba, 2011). The methodology for risk analysis of GMOs has evolved over the past years. An integrated framework for assessment of risk, prevalent in most regulatory systems, allows for its various components to be organised and arranged in a way that facilitates decision-making (OGTR, 2013).

Article 15 of the Cartagena Protocol indicates specific goals for risk assessment with respect to determining the potential adverse effects that could be posed by an LMO. Four general principles of risk assessment are specified in Annex III of the Protocol:

- "Risk assessment should be carried out in a scientifically sound and transparent manner and can take into account expert advice of, and guidelines developed by, relevant international organizations"
- "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk"
- "Risks associated with living modified organisms or products thereof should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment"
- "Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the LMO concerned, its intended use and the likely potential receiving environment"

Hill (Hill, 2005) through a five step process attempted to show some of the most commonly defined steps and associated terminology used in risk assessment frameworks of various countries/ organizations. The first step of hazard identification involves identification of characteristics of a GMO that may have any adverse effect on the environment or the "what could go wrong" step. The steps 2 and 3 involve exposure assessment which refers to assessment of the likelihood of occurrence of particular adverse outcomes or the likelihood that these would happen; consequences assessment refers to assessment of severity of effects if they occur or the extent to which these would

be a problem. The fourth step refers to risk characterization which refers to the risk estimation/ evaluation and consequences of the identified adverse effects being realized. And the last and fifth step involves mitigation options referred to as application of risk management strategies.

A *Guidance on Risk Assessment of Living Modified Organisms* has been developed by the CBD's Ad-Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, with inputs from the Open-ended Online Expert Forum, in accordance with terms of reference set out by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) in its decisions BS-IV/11 and BS-V/12 in response to an identified need for further guidance on risk assessment of LMOs. It is intended to be a "living document" that may be updated and improved as appropriate and when mandated by the Parties to the Protocol (CBD, 2012).

The Guidance document provides a detailed roadmap for risk assessment on LMOs taking into account risks to human health and elaborates on the steps and points to consider in environmental risk assessment and by pointing users to relevant background materials. The flowchart reproduced in Figure 3, which elaborates the steps in the risk assessment, categorizes the risk assessment procedure on similar lines to those outlined by Hill (Hill, 2005).

Below case studies on risk assessment carried out on some crops approved for environmental release in Asia-Pacific countries are presented and discussed.

4.1 Case Study I: Bt Cotton in India

Bt cotton was first approved for environmental release in India in 2002. The following section give a summary of the risk assessment carried out on three Bt cotton hybrids containing *cry 1* genes for insect resistance developed by Maharashtra Hybrid Seeds Company. Box 1 summarizes the studies carried out, details of which are available at http://bch.cbd.int/database/record.shtml?documentid=103020.

Box 1: Summary of Risk Assessment of Three Transgenic Bt Hybrid Cotton Varieties Containing Cry 1Ac Gene and *nptII* and add Marker Genes developed by Maharashtra Hybrid Seeds Company (MAHYCO)

The environmental safety assessment of Bt cotton hybrids included extensive studies on pollen escape, out- crossing, aggressiveness and weediness, effect on non-target organisms, presence of Cry1AC protein in soil, effect of Cry1AC protein on soil micro-flora, confirmation of the absence of terminator gene, and baseline susceptibility studies

Studies conducted on pollen escape/ out crossing

Multi-location experiments conducted in 1996, 1997 and 2000 revealed that out-crossing occurred only upto 2 meters, and only 2% of the pollen reached a distance of 15 m. As the pollen is heavy and sticky, the range of pollen transfer is limited. Also, there is essentially no chance that the Bt gene will transfer from cultivated tetraploid species such as the present Bt hybrids to traditionally cultivated diploid species.

Aggressiveness and weediness

To assess the weediness of Bt cotton the rate of germination and vigor was compared by laboratory test and in soil to the non-transformed parental line. The results demonstrated that

there are no substantial differences between Bt and non-Bt cotton for germination and vigor. This also indicates that there is no substantial difference between transgenic Bt and control non-Bt cotton with regard to their weediness potential.

Studies conducted on the effect of Bt on non-target organisms

Studies conducted during the multi-location field trials revealed that the Bt cotton hybrids do not have any toxic effects on the non-target species, namely sucking pests (aphids, jassids, white fly and mites). The population of secondary lepidopteran pests, namely tobacco caterpillar remained negligible during the study period in both Bt and non Bt hybrids. The beneficial insects (lady beetle, spiders) remained active in both Bt and non Bt varieties.

Studies conducted regarding presence of Bt gene in soil

Studies were conducted to assess the possible risk of accumulation of Bt gene in the soil, by insect bioassays. Bt protein was not detected in soil samples indicating that Bt protein is rapidly degraded in the soil on which Bt cotton is grown. This study showed that the Cry 1AC protein was rapidly degraded in the soil in both the purified form of the protein and as part of the cotton plant tissue. The half-life for the purified protein was less than 20 days. The half-life of the Cry 1AC protein in plant tissue was calculated to 41 days which is comparable to the degradation rates reported for microbial formulations of Bt.

Studies to evaluate the effect of Bt gene on soil micro-flora

Studies were conducted to evaluate any impact of Bt protein leached by roots of Bt cotton on the soil micro-flora. There was no significant difference in population of microbes and soil invertebrates like earthworm and Collembola between Bt and non-Bt soil samples.

Studies to evaluate the food/ feed Safety

For evaluating food/feed safety, the studies conducted included: compositional analysis, allergenicity studies, toxicological study, presence of Bt gene and protein in Bt cotton seed oil and feeding studies on fish, chicken, cows and buffaloes.

Feeding experiments conducted with Bt cotton seed meal on fish, chicken, cows and buffaloes indicated that Bt cotton seed meal is nutritionally equivalent, wholesome and safe as the non-Bt cotton seed meal.

The feeding experiments on poultry, fish, cows and buffaloes were conducted at National Dairy Research Institute (NDRI), Karnal on lactating cows; Department of Animal Nutrition, College of Veterinary Sciences, G.B. Pant University of Agriculture & Technology, Pantnagar on lactating buffaloes; Central Avian Research Institute (CARI), Izzatnagar on poultry; and Central Institute of Fisheries Education (CIFE), Mumbai on fish.

The composition of cotton seed and oil from Bt cotton hybrids was compared to that of non-Bt cotton hybrids and other conventional cotton varieties. The nutrients measured in the cotton seed included protein, fat, fiber, moisture, ash, amino acids, fatty acids, and the anti-nutrients gossypol, cyclopropenoid fatty acids and aflatoxins. These analyses demonstrated that Bt cotton hybrids are substantially equivalent and as safe and nutritious as non-Bt hybrids and other conventional cotton varieties. Further, nutritional studies in cows and buffaloes showed no difference on feed intake, milk yield and composition between Bt and non-Bt groups and safety studies confirmed the food and feed safety of Bt cotton.

The results of the mammalian acute oral toxicity studies supported the specificity and the safety of the Cry1Ac protein. No significant acute effects were observed even at extremely high dose levels (4200mg/kg of body weight), when the Cry1Ac protein was administered orally to mice. Also, the Cry1Ac protein expressed in the cotton plant is not expected to present a risk of inhalation toxicity. The proteins that are non-toxic by the oral route are not expected to be toxic by the dermal or pulmonary route.

Feeding studies on ruminants conducted at the Industrial Toxicology Research Center (ITRC), Lucknow, showed that Bt cotton seed when fed for 90 days to goats, was as nutritious as non Bt cotton seeds and did not cause any deleterious effect on the ruminants compared to non-Bt cotton seeds. Nutritional studies on cows and buffaloes conducted in India reconfirm these conclusions.

The toxicological studies on chicken and fish under Indian conditions confirmed the safety and wholesomeness of cotton seed meal derived from Bt cotton.

Studies conducted by Central Institute of Cotton Research (CICR), Nagpur to determine the presence of Cry1Ac protein in refined oil and lint obtained from Bt cotton showed absence of Cry1Ac protein at the detection standard of the experiment. Cry1Ac protein was detected in crude seed oil samples of Bt cotton (100pg/500 ml oil). The presence of Cry1Ac protein only in crude oil samples was due to estimated quantity of 0.2 ppb of Cry1Ac protein in the seed debris that is usually present in crude extractions.

Similarly, studies conducted to determine the presence of Cry1Ac gene fragments, in cotton seed oil obtained from Bt cotton by using forward and reverse primers specific for internal sequence of the gene and their amplification by use of PCR, were also undertaken at CICR, Nagpur. No amplification for the primers was observed in the oil samples.

Allergenicity studies

Allergenicity studies were conducted in Brown Norway rats. No significant differences in feed consumption, animal weight gain and general animal health were found between animals fed with Bt cotton seed and no cotton seed. At the end of the feeding period, the relative allergenicity of traditional cotton hybrids and Bt cotton were compared to Bt and non-Bt protein extract in active cutaneous anaphylaxis assays. Results of the study concluded that there is no significant change in endogenous allergens of Bt cotton seed compared to non-Bt cotton seed.

Confirmation of the absence of "Terminator Gene"

The transgenic Bt Cotton plant was developed by incorporating Bt gene into it. Therefore, it was desirable to assess that no other gene including *cre recombinase* gene which is an integral component of the so called "terminator technology" is present in Bt cotton. A study was carried out by The Department of Genetics, University of Delhi (South Campus) Delhi to check the presence/absence of such gene in the Bt cotton. The PCR analysis of DNA samples isolated from individual seedlings derived from Bt cotton hybrids showed that Bt cotton hybrid lines positive for *Cry1Ac* amplification did not show any amplification product using *cre* primers. This conclusively demonstrated the absence of "terminator gene" in Bt cotton hybrids.

Baseline susceptibility study

The Project Directorate of Biological Control, Bangalore carried out baseline susceptibility study for *Helicoverpa armigera*, for two years in 2000-01 and 2001-02 at six and fourteen

locations, respectively. In the study different geographical populations of American bollworm (*H. armigera*) collected from six major cotton growing states of India (viz. Madhya Pradesh, Gujarat, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu) were exposed to insecticidal protein Cry1Ac through bioassays using *probit* analysis. LC50 ranged from 0.114 to 0.594, LC90 from 1.016 to 6.700 and LC95 from 2.004 to 19.462. However, the moult inhibitor concentration (MIC) ranged for MIC50 from 0.051 to 0.140, MIC90 0.246 to 0.910 and MIC95 from 0.024 to 1.826 of Cry1Ac. These values are from the baseline data for susceptibility of American bollworm to Cry1Ac protein and can be used as benchmark for monitoring resistance in the bollworm pest to Cry1Ac protein, in future.

It was concluded that Bt cotton does not present any additional safety concerns compared to conventional cotton even as a result of processing or handling of the transformed plants or fruits.

The approval for environmental release for three Bt cotton hybrids expressing Cry1Ac gene (MON 531 event) was initially for a period of three years (2002-2005). Subsequently the approval was extended after performance evaluation and currently several Bt cotton hybrids containing the same events are under commercial cultivation in cotton growing states across the country.

(*Source:* http://bch.cbd.int/database/record.shtml?documentid=103020)

The risk assessment conducted for Bt cotton in India prior to according permission for release was quite elaborate. Moreover, Bt cotton in several ways was an ideal candidate for introduction as first transgenic commercial crop for several reasons. It is grown basically as a fibre crop, cotton seed oil used for consumption is free of proteins, including Bt protein, which would otherwise have raised more issues. Environmental safety concerns for Bt cotton in Indian environment are limited because there is no known sexually compatibile related species occurring in India. Cotton is not found as a weed in the global production systems and Bt is unlikely to confer any advantage that would result in Bt cotton establishing as a weed (Karihaloo and Kumar, 2009; Choudhary and Gaur, 2010).

The safety of Bt toxins in terms of toxicity and allerginicity towards mammals and other non-target organisms are well documented (Glare and O'Callaghan, 2000; Betz *et al*., 2000, OECD, 2007; Lemaux, 2008) and this was also confirmed through the food/feed safety studies and the allerginicity tests conducted by the developers of Bt cotton in India.

Studies on effect of Bt toxins on non-target organisms especially on predators did not show any adverse effect on beneficial invertebrates (lady bird beetles and spiders) and the effects on non-target organisms were negligible in comparison to those of conventional insecticides which was in line with the findings by other workers across the world (Clark *et al*., 2005; Marvier *et al*., 2007; Babendreier *et al*., 2008; Chen *et al*., 2008; Lawo *et al*., 2009; Naranjo, 2009).

However, since Bt cotton is grown primarily for its fibre, more elaborate studies on dermatological effects of Bt cotton fibre *per se* would have been desirable. This would have been more in line with the case-by-case concept of risk assessment in view of its end use. It must be mentioned though that no authenticated cases of skin allergy with the use of GM cotton fibre have been reported so far.

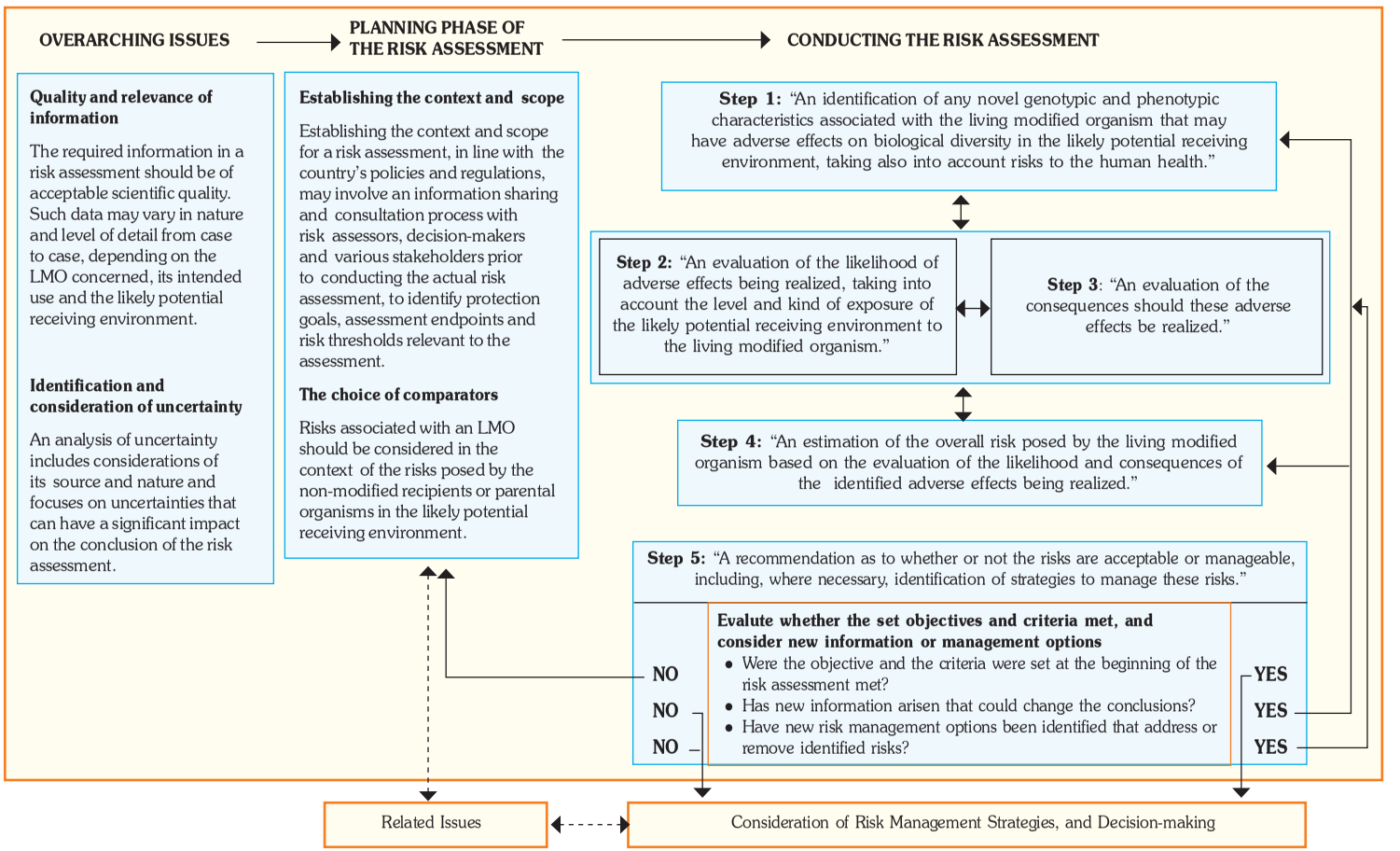

Figure 3. The Roadmap for Risk Assessment

The flowchart illustrates the risk assessment process, which includes " Overarching issues", Planning phase of the assessment" and" Conducting the risk assessment", to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health. As results are gathered at each step and new information arises, risk assessments may need to be conducted in an iterative manner, where certain steps may be revisited as shown by the solid and double-headed arrows. The box around steps 2 and 3 shows that these steps may sometimes be considered simultaneously or in reverse order. Dotted arrows indicate the flow to and from issues outside the risk assessment process. (from the Guidance on Risk Assessment of LMOs available at: http://bch.cbd.int/protocol/testing_guidance_RA.shtml)

4.2 Case Study II: Round-up Ready Canola in Australia

GM herbicide-tolerant canola was approved by Australia's Gene Technology Regulator in 2003 for commercial release and started to be grown commercially for the first time in 2008 (Holtzapffel, *et al*., 2008). The following section summarizes the risk assessment and risk management plan (RARMP) for commercial release of GM canola conducted by Bayer Crop Science Pvt Ltd. and detailed at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR021-2002.

Box 2: Summary of Risk Assessment and Risk Management Plan DIR 021/2002 for Commercial Release of Genetically Modified (InVigor® hybrid) Canola by Bayer Crop Science Pvt Ltd

The Regulator took into account all matters relevant to the protection of human health and safety and the environment that were raised during the consultation process in finalising the RARMP for application number DIR 021/2002.

Application

Bayer applied for a licence (application number DIR 021/2002) for the commercial release of seven similar GM 'lines' of canola: T45, Topas19/2, MS1, RF1, RF2, RF3 and MS8. Lines MS1, MS8, RF1, RF2 and RF3, and hybrids derived from MS x RF crosses, covered by the registered trade name I*nVigor*® canola. The term 'line' has been used throughout this risk assessment. 'Line' is used to denote canola with a specific genetic modification derived from a single transformation event.

The GM canola from the proposed release would be used as oil in human food, or in animal feed, in the same way as conventional (non-GM) canola. All seven lines are approved for growing and human consumption in the USA and Canada, and oil derived from all seven canola lines has been approved for use in human food in Australia (ANZFA 2001).

The hybrid canola seed which Bayer sought to commercialize in Australia as *InVigor*® canola was produced with a novel hybrid generation system. This system was based on two genetically modified 'parent' lines of canola: a male sterile (MS) line that contained a male sterility gene (*barnase*), and a fertility restorer (RF) line containing a fertility restorer gene (*barstar*). The development of the pollen-producing parts of canola flowers (anthers) are suppressed in MS plants. Crossing an MS line with an RF line overrides the suppression and makes the progeny fertile. The progeny was expected to have enhanced agronomic performance, otherwise known as 'hybrid vigour'.

All seven GM canola lines included a gene that confers tolerance to the herbicide glufosinate ammonium enabling its use for control of weeds in the GM canola crop.

The Australian Pesticides and Veterinary Medicines Authority (APVMA), granted Bayer registration of glufosinate ammonium for use on *InVigor*® canola under the trade name Liberty®. The APVMA has registered Liberty® for use only *InVigor*® canola crops, not for weed control in other crops.

Under the system overseen by the Genetic Manipulation Advisory Committee (GMAC), Bayer conducted 14 field trials (PR62, PR63 and extensions) with all seven GM canola lines in Queensland, New South Wales, Victoria, Tasmania, South Australia and Western Australia.

In addition, the Regulator issued a licence on 30 July 2002 to Bayer (DIR010/2002) to conduct a limited and controlled release of the same GM canola lines at 30 trial sites, totaling 106 hectares, in New South Wales, Victoria and South Australia for the summer and winter growing seasons in the three years from 2002-03. There were no adverse effects reported on human health or the environment from any of these releases.

The evaluation process

Licence application DIR 021/2002 from Bayer was evaluated, and a risk assessment and risk management plan (RARMP) prepared, in accordance with the Act and the Regulations, using a Risk Analysis Framework. This framework was developed by the Regulator in consultation with the public and key local, State, Territory and Commonwealth government stakeholders and the Gene Technology Technical Advisory Committee (OGTR, 2005).

Through the risk assessment process, potential hazards to human health and safety or the environment that may be posed by the commercial release of the Bayer canola were identified. These were evaluated on the basis of the likelihood of each hazard occurring and the likely impact of the hazard, were it to be realized. These hazards were considered and evaluated previously for limited and controlled trials with the same GM canola under licence application DIR 010/2001 and were reassessed for this release to determine whether the proposed commercial scale, and the removal of specific licence conditions to limit the movement of the GMOs and the introduced genes, posed any additional risks. The identified potential hazards relate to:

- Toxicity and allergenicity for human and other organisms
- Weediness
- Transfer of introduced genes to other organisms
- Herbicide resistance

Conclusions of the risk assessment

The Regulator considered that the risks to human health and safety, or to the Australian environment, from the commercial release of any of Bayer's seven GM canola lines were no greater than those posed by non-GM canola i.e. they were as safe as conventional canola. The assessment of each identified potential hazard is summarized under a separate heading below.

Toxicity or allergenicity to humans and other organisms

The GM canola lines were very unlikely to prove more toxic or allergenic to humans or other organisms than conventional canola. Therefore, the risks were considered negligible and it was not considered necessary to impose any management conditions in relation to potential toxicity or allergenicity. As noted above, FSANZ had previously approved the use in food of oil from the seven GM canola lines, concluding that products from these GM canolas are as safe as are those from non-GM canola.

Weediness

The risk of the genetic modifications making this GM canola more invasive or persistent than conventional canola in Australia was negligible.

The growth characteristics and agronomic performance of the seven GM canola lines were within the range of conventional canola. The hybrid vigour displayed in *InVigor*®

canola hybrids was not a function of the genetic modification, resulted from the breeding of the two genetically distinct parents. The growth characteristics and agronomic performance of *InVigor*® canola hybrids were within the range of conventional canola hybrids.

The introduced genes did not confer a selective advantage in the absence of the herbicide glufosinate ammonium. Glufosinate ammonium was not registered for use in any broad-acre agriculture except on Bayer's GM *InVigor*® canola. It was used in viticulture and horticulture but was rarely used in non-agricultural areas.

Therefore, it was not considered necessary to impose any conditions to manage the risk of weediness.

Transfer of introduced genes to other organisms

The introduced genes did not confer any selective advantage in the absence of the herbicide glufosinate ammonium. The hybrid vigour displayed in *InVigor*® canola hybrids was not a function of the genetic modification that could be transferred as a single trait, but was a result of the breeding of the two genetically distinct parents.

The likelihood of some gene transfer from the GM canola to other cultivated canola was high but diminishes rapidly away from close proximity to the crop. The likelihood of some transfer of the introduced genes to the closely related weedy *Brassica* species *B. rapa* and *B. juncea* was high, although less than for conventional (non-GM) canola. However, due to the lower incidence of these species and the reduced 'fitness' of any progeny eg. vigour, fertility etc., the overall frequency and persistence were considerably low.

The likelihood of transfer of the introduced genes from the GM canola to the less closely related brassicaceous weed species *Raphanus raphanistrum, Hirschfeldia incana* and *Sinapis arvensis* was very low, because of genome incompatibility and the severely reduced fitness of any progeny and no additional management practices would be needed to control any transgenic hybrids, if they occur, and management strategies would be the same as for other brassicaceous weeds.

The likelihood of gene transfer to any other brassicaceous species was also considered negligible. Even if gene transfer to these species did occur, it would not pose any additional risks for the control of these weeds.

The likelihood of transfer of the introduced genes to other organisms was negligible, but even if such transfer did occur it would be unlikely to pose any hazard to human health and safety or to the environment.

Herbicide resistance

There was a potential for development of herbicide-resistant weeds if the InVigor® crop-Liberty® herbicide combination is used inappropriately. The APVMA noted that the resistance management plan contained in Bayer's *InVigor® Canola Crop Management Plan* was an essential part of managing herbicide resistance to glufosinate ammonium. The APVMA required that the plan be available to all users of Liberty® herbicide. The APVMA had regulatory responsibility and had stipulated a number of conditions on the use of Liberty® herbicide on *InVigor*® canola crops. Therefore, no herbicide resistance management conditions were required under the Gene Technology Act 2000.

The risk management plan (key licence conditions)

The Regulator considered that the proposed release did not pose risks to the health and safety of people or the environment in Australia that require management through specific licence conditions. Accordingly, the licence the Regulator issued in respect of the Bayer application DIR 021/2002 contained only minimal oversight conditions. The key licence conditions are outlined below.

Toxicity or allergenicity to humans and other organisms

Based on the risk assessment, no management conditions were imposed in relation to toxicity or allergenicity.

Weediness

Based on the risk assessment no management conditions were imposed in relation to weediness.

Transfer of introduced genes to other organisms

Based on the risk assessment no management conditions were imposed in relation to the transfer of introduced genes to other organisms. The licence includes a condition that required the applicant to provide the Regulator with a testing methodology that was able to reliably detect the presence of each of the GMOs or their genetic material.

Herbicide resistance

No conditions were imposed in relation to the management of herbicide resistance, as this was the responsibility of the APVMA. The licence holder's obligation to comply with any conditions imposed by the APVMA was noted in the licence.

Reporting conditions

Bayer sought regulatory approval for seven GM canola lines, although it had indicated that only lines RF3 and MS8 would be commercialized in Australia as *InVigor*® canola. The licence included a condition that Bayer report to the Regulator the amount of each GM canola line sold commercially or otherwise grown in each growing season for each State and Territory.

Licence decision

On July 25, 2003 the Regulator issued a licence to Bayer Crop Science Pvt Ltd (Bayer) approving the commercial release of genetically modified (GM) *InVigor*® hybrid canola, including lines T45, Topas19/2, MS1, RF1, RF2, RF3 and MS8.

Monitoring and enforcement of compliance by the OGTR

The Regulator can direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people or the environment. In this regard, the reporting requirements imposed by the licence conditions would enable the Regulator to monitor and review the progress of all commercial releases of GM crops in Australia.

(*Source:* http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR021-2002)

Perusal of the above case reveals that the risk assessment process involved identification of potential hazards to human health and safety or to environment that may be posed by the commercial release of the Bayer HT canola. The identified potential hazards relate to toxicity and allergenicity for human and other organisms; weediness; transfer of introduced genes to other organisms and development of herbicide resistance. The GM canola was not expected to have any additional weediness traits and would be as susceptible to environmental stresses (such as climate and disease) as non-GM canola (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir108-3/$FILE/dir108qa3.pdf). Canola plants with tolerance to both glufosinate ammonium and glyphosate could still be controlled by other approved herbicides or mechanical means. Some transfer of the introduced genes could occur to a small number of compatible plants at low levels. Even if this did occur, it would not pose a risk to people or the environment. Weeds which acquire the herbicide tolerance genes only have a survival advantage when glyphosate and/or glufosinate ammonium is used to control them. The plants remained susceptible to all other approved herbicides, cultivation practices and other environmental factors (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/fact-roadside-canola2013-htm).

4.3 Case Study III: Rose with Altered Colour in Australia

Florigene Pty Ltd (Florigene) received approval for the commercial release of one line of GM Hybrid Tea rose (*Rosa x hybrida*) into the Australian environment. This is a classic example of a GM crop developed purely for aesthetic purposes and Florigene intended to grow GM rose plants and handle their products (i.e. cut-flowers) in the same manner as non-GM rose plants. Flowers that are produced would be sold through normal commercial distribution channels to the public, Australia-wide (OGTR, 2009). The following section (Box 3) deals with the risk assessment and management plan for GM tea rose by Florigene Pty Ltd.

Box 3: Summary of the Risk Assessment and Management Plan for Application No. DIR 090 on GM Hybrid Tea Rose from Florigene Pty Ltd

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 (the Regulations) and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether to issue a licence to deal with a GMO. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public.

Application

Florigene applied for a licence for dealings involving the intentional release of one line of GM Hybrid Tea rose (Rosa x hybrida) into the Australian environment.

The GM rose line contained two genes that have been shown to alter flower colour from pink to purple/blue: the *Flavonoid 3'5'-hydroxylase (F3'5'H)* gene from *Viola x wittrockiana* and the *Anthocyanin 5-acyltransferase (5AT)* gene from *Torenia x hybrida*. In addition, the line contains an antibiotic resistance gene (*nptII*), which provides resistance to the antibiotic kanamycin and was used for the selection of transformed plants in the laboratory.

The GM rose line approved for commercial release was one of three lines that were approved for a limited and controlled release (see DIR 060/2005) under the current regulatory system. There have been no reports of adverse effects on human health and safety or the environment resulting from this release.

The purpose of the release is the ongoing commercial propagation of parent plants and the growing of plants for cut-flowers. Florigene intends to grow GM rose plants and handle their products (i.e., cut-flowers) in the same manner as non-GM rose plants. Parent plants and plants for cut-flowers would be grown by one or more growers registered with Florigene. Flowers that are produced would be sold through normal commercial distribution channels to the public, Australia-wide.

Risk assessment

The risk assessment considered information contained in the application, relevant previous approvals, current scientific knowledge, and advice received from a wide range of experts, agencies and authorities on the application and the consultation RARMP. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

Similarly, advice received from the public on the consultation RARMP was considered. A reference document on the parent organism, *The Biology of Hybrid Tea Rose* (Rosa *x* hybrida) was produced to inform the risk assessment process for licence applications involving GM rose plants. The document is available from the OGTR or the OGTR website.

The risk assessment began with a hazard identification process to consider what harm to the health and safety of people or the environment could arise during this release of GMOs due to gene technology, and how it could happen, in comparison to the non-GM parent organism and in the context of the proposed receiving environment.

In taking into account a potential risk, the Regulator considered the probability and/or impact of an adverse outcome over the foreseeable future.

Seven events were identified whereby the proposed dealings might give rise to harm to people or the environment. This included consideration of whether, or not, expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM plants; or produce unintended changes in their biochemistry, physiology or ecology. The opportunity for gene flow to other organisms and its effects if this occurred was also assessed.

A risk was only identified when a hazard is considered to have some chance of causing harm. Events that do not lead to an adverse outcome, or could not reasonably occur, do not represent an identified risk and do not advance any further in the risk assessment process.

The characterisation of the seven events in relation to both the magnitude and probability of harm did not give rise to any identified risks that required further assessment. The principal reasons for this include:

- the proteins encoded by the introduced genes are widespread in the environment and unlikely to be toxic/allergenic to people or toxic to other organisms

- the levels of delphinidin and myricetin end products in the GM rose line are within the ranges found normally in non-GM plants
- the genetic modifications are not expected to affect the survival or low weediness potential of the GM lines
- the low fertility of the non-GM rose parent organism is not expected to be altered by the introduced genes
- a range of morphological and physiological characteristics have been compared in the GM line and the non-GM parent and no differences have been detected apart from flower colour
- plants of the GM rose line have now been grown for several years without any unintended changes being detected.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed commercial release of the GM rose line into the environment are considered to be negligible. Hence, the Regulator considered that the dealings involved in this proposed commercial release do not pose a significant risk to either people or the environment.

Risk management

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people and/or the environment. As none of the seven events characterized in the risk assessment are considered to give rise to an identified risk, either in the short term or the long term, that requires further assessment, the level of risk is considered to be negligible**.**

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. Nonetheless, as part of the Regulator's oversight of licensed dealings involving the release of genetically modified organisms, the licence contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by other agencies that also regulate GMOs or GM products including Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Quarantine and Inspection Service (AQIS).

FSANZ is responsible for human food safety assessment, including GM food. It is not intended that any material from the GM rose lines be sold for human food. Accordingly the applicant has not applied to FSANZ for evaluation of the GM rose line for use in human food. FSANZ approval would need to be obtained before any products from the GM rose line is sold for food.

Conclusions of the RARMP

The risk assessment concludes that this commercial release of one GM rose line, Australia-wide, poses negligible risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concludes that these negligible risks do not require specific risk treatment measures. However, general conditions have been imposed to ensure that there is safe oversight of the ongoing release

The Gene Technology Regulator (the Regulator) made a decision to issue a licence for dealings involving the intentional, commercial scale release of a rose line genetically modified (GM) for altered flower colour in respect of application DIR 090 from Florigene Pty Ltd.

(Source: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir090-3/$FILE/dir090rarmp.pdf)

Since blue rose was developed for aesthetic purposes, the RARMP included consideration of expression of the introduced genes resulting in products toxic or allergenic to people or other organisms; altered characteristics impacting their spread and persistence; or unintended changes produced in them. The opportunity for gene flow to other organisms and its effects if this occurred was also assessed. Since the risk posed was considerably less that any food/ feed crop, the RARMP was tailored according to the risk posed.

The RARMP concluded that the proposed release posed negligible risks to people and the environment, and that specific risk treatment measures were not required. Nonetheless, general license conditions were imposed to ensure that there is no ongoing oversight of the release.

4.4 Case Study IV: Genetically Modified Rainbow Papaya in Japan

GM papayas are the first GM fruit to enter the Japanese market for consumption in an unprocessed form. The Food Safety Commission of Japan (FSCJ) assessed the GM papayas and allowed their import as food in 2011. The following section (Box 4) summarizes the sequence of regulatory approvals for Hawaiian ring-spot virus resistant papaya for release into Japan details of which are given at http://www.gmo-compass.org/eng/news/515.japan_allows_genetically_modified_papayas.htm.

Box 4: Summary of the Regulatory Approvals for Hawaiian GM Papaya in Japan by Hawaii Papaya Industry Association

In 1999, the Hawaii Papaya Industry Association (HPIA) applied for regulatory approval GM papaya in Japan with a formal submission to the Ministry of Health Labour and Welfare, and the Ministry of Agriculture, Forestry and Fisheries. This process required an evaluation of the environmental impact, a full food-safety evaluation, and an approval of HPIA's identity preservation procedures.

In the case of GM papaya (event name, 55-1), a short sequence of the PRSV's coat protein (protein at the surface of virus membrane) was combined with a marker and other necessary genes, and then inserted into papaya genome through the use of a 'gene gun', a

device used to transform plants by injecting cells with particles of heavy metal coated with new genetic materials. For the development of PRSV resistant papaya, Sunset, a solo type papaya was used as the host plant. The first generation of recombinant papaya was named 55-1 and subjected to regulatory review in the United States and Japan. "Rainbow" papaya, a commercial GM papaya resistant to PRSV, is developed by conventional breeding of 55-1 and non-GM solo type papaya. The generation diagram shown below details this development.

Japan mandates the labelling of all GM-derived products. At the same time, to claim the products are non-GM, the identity of the product has to be preserved throughout the process, from the beginning (farm) to the end (retail shelf), even though the labelling as non-GM is not mandatory. In case of GM papaya, the product is a consumer-ready fruit. For shipment, several fruit would be packed into a box and the volume of trade would be significantly smaller compared with bulk products. In addition, the scale of specialty crop production is much smaller than grains, and it may be a financial burden for the industry to practice Identity Preservation Programme (IPP) of non-GM and GM papaya based on laborious documentation. As the result of close communication between Japan's Consumer Affairs Agency, the Hawaii Papaya Industry Association, the Hawaii Department of Agriculture, and FAS Tokyo, the industry agreed to apply labelling to individual fruit. By placing labels to indicate GM or non-GM throughout the process, the label on individual fruit functions as IPP, preserving its identity. Therefore, the industry did not have to use other resources to prepare documentation for each shipment.

After nearly 12 years of navigating the Government of Japan's biotechnology regulatory system, full approval of GM papaya from GOJ was granted on September 1, 2011, and commercial imports into Japan were permitted starting December 1, 2011.

Timeline of events:

- October 29, 1999 – Submission to Ministry of Health and Welfare and MAFF
- July 1, 2003 – Establishment of Food Safety Commission
- August 18, 2004 – Re-submission of the environmental safety review under Cartagena Law to MAFF/MOE
- October 6, 2005 – First discussion in Expert Subcommittee group of MAFF/MOE
- January 26, 2006 – Re-submission to MHLW. Food safety review by FSC started
- February 27, 2006 – First review by FSC"s GM Food Expert Group at 37th meeting
- March 17, 2008 – Second review by the expert group at 60th meeting
- May 19, 2009 – Final review by the expert group at 70th meeting and safety approved
- May 28, 2009 – Draft review report from FSC
- May 28 – June 26, 2009 - Public comment

The first step of regulatory approval for Rainbow Papaya was submitted to Government of Japan (GOJ) was on March 1999 for the Stage-3 field trial for environmental risk assessment in Japanese soil. On July 2009, Food Safety Commission (FSC) finalized the risk assessment report and concluded that the product was, "…unlikely to negatively affect human health", a significant step to full approval. On December 1, 2011, Rainbow Papaya was fully de-regulated by GOJ after 12 years since its first official submission.

Source: http://www.gmo-compass.org/eng/news/515.japan_allows_genetically_modified_papayas.html

Although Japan has provided for the option of seeking "import only" approval, the level of risk assessment data required for such approval (e.g., for food, feed and processing) is practically the same as the one for intentional release into the environment (e.g., planting as a commercial crop), because MAFF still reviews the effect on biodiversity in case of spillage during transportation. Further, Japan is one of the few countries requiring field trials in domestic soil to assess the effect of GM crop "release" to local biodiversity irrespective of the intended use. International standard-setting bodies for agricultural biotechnology generally do not consider domestic field trials as a necessary step for food safety or environmental risk assessment. So far, there are only two countries, Japan and China, who require domestic field trials for GM crops intended only for import (USDA, 2013). Japan is also the first country to stipulate the labelling of the GM papayas (http://www.gmo-compass.org/eng/news/515.japan_allows_genetically_modified_papayas.html).

4.5 Case Study V: Bt Brinjal in Bangladesh

Bt brinjal or eggplant carries an additional gene that provides an in-built insect protection against fruit and shoot borer (FSB) *Leucinodes orbonalis*, a serious constraint in brinjal production. The Indian seed company MAHYCO developed a new DNA construct encoding insecticidal protein in all parts of brinjal plant throughout its life. The following section (Box 5) summarizes the risk assessment procedure followed in Bangladesh for release of Bt brinjal.

Box 5: Summary of the Risk Assessment Procedure for release of Bt Brinjal (Begun/ Eggplant) in Bangladesh by MAHYCO

Seeds of Bt brinjal were imported (with the approval of the Bangladeshi government) from Mahyco Seed Research Centre, Maharashtra Hybrid Seed Company Ltd, Jalna, India.

- The seed was grown in a sophisticated isolated contained field (i.e., greenhouses) at Bangladesh Agricultural Research Institute (BARI) and its seven regional agricultural research stations in Rangpur, Jessore, Mymensingh, Tangail, Bogra, Dinajpur, and Jamalpur districts. The plots were marked with wire mesh net which was alienated and no same species of crops were permitted to grow within the 200m isolation distance.
- Trial results suggested a sizeable yield increase in Bt brinjal plots. On average the pest force of FSB was significantly reduced on Bt plots. The average shoot damage as well as the fruit infestation in Bt hybrids was far lower than that in non-Bt brinjal.
- In addition to growth and pest studies, a variety of safety studies were conducted for Bt brinjal at BARI in order to comply with the Bangladeshi regulatory process. Data from such studies demonstrate that the protein which is inserted into genes causes no adverse effects on humans, wild and domesticated animals, birds, fishes and non-target insects, including beneficial insects. The safety of Bt proteins is attributed to the mode of action, specificity and digestibilit.
- Tests conducted to ensure that Bt brinjal is safe for human consumption showed that Bt brinjal is substantially equivalent to food and feed from non-Bt brinjals.
- The safety of Bt brinjal was also tested in various feeding studies (including among others chicken, cow and fish,) and no toxicity was detected and no new allergenic compounds were found due to feeding Bt brinjal.

- A chicken feeding study was conducted at BARI, Gazipur. The study showed that body weight gain, feed intake and feed conversion ratio did not differ among Bt and non-Bt treatments. Several blood biochemical constituents did not differ statistically due to dietary treatments including Bt and non-Bt brinjal incorporated diets. This study found Bt brinjal to be as safe as non-transgenic brinjal.
- Various cow feeding studies were conducted to assess the nutritional value of transgenic Bt brinjal fruit in comparison to non-transgenic (non-Bt) brinjal fruit in lactating cows in terms of feed intake, milk production and milk composition and to determine if the Bt protein was detectable in milk and blood of lactating cows fed ration containing transgenic brinjal fruits. From the study, it was concluded that the nutritional value of both transgenic and non-transgenic brinjal fruits were similar in terms of feed intake, milk yield and milk constituents without any adverse effect on health of lactating cows.
- A fish feeding study was conducted at Central Institute of Fisheries Education, Bangladesh Agricultural University in Mymensingh. The objective of this study was to evaluate Bt brinjal as a feed ingredient for common carp and to study the comparative growth and survival of fish fed with Bt brinjal. The study found that fish fed with Bt brinjal showed similar growth patterns to those fed with non-transgenic brinjal. There were no significant differences in terms of food conversion ratio, feed efficiency ratio and protein efficiency ratio among Bt and non-Bt brinjal treatments. Bt brinjal and non-Bt brinjal were found to be statistically similar in terms of fish growth responses and histopathological alterations in common carp.
- Finally, Bt brinjal fruits were used to determine whether the Bt protein was present in cooked fruits. The Bt protein was undetectable in cooked fruits. This study indicates that the Cry1Ac protein in Bt brinjal fruits is rapidly degraded upon cooking.
- Based on these results, a series of consultations and focus group discussions with scientific, agricultural, and regulatory experts were conducted in Bangladesh in July 2007, focusing on the potential effects of biotechnology improvements to resist biotic and abiotic stresses. The status of research, agricultural constraints, the potential of biotechnology, and other issues related to regulatory approval and consumer acceptance of transgenic crops were discussed with relevant experts.
- Questionnaires were provided among the participants in order to elicit subjective estimates of potential yield and input effects of future new technologies. In parallel, existing national and international studies of GM technology, productivity constraints, and technology potential were obtained.

(*Source:* Meherunnahar and Paul, 2009; ISAAA, 2014)

4.6 Conclusion

The five case studies elaborated above have been chosen to demonstrate the risk assessment approaches followed by regulatory authorities in some Asia-Pacific countries for approval of GM crops for different end uses. Bt cotton is a classic success story of GM technology adoption at a large scale. GM canola was considered for the herbicide tolerance, however, its end use is oil which does not contain the protein and, therefore, poses lower risk to human health. Blue rose

developed for its altered colour is ornamental and end use would only be for aesthetic purposes. Rainbow papaya fruit was approved for direct use as food and for placing in the market.

These case studies highlight the broad similarity among the risk assessment criteria being followed by different countries. However, developments during the last few years with respect to approval of Bt brinjal in Bangladesh, India and the Philippines also point to the differences in approval process.

Bt brinjal submitted for regulatory approval in India, Bangladesh and the Philippines has the same proprietary gene *Cry1Ac* developed by Mahyco and transferred to BARI and Philippines way back in 2005-06 through a USAID-funded and Cornell University-managed 'Agricultural Biotechnology Support Project' (http://www.thehindubusinessline.com/industry-and-economy/agri-biz/bt-brinjal-gets-bangladesh-nod-for-commercial-cultivation/article5301651.ece; Akter, 2014).

In India, after the biosafety studies were conducted and submitted to the regulatory authorities, an expert committee (EC-I) was set up in 2006 to examine the data presented by Mahyco, which recommended that large scale trials be allowed to go ahead. In 2009, a second expert committee (EC-II) examined the data from these trials and recommended its commercialization on October 14, 2009. However, on October 15, 2009 the then State Minister of Ministry of Environment and Forests intervened to stop the approval process because of the nationwide criticism of the EC-II and the apparent haste with which the Genetic Engineering, Appraisal Committee (GEAC) gave its consent. Thereafter, nation-wide consultation with farmers groups and environmentalists followed and the minister declared an indefinite moratorium on February 9, 2010 on the commercial approval of Bt Brinjal, citing the inadequacy of the risk assessment conducted and the need for further safety testing (MoEF, 2010).

On the same lines, in the Philippines too, a group of scientists, farmers, and concerned individuals filed a writ petition in the Supreme Court, the Writ of Kalikasan, to stop the government from introducing GM brinjal into Philippine soil, citing health and environmental hazards. On May 17, 2013, the Court ruled "Field trials of Bt talong could not be declared by this Court as safe to human health, and to our ecology, with full scientific certainty, it being an alteration of an otherwise natural state of affairs in our ecology." On September 20, 2013 the Court of Appeals (CA) upheld the earlier ruling, denying field testing for the plants, thus preventing the government from conducting field testing of GM, brinjal the first step for initiating the risk assessment process (Akter, 2014).

However, Bt Brinjal was approved by the National Committee on Biosafety (NCB) in Bangladesh for limited scale cultivation by farmers. In an October 30, 2013 notification, the Ministry of Environment and Forestry provisionally approved the petition of Bangladesh Agricultural Research Council (BARC) to cultivate four varieties on a limited scale, at the field level with several conditions. After its initial release in 2013, there were protests in Bangladesh similar to those in India and the Philippines. However, on January 16, 2014 Bangladesh formally approved the cultivation of Bt brinjal and BARI distributed saplings of the new crop among farmers of four regions. As a safety precaution, it was decided to observe the performance of Bt brinjal for three more years before commercially releasing the Bt varieties. (http://www.dhakatribune.com/long-form/2014/jan/16/approval-bt-brinjal-india-bangladesh#sthash.DDbgLfF8.dpuf; ISAAA, 2014).

The release of Bt brinjal in Bangladesh has raised the issue of contrasting perception of risk vis-à-vis the acceptance of risk assessment data among regulators in similar Asian countries.

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Chapter 5

TRADE-RELATED ISSUES IN GM CROPS

Transboundary movement of GM crops is primarily governed by the Cartagena Protocol on Biosafety (the Protocol), the binding international legal instrument which establishes procedures for safe transport, handling, and use of LMOs as per the Article 19.3 of the CBD. In addition, to the provisions for "transboundary movement" within its procedures for the safe transportation of LMOs, of particular concern is the Protocol's procedure for agreement prior to movement of LMO, which calls for prior assessment of detrimental impact on the importing country based on information disclosure and public participation (Chapter 2). This provision also recognizes the importing country's right to decide whether to accept or refuse importation. In making this decision, the Protocol allows a "precautionary approach" to be used. The Protocol also deems importation to be declined should measures sought by the importing country fail to be taken (Article 9.4, Article 10.5 and Article 11.7). This is also a reflection of the "precautionary approach". With the single exception of LMOs that are used as pharmaceuticals for humans and are addressed by other relevant international agreements or organizations, all transboundary movements, transit, handling and use of LMOs are within the scope of the Protocol.

Among other provisions, the Protocol also foresees: a) the requirement for countries to finalize an advance informed agreement with the receiving country before any intentional transboundary movement of LMOs for intentional introduction into the environment of the importing country; and b) the requirement for countries authorizing the domestic use of LMOs in their territory through the Biosafety Clearing House if the transboundary movement of the LMOs is for direct use as food or feed, or for processing. The Protocol also requires that environmental risk assessments be carried out for the LMOs implicated in both cases described above (CBD, 2014).

Countries' positions on trade in GM crops depend on many factors, such as their policy awareness, the level of risk they are willing to accept, their capacity to carry out risk assessments in the sector and implement adequate legislation, their perception of the benefits they could gain, their dependence on agricultural exports, their reliance on food aid, and the investments they have already made in the sector (Zarrilli, 2005). For instance, EU Directive 90/220/EEC on the deliberate release of GMOs into the environment governed for over a decade the approval, planting, and marketing of GM foods and crops within the EU. Directive 90/220/EEC was later supplemented by Regulation 258/97; the so-called Novel Foods Regulation. The Novel Foods here were defined as all foods and food ingredients that had not been used for human consumption to a significant degree within the EU and included both foods that were GM as well as foods produced from, but not containing GMOs. The regulation established an authorisation procedure similar to that of the directive, as well as labelling requirements for all approved GMOs used in food and foodstuffs. Moreover, the regulation contains a safeguard clause allowing EU member states, to temporarily restrict or suspend the trade in and use of the food or food ingredient in question in their territory as a result of new information or a reassessment of existing information (Kaditi, 2009).

From an international trade perspective, the major preoccupation of GM producing and exporting countries is to have easy and reliable access to foreign markets for the GMOs they

have already developed and for those they might develop in the future. The international policy differences about GMOs is creating a divided international market, dependence on economies of scale to recoup the considerable research and development costs the developers incur (Philips and Kerr, 2000). Moreover, the rate of technological advance in biotechnology is likely to be rapid in future, meaning that the commercial life of any new GMO is likely to be short. This means that easy and quick access to foreign markets is a critical determinant for profitability in trade.

There are several trade related issues to be addressed or being addressed by trading partners for safe transboundary movement of GM products as elaborated below:

5.1 Labelling of GM Products

During the last fifteen years, more than 40 countries have adopted labelling regulations, but the characteristics of the regulations and their degree of implementation vary greatly (Phillips & McNeill, 2000; Carter & Gruère, 2003; Haigh, 2004, Gruère and Rao, 2007). While a large majority of countries belonging to OECD having implemented some type of labelling policy, only a few countries in Asia-Pacific region have introduced labelling laws, and even fewer have implemented them.

The Codex Alimentarius Commission is the body that determines international standards for foods. It has had several focuses for its studies including labelling of GM foods and ingredients (Codex Committee on Food Labelling). The Codex Committee on Food Labelling has discussed two options: 1) an obligation to indicate "different composition, nutritional value or intended use from conventional food products" when there are substantial changes from conventional food products that would warrant informing consumers about composition, nutritional value, and intended use, but not requiring indications of GM foods *per se;* and 2) in addition to Option 1 above, obligating indications that foods and food ingredients are GMOs. The United States, Canada, and Australia support Option 1, and the EU and Japan support Option 2. In other words, the countries engaged in commercial cultivation of GM agricultural products support Option 1 while other countries support Option 2. Wide gaps between the countries supporting the two different options continue to be evident (Gruère and Rao, 2007, http://www.meti.go.jp/english/report/downloadfiles/gCT0118e.pdf).

Labelling is mandatory for these products in countries with regulations as they recognize that consumers should be informed of the novel traits and properties of the food products in order to make informed decisions. On the other hand, for products that are considered substantially equivalent to their conventional counterparts, which includes products derived from all transgenic crops with input-related traits (i.e., virtually all GM products today), there is a large international heterogeneity in labelling regulations.

The EU labelling and traceability requirements are laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003, covering all GMOs that have received EU authorisation for their placing on the market, namely all products containing or consisting of GMOs, including food and feed (Kaditi, 2009). In comparison, the US has no special laws that specifically apply to GM foods. The biotechnology approval process involves three departments: the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). However, biotechnology companies are only required to consult the FDA as they bring new biotechnology products to market, so long as the added genes do not substantially change the nature of the foods. Labelling is also not required (Hobbs and Kerr, 2006).

In the Asia Pacific region, a major dichotomy separates countries with voluntary labelling guidelines (e.g., Hong Kong) from those with mandatory labelling requirements (e.g., Australia, Japan and China). Voluntary labelling guidelines dictate rules that define what food can be called GM or non-GM, and allows the food companies to decide if they want to use such information on their products. In contrast, mandatory labelling requires food companies (processors, retailers, and sometimes food producers) to display whether the targeted product/ingredient contains or is derived from GM materials. A certain number of countries with mandatory labelling for GM ingredients also have voluntary guidelines for the labelling of non-GM food (e.g., Japan). This mixed mandatory/voluntary system is in place in countries with mandatory labelling for which consumers are willing to pay a premium to completely avoid GM ingredients, even at a residual level (Gruère, *et al.*, 2007).

Table 4. Labelling requirements in various Asia Pacific Countries

Countries	Labelling requirement
Australia, New Zealand	Mandatory for all GM food and ingredients (containing novel DNA and/or novel protein in final product, or having altered characteristics). Foods derived from but no longer containing GMOs are exempted from labelling
Japan	Mandatory for all GM food and ingredients. Japan, presently, has seven mandatory and 22 voluntary labelling requirements
China	Mandatory labelling for five listed GM products: soybean, corn seeds, rapeseeds, cotton seeds and tomato seeds.
Malaysia, South Korea and Taiwan	Mandatory labelling enforced
India	Mandatory for packaged food with GM ingredients. Nineteen commodities notified include baby food, biscuits, breads, edible oils, milk powder, cereals and pulses announced by the government.
Hong Kong	Voluntary labelling
Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates and Yemen	Labelling standard under the Gulf Cooperation Council (GCC) implemented mandatory nutrition labelling
Indonesia, Philippines, Singapore, Sri Lanka, Thailand, Vietnam	Efforts are under way to implement labelling regulations

(Compiled from: Zarelli, 2007, Gruère and Rao, 2007, Leatherhead Food Research, 2014)

In particular, one of the major differences in regulations among countries with mandatory labelling depends on whether the regulation targets the presence of GM in the finished product (like Australia, New Zealand, and Japan) or on GM technology as a production process (like in China). In the former case, only products with detectable and quantifiable traces of GM materials or ingredients are required to carry a label. In contrast, in the latter case, any product derived from GM crops would have to be labelled, whether it contains any traces of GM material or not (Gruère, 2006b). This means that canola or soybean refined oils are required to be labelled even if current detection techniques cannot detect significant traces of transgenic DNA or proteins in the final product.

Gruère and Rao, 2007 divided the countries into three groups according to the relative degree of stringency of their regulations. At one end of the spectrum, a first group of countries

have introduced stringent process, with wide coverage, few exceptions, and a very low threshold, which follows the EU model of labelling regulation. This group includes all European countries (outside of the EU). At the other end of the spectrum, a third group, that includes Canada and the US, has voluntary labelling guidelines for GM or non-GM food. Most of the Asia–Pacific countries with labelling regulations fall in the second and intermediary group, which includes Australia, New Zealand and Japan which have mandatory labelling requirements based on differences in the finished products, with intermediate or higher threshold levels, and a number of exemptions. Other developing countries still have to implement or enforce the regulations. China belong to the EU group while Thailand and Indonesia follow the Japanese type of regulation, and the Philippines follow the US/Canada type of regulation.

5.2 Low Level Adventitious Presence of GM Crops

The low level presence (LLP) and adventitious presence (AP) of GMOs in internationally traded food crops have recently become an issue for discussion. The production (research and commercial use) of GM food crops is increasing in both developed and developing nations, but countries have diverse GMO regulations. Asynchronous approvals (AA) and zero tolerance policies have been reported by some exporters to have a trade alteration effect. Therefore, the FAO conducted a survey and a Technical Consultation to evaluate this issue and an econometric analysis to examine the impact of LLP on trade flows (FAO, 2014a, 2014b, 2014c).

LLP refers to the detection of low levels of GM crops that have been approved in at least one country on the basis of a food safety assessment according to the relevant Codex guidelines (FAO, 2014a). Few examples include 59122 maize (2007) that was already approved for the market in the US, but not in Europe; FP967 linseed (2009) that was already approved for the market in Canada, but not in Europe and Japan; virus-resistant papaya that had already been approved in the US, but not in Europe.

New GMOs are being developed in exporting countries. The regulatory procedures for the approval of GMOs in importing countries may differ from those of exporting third countries, including differences in the time for treating authorisation dossiers. The time it takes for GMO authorisations to be completed in the EU takes more than 2.5 years, as compared with a US average of 15 months. This discrepancy could lead to "asynchronous authorisations", where a GMO is fully approved for commercial use in food and feed in one country, but not in others. The above examples have been linked to an asynchrony of approval systems as in the case of 59122 maize. However, there are also cases in which companies have decided to seek approval for a GM variety in some countries, but (so far) not in others (e.g. FP967 linseed, GM papaya).

AP refers to detection of the unintentional presence of GM crops that have not been approved in any countries on the basis of a food safety assessment according to the relevant Codex guidelines (FAO, 2014a). Some examples include the unintended production of Bt10 maize in relatively large quantities, reported by, Canada, France and the Netherlands; a mixture of low quantities of Bt63, LL601 and KeFeng rice varieties, reported by European countries; and a mixture that included the Amadea potato in potato fields in Sweden in 2010 (Jordbruksverket, 2011).

There are several reasons as to why LLP/AP occurs. Once a GM crop has been released, trace amounts of the crop could become mixed with other varieties of crops at various field stages (including trials), processing, packing, storage and transportation. The movement might stop in

the same country or continue into another country. Furthermore, the GM crop might freely move between provinces, or states within a large country where state-to-state movement is not regulated or different policies towards GM crop approvals have been enforced.

FAO STUDY ON LLP/ AP IN MAIZE

FAO conducted a study (FAO, 2014a) on maize to test the impact of LLP/AP partly because maize is a major commodity subject to trade and also because, in the FAO survey, it was reported as one of the major commodities associated with LLP incidents by the respondents (around 30 incidents in the last 10 years).

This study aimed to examine the current production, trade and regulation issues related to GM crops on a global scale and the impact of LLP/AP of GM crops on trade flow. These issues were evaluated by utilizing available statistics, a related literature review, a survey and an econometric analysis. As the FAO survey highlighted (FAO, 2014c), many responding countries (41 per cent) produce GM crops for commercial or research purposes. However, 49 per cent of the respondents indicated that they have no, or limited, technical capacity to detect GMOs according to Codex guidelines. Therefore, capacity development and technical assistance are essential, particularly for developing countries. Some of the respondents (35 per cent) indicated that they had faced LLP/AP incidents in their imports over the last decade. Given the fact that more countries are producing GM crops every year and there are several GM events in the pipeline, it is probable that more LLP/AP incidents would be observed in future.

The issue of LLP/AP in trade of GM crops contributes to the trade risk between trading partners, unintentional movement of GM crops, and the asynchronous timing of approvals. Employing a bilateral trade flow model and utilizing cross-sectional data, including the responses to the FAO survey, the study found that the restrictiveness of regulations, including zero tolerance, does have a deterrent impact on maize trade. However, the restrictive LLP threshold itself has a limited deterrent effect on bilateral export flows in general.

The FAO survey revealed some incidents reported by importing countries related to LLP/AP. Generally, such situations are handled through rejection or market withdrawals by importers in developed countries, but in some cases consignments were accepted by some developing countries because of the lack of regulation. These incidents may have socio-economic impacts on producers, consumers and agri-business firms. The occurrence of incidents beyond a certain level could lead to income loss for exporters and consequently for producers, and consumers in importing countries can face higher domestic prices when imports are restricted.

The results of the econometric study were similar to previous findings that favour non-zero tolerance policies from the perspective of regulation restrictiveness, but suggest caution in assessing the impact of LLP itself on trade flows because this was estimated to be insignificant in the ad hoc model, while the theoretically robust estimation yielded a negative impact at the margin.

(Source: FAO, 2014a, 2014b and 2014c)

5.3 Maintenance of GM Status

The issue of GM status in the developing countries has several facets. While some countries in Asia-Pacific produce GMOs for domestic consumption, very few export them. However, many of the countries are exporters of conventional agricultural products. Those countries find themselves in a particularly difficult situation: in order to preserve their export opportunities, especially in markets that are sceptical about GM products, they may need to be "GM-free" countries. This means not only that they should not be exporters of GMOs, but also that they should not be producers of GMOs for domestic consumption and not even importers of GMOs. Losing "GM-free" status is perceived by some countries as having negative repercussions for their export opportunities for all agricultural products. This is due to the perception that consumers, especially in Europe, that have adopted a "no-risk" approach, may react negatively towards products that could be linked even remotely to genetic modification. Some trade-diverting effects are apparently already taking place because companies substitute some inputs with others (which do not bear the risk of being GM) or use inputs coming from alternative countries, which are supposed to be "GM-free", to avoid cumbersome documentation and traceability requirements, as well as to meet consumers' expectations, especially in Europe (Gruère, *et al.*, 2007).

Table 5. LLP/AP incidents concerning Asia-Pacific Countries

Reporting country	Imported from	Year	Commodity	How situation was discovered and managed?
Cyprus	**China** via the Netherlands	2007	Rice protein	Control on market and returned to the sender
France	**China**	2006	Rice Bt63	Greenpeace discovered and EU emergency measures taken
	China	2012	Rice Kefeng6 and KMD	Official control and market withdrawal and consumer recall
	Thailand	2012	Papaya	Official control and market withdrawal and consumer recall
	Pakistan/India	2012	Rice OGM	Operator auto control and market withdrawal and consumer recall
Germany	**China, Thailand, Pakistan, India, Philippines**	2003 to 2013	Rice and its products, maize and products, papaya, pet food	Recall, withdrawal and destruction
Iran	Argentina and Brazil	2005 to 2012	Maize and Soy	Discovered during random checks by public research institutes
Japan	USA	2005	Maize (Bt10)	Detected in Japan but notified by exporting country. The consignments tested positive were shipped back and only when consignments tested and certified free from Bt10 they were accepted.
	China	2006, 2007 2008	Rice (powder, noodle)	Testing at the time of importation and consignment rejected
	USA	2008	Maize (DAS59132)	Notified by exporting country. The consignments tested positive were shipped back and only when consignments tested and certified free from DAS59132 they were accepted.
	Canada	2009	Flax (FP967)	Notification by industry, consignments tested and found free from or with <1% FP967 were allowed. If FP967 was detected at <1%, the consignment could be used as feed but only for processing under appropriate measures to limit the contact with the environment. At FP967 >1%, the consignment was rejected
	China	2009, 2011	Rice (powder, noodle)	Tested at time of import and consignments rejected
	Canada	2009, 2010, 2011	Flax seed (roasted/ fresh/granola)	Tested at time of import and consignment rejected
	Chinese Taipei	2011	Papaya	Tested based on information by researcher and recalled unplanted seeds from distributors and all plants germinated from seeds were destroyed
	Vietnam	2011, 2012	Rice noodle	Tested at time of import and consignment rejected

Reporting country	Imported from	Year	Commodity	How situation was discovered and managed?
Netherlands	**China**	2006	Chinese rice (Bt63) in food	Greenpeace/ Friends of the Earth. EU emergency measures taken
New Zealand	USA	2001, 2002	Maize	In-house testing of growing crop by company. Seed testing and field management undertaken
	USA	2004	Maize	Re-testing of seeds from earlier season and grain used as feed rather than food
	USA	2003, 2006	Sweetcorn product	Testing of product in Japan/ Ministry of Primary Industry. Seed tested and unplanted seed and young plants destroyed.
Norway	**China**	2008	JiangXi rice vermicelli	Compulsory testing by authorities
		2012	Dongguan Rice Vermicelli	Consignment held and rejected after testing, notified in the European RASFF system
		2012	Oriental rice cracker mix	
	United States (origin **Thailand**)	2010	Rice Mix	Testing under national surveillance programme. The product was not allowed to sell and findings notified in the European RASFF-system.
Philippines		2006	Liberty Link rice LL601 (for food use)	Report of alleged presence in the local market by Greenpeace All commercial rice alleged to contain LL601 was recalled by the National Food Authority; Further shipments from the source were required for testing (negative) by Philippine authorities (Department of Agriculture-Bureau of Plant Industry)
		2008	TC 1508 (for propagation)	Declaration by technology developer Whole shipment was quarantined and destroyed

Source: After FAO (2014a)

The fear of export loss is a major driver in the reluctance to use GM technology in developing countries (Paarlberg 2002; Gruere 2006). That fear may be driven by large traders in exporting countries afraid to lose market access. Following a detection of unapproved U.S. GM rice in EU and Japanese markets, prompting rapid import bans, Thailand and Vietnam, two of the largest rice exporters, announced that they would remain GM-free and would not approve any GM rice. Rice exporters in India have argued against field-testing of GM rice for similar reasons. In many cases such fears are largely exaggerated and based on misinformation of the global trade system. Paarlberg (2006) showed that African countries have virtually no export to lose from adopting current GM crops. Smythe, *et al.*, (2006) show that despite claims by GM crop opponents, major exporters who adopted GM crops in the 1990s have experienced no loss in export value or volume; rather, their exports have been diverted to other markets. Several ex ante simulation models have also shown that China or Sub-Saharan Africa are bound to gain largely from adopting GM food or feed crops even with bans in large importing nations (Huang *et al.* 2004; Anderson and Jackson 2005). Lastly, the fear is also based on the mistaken idea that segregating GM and non-GM crops is infeasible or prohibitively costly. In fact, virtually all large GM-food- or feed-producing countries (the United States, Canada, Argentina, Brazil, South Africa) produce alternative non-GM crops, and even organic crops for domestic and/or international markets.

In this context, many Asia Pacific countries that have invested in research and regulations on GM food crops are confronted with what they see as three possible alternatives: (1) allow the production of GM food crops with the risk of losing potential exports; (2) reject the commercialization of any GM food crop; or (3) produce both GM and non-GM crops separately at a marketing cost (Gruere, *et al.*, 2007).

5.4 Presence of Unapproved GMOs in Neighbouring Countries

Trade disruptions (affecting maize products and rice imports) have mainly concerned GMOs that were also not authorised in the exporting countries, and which had entered the supply chain in these countries accidentally. Such cases have been reported from the EU, for example, the commercial cultivation of the DAS-59122 maize in the US since 2006, a major exporting country for EU, is an issue as it is not yet authorised in the EU (EU, 2007).

Country legislations, where present in the region, in general do not provide for any tolerance threshold for the accidental presence of unapproved GMOs that have received approval in other countries. The likelihood that a non-approved GMOs may turn up in consignments planned for export, depends on the rate at which new GMOs are developed and adopted in the exporting countries, and on the possibilities to segregate approved from non-approved varieties under the local and regulatory conditions in the production regions. It also depends on the way the authorisations are handled in the exporting countries, given that the authorisation of GMOs that are not authorised at the same time in the importing country, may impact on their export markets. However, even if they do so, unwanted mixing of GMOs resulting from illegal or experimental cultivation in some of these countries, in combination with a lack of co-existence policies, might undermine the effectiveness of such policies.

Such a situation could arise with Bt brinjal release in Bangladesh while it has been banned in India. With the more widespread cultivation of Bt brinjal which is approved in Bangladesh but not in India, potential trade disruptions could become severe, frequent, and affect products.

5.5 GMO Trade related Disputes

The Preamble of the Protocol states that it would not be interpreted as implying a change in the rights and obligations of the parties under existing international agreements and that the Protocol is not intended to subordinate to other international agreements. These provisions may not prove helpful in case a conflict arises between countries with divergent interests in the area of agro-biotechnology. Also, disputes may occur between parties to the Protocol, for instance on the interpretation of the role that the precautionary approach can play in decision-making, or between parties and non-parties on such issues as import restrictions, notification and identification requirements, delays in evaluating requests and authorizing imports, or on special conditions attached to imports, such as mandatory labelling requirements.

As a general rule, domestic regulations should be scrutinized in the light of multilaterally agreed trade rules, if they are likely to have an impact on international trade. The two main legal frameworks applying to trade in agro-biotechnology products are the WTO framework – which is not specific to biotechnology and was actually developed at a time when biotechnology was not much of an issue – and the Protocol which, on the contrary, is a more recent multilateral instrument specifically targeted at GMOs and GM commodities. The two legal frameworks do not seem to be fully consistent with each other. The inability of the international community to decide on how to deal with sectors that are covered by specific multilaterally agreed legal instruments but at the same time are covered by the WTO discipline is *de facto* shifting the responsibility to settle the issue from the decision making level to the dispute settlement level, from the "legislative" to the "judiciary" branch of the WTO system (Zarrilli, 2005).

The lack of scientific certainty *vis-à-vis* the possible impacts of agricultural biotechnology on health and on the environment and the complexity of the legal framework applying to it – along

with the huge economic interests involved and the links that the sector has with human and animal life and health, biodiversity preservation, and ethical and religious concerns – make the whole issue quite prone to disputes. In the event of trade disputes, it is rather uncertain which legal arguments might prevail. They are likely to be different depending on whether GMOs for intentional introduction into the environment, GMOs to be used as food, as feed or for processing, or consumer products derived from GM material are at stake. The relevant WTO provisions may be interpreted in a way supporting the arguments of the claimant, as well as those of the defendant. It is very uncertain what role the Protocol may play, the issue of the role of non-WTO law within WTO dispute settlement being controversial. Also, the WTO affects this issue through its treatment of intellectual property. WTO's agreement on Trade-Related Intellectual Property Rights (TRIPs) requires countries to adopt greater protection of intellectual property, including protection of private property rights in agriculture (Victor, 2014). The Protocol may play a role only within its scope, i.e. living organisms for intentional introduction into the environment, LMOs for contained use, and for direct use as food, as feed or for processing, while products thereof are not included. If the WTO Members involved in the dispute are both parties to the Protocol, its provisions may be used as factual evidence, as an instrument that can help in interpreting WTO provisions, or even as the applicable law. However, if only one disputing Member is a party to the Protocol, the Protocol could not be used as applicable law, but it may still play a role as proof of certain factual circumstances or as an instrument to interpret WTO treaty terms.

5.6 Conclusion

Countries' attitudes towards agro-biotechnology depend on many factors, but their positions can be classified into three main categories: (i) the position of those countries that have adopted the equivalence principle, have authorized most GM products for production and consumption, and strive for easy and reliable access to foreign markets for their biotechnology exports; (ii) the position of those countries that have mainly adopted the precautionary approach and are imposing strict rules on approval and marketing of GMOs and GM products; and finally (iii) the position of those countries that are still in the first phase of evaluating the risks and benefits that agricultural biotechnology may imply for them, that are striving to develop comprehensive regulatory systems on the issue, and whose main trade-related preoccupation at present is to preventing GM-related regulations and concerns having negative repercussions on their agriculture exports, including exports of conventional products. Most of the Asia Pacific countries fall into this third category. While few of the better developed countries in the region have established their national frameworks to deal with agro-biotechnology and biosafety issues focusing primarily on their domestic priorities and strategies.

Presently, the main concern of the Asia Pacific countries seems to be to find the appropriate balance between pursuing their development objectives and at the same time complying with their multilaterally agreed obligations. The preoccupations that many countries have as exporters of agricultural and food products needs to be balanced against their role as producers and their responsibility for improving the quantity and quality of agricultural and food products made available to the population, as well as their commitment to environmental protection. This is not an easy task and additional capacity-building efforts on agro-biotechnology and biosafety would be required, including the need to strengthen the country's ability to deal with the international trade issue.

According to Nielsen and Anderson (2011), it may be noted that a major international trade dispute concerning GMOs could prove very harmful to agricultural-exporting countries, in particular those countries that are highly dependent on exporting to Western Europe. Even if these countries were fortunate enough to benefit from the new technology in producing for their own consumption, they might risk having their products refused at the European borders solely because they are GM. A market-based segregation of agricultural production into GM-inclusive and GM-free varieties, on the other hand, would allow for a broader choice of production methods, particularly if GM-free products carry a price premium. This would, however, require the imposition of comprehensive testing, certification and labeling systems that could satisfy the requirements of importing countries. Such systems might prove to be very demanding financially and in terms of technical expertise, especially for developing countries. Further, for the label to be meaningful abroad for exported GM-free products, multilateral agreement on their threshold levels would be needed.

Thus, there are a number of potentially contentious issues relating to trade in GM foods. Whether or not these issues develop into actual trade disputes only time would tell. However, if they do, there is a risk that the second generation of GM foods, that have the potential of benefiting consumers directly, might never materialize. One of these is Golden Rice, which has been developed specifically to combat vitamin A deficiencies, and could be a boon to Asia Pacific countries which are the major consumers of rice in the world.

The relevance of the Protocol for countries for trade purposes would imply the following:

- The Governments should incorporate the information for the identification of LMOs to be in the documentation accompanying their transboundary movement, such as the bill of loading or the commercial invoice.
- Use of the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations and the OECD's system of unique identification for transgenic plants in the implementation of the documentation and identification requirements of paragraph 2 of Article 18 is to be encouraged. However, the OECD should renew its efforts to develop unique identification systems for LMOs and animals.
- There is a need to develop a proposal for the addition of new codes for LMOs and their different intended uses (direct use as food or feed, or for processing; contained use; or intentional introduction into the environment) for inclusion in the next revision of the Harmonized Commodity Description and Coding System of the World Customs Organization.
- The international agencies such as CBD Secretariat should have an active mechanism to keep a vigil on identification of any LMO or specific traits of LMOs that may be identified to having an adverse effects on the conservation and sustainable use of biological diversity. The affected Party needs to be consulted for quantifying the impact based on the intended use of the LMO.
- Based on the seriousness of the potential impact it may develop advice for the United Nations Committee of Experts on the Transport of Dangerous Goods and propose appropriate adaptations to the United Nations Model Regulations on the Transport of Dangerous Goods.

Besides, not only for Asia-Pacific but also at global level certain points need to be considered to facilitate trade of GM products as enumerated below:

- There is a dire need to have a clear, specific and simplified procedure/method to establish and maintain appropriate measures to prevent unintentional transboundary movements of LMOs. The domestic norms can thus be harmonised for achieving the same.
- Capacity building would require expertise in specific areas both at technical and implementing level and also necessary funding for the same. Also the regional existing capacity in the field should be reviewed, developed and shared with Parties to collaborate. Certain developing countries such as India has a rich technical capacity that could be shared.
- There is an urgent need for many of the countries in Asia Pacific to comply with Article 18 of the Protocol for which there is a need for an in depth review of the existing regulatory system, technical preparedness and infra-structure in place with respect to implementation of the Article 18 in the true sense.
- A review of laboratories engaged in LMO testing has to be done and a mechanism to be proposed so that a strategy is available for the national networking for sampling, detection and identification of LMOs that is so crucial for trade.
- The customs and quarantine officials have to be sensitized and oriented for identifying, detecting and intercepting LMOs at the port of entry. A strategy has to be put in place for effective enforcement of legal provisions of detection of LMOs during trade and exchange. All the relevant national information on standards, their use and methods of identification need to be available at the BCH. The feasibility of initiating an electronic network of laboratories to facilitate the identification of LMOs needs to be exploredudied.

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Chapter 6

BIOTECHNOLOGY AND BIOSAFETY IN ASIA-PACIFIC – THE WAY FORWARD

World population is estimated to cross 10 billion by 2050, 8.2 billion of whom would be living in less developed countries (United Nations, Department of Economic and Social Affairs, Population Division, 2013). Most countries of Asia-Pacific will contribute significantly to this population growth which will pose severe challenges to their food production systems. Adoption of new technological innovations along with conventional crop improvement and management practices would be imperative to meet the food and nutrition requirements of the burgeoning population.

More than a decade of experience in GM crop cultivation in some Asia-Pacific countries has produced enough evidence to conclude that GM technology has an important place in the repertoire of scientific tools to increase agricultural production. As detailed in Chapter 1, Bt cotton has been adopted on a large scale by farmers in India, China, Pakistan and Myanmar. Bt brinjal seedlings were distributed to Bangladeshi farmers in January 2014. Initial reports indicate that the crop remained free of shoot and fruit borer, the most serious pest of brinjal in the region (Choudhary *et al.*, 2014).

However, several countries have so far not grown any GM crops despite policy support and investment in the technology. In India, Bt brinjal after having been approved by the regulatory authorities for environmental release in 2009, is still under government moratorium and the case is under consideration of Indian Supreme Court (Padmanaban, 2009; Rao, 2010). In Thailand, after an initial phase of GM R&D activity, all field cultivation of GM plants was banned in 2002 (Davidson, 2008). It is widely perceived that besides biosafety, economic and trade concerns often play a role in shaping GM policies.

APCoAB and APAARI have been organizing expert meetings for over a decade on a range of agricultural policy and technology related topics with the objective of reviewing the agricultural and food needs of Asia-Pacific countries and biotechnological options to meet these needs (www.apaari.org, www.apcoab.org). Diverse stakeholders comprising policy makers, scientific experts, GM product developers, farmers' organizations and Civil Society Organizations (CSOs) participating in these meeting have discussed relevance and status of GM technology adoption, biosafety regulatory systems, and suggested regional and sub-regional actions required for facilitating safe adoption of the technology for the benefit of farmers and consumers. A synthesis of the recommendations especially made during these meetings is give below:

Enabling Policy Environment:

- Recognize biotechnology as an integral component of agricultural development strategy
- Commit appropriate and sustained funding support
- Adopt need-based biotechnology options and integrated strategies and package of practices to improve small farm-level productivity and profitability

- Encourage public-private participation to synergize development and commercialization of biotechnology products
- Develop IP and benefit sharing policies that balance the needs to facilitate adoption of technologies while providing fair share of benefit to technology developers

Improve Regulatory Management

- Adopt robust, science-based and transparent biosafety regulatory systems
- Simplify regulatory norms for GM events of established environment and human safety
- Align biosafety related policies under different national competent authorities wherever needed
- Generate research data on biosafety related issues, particularly of local relevance, e.g. impact on biodiversity

Enhance Awareness through Education and Communication

- Include agriculture and biotechnology oriented courses in school syllabi and develop appropriate educational tools
- Train scientists not just in the field of biotechnology but also in related sciences and communication skills
- Develop success stories, status reports and web-based information systems on developments in biotechnology and biosafety
- Organize dialogues between scientists, CSOs, farmers organisations and consumer groups

Regional and Sub-regional Collaboration

- Collaborate in biotechnology R&D in crops and traits of common interest, biosafety management and capacity development
- Cooperate and harmonize at regional/ sub-regional level GMO risk assessment and risk management protocols
- Establish regional/ sub-regional information centres on developments in biotechnology, biosafety and intellectual property issues
- Strengthen some existing national institutions to serve as regional hubs for sustained capacity development

6.1 Regional Cooperation in Biosafety Implementation

The need for cooperation among countries is widely recognized as a means of reducing commercialization cost by improving regulatory oversight through shared expertise, building capacity and facilitating trade. The Protocol recognises the role of regional and sub-regional cooperation in developing institutional and human resources capacities for proper management of biotechnology and in the use of risk assessment and risk management. UNEP-GEF identified four areas of regional cooperation in biosafety, resource sharing (technical, material and expertise), experience sharing (methodologies, materials and know-how), information sharing, and capacity building (UNEP-GEF Biosafety Unit, 2006).

Effective regional cooperation in biosafety implementation would require some level of harmonization in risk assessment and evaluation protocols and information requirements. A number of biosafety harmonization models functional at regional or economic group levels exist.

In the European Union, EU Directive 2001/18/EC requires GM crops meant for environmental release to meet a common set of criteria, the objective being to harmonize risk assessment between member states. The European Food Safety Authority (EFSA) in collaboration with national authorities and other stakeholders provides independent scientific advice on safety of GMOs, provides opinion on specific cases and produces guidance documents (www.efsa.eu).

Food Standard Australia New Zealand develops and administers Australia New Zealand Food Standards Code which includes safety requirements of GM foods (www.foodstandards.gov.au/pages/default.aspx). Implementation of the code is left to states within Australia and New Zealand.

The Organization of Economic Co-operation and Development (OECD) has a Working Group on Harmonization of Regulatory Oversight in Biotechnology (WG-HROB) which deals with the environmental risk/safety assessment of transgenic plants and other GMOs (OECD, 2013). OECD has produced consensus documents on biology of plants and selected topics to facilitate harmonization (www.oecd.org/env/ehs/biotrack/).

The Common Market of Eastern and Southern Africa (COMESA) initiated a project on the Regional Approach on Biotechnology and Biosafety Policy in Eastern and Southern Africa (RABESA) in 2003 to address issues relating to transboundary movement of GM crops in its 19 member countries (Timpo, 2011). RABESA has developed a draft policy on GM crops, trade and access to emergency food aid with content from GM crops. The draft policy has been adopted by the COMESA Council of Ministers and is now under implementation by states.

Harmonization at regional and sub-regional level among Asia-Pacific countries could follow one of the above or a different model depending upon countries' policies on adoption of GM crops and priorities for their development and trade. It is recognised that decision on harmonisations would also be influenced by perceived impacts on other national policies and prerogatives. There is indeed a challenge in the region keeping in view the very different level of growth and economy of the countries.

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Annexure I

National Focal Points of Asia Pacific Countries

Country	Cartagena Protocol		Nagoya Kuala Lumpur Supplementary Protocol		Competent National Authority	Cartagena Protocol National Focal Point	BCH National Focal Point
	Date of		Date of				
	Signature	Ratification	Signature	Ratification			
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Afghanistan	–	February 20, 2013	–	–	–	–	**H.R.H. Prince Mostapha Zaher** Director General/ Advisor to the President of Afghanistan on Environment National Environmental Protection Agency, Central Post Office, Box Number 209 Kabul, Afghanistan. Phone: +93 752 017 633 Email: mostapha_zaher@hotmail.com dg.nepa@hotmail.com
Australia	–	–	–	–	Office of the Gene Technology Regulator MDP 54 GPO Box 9848 Canberra, ACT Australia, 2601 Phone: +61–2–6271–4215 Fax: +61–2–6271–4202 Email: ogtr@health.gov.au Url: http://www.ogtr.gov.au/ **Food Standard Australia New Zealand** Url: http://www.foodstandards.gov.au/contactus/	–	**Dr. Peter Thygesen** Manager, Regulatory Practice and Secretariat Section, Regulatory Practice and Compliance Branch Department of Health and Aging Office of the Gene Technology Regulator MDP54 GPO Box 9848 Canberra, ACT 2601 Australia Phone: +61 2 6271 4215 Fax: +61 2 6271 4202 Email: Peter.Thygesen@health.gov.au
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Malaysia	May 24, 2000	September 03, 2003	–	–	**Ministry of Natural Resources and Environment Malaysia** Level 6, Tower Block 4G3 Precinct 4 Federal Government Administrative Centre, 62574 Putrajaya, Malaysia Phone: +603–8886 1128 Fax: +603–8888 4473 Email: nagu@nre.gov.my Url: Ministry of Natural Resources and Environment Malaysia **Malaysian Department of Biosafety** Level 1, Podium 2 Wisma Sumber Asli No. 25, Persiaran Perdana Precinct 4 Putrajaya, Federal Territory Malaysia, 62574 Phone: +603 8886 1746 / 1579 Fax: +603–8889 5604 Email: biosafety@nre.gov.my letchu@nre.gov.my Url: Ministry of Natural Resources and Environment, MALAYSIA Department of Biosafety Malaysia **Department of Veterinary Services** Ministry of Agriculture and Agro–Based Industry, Wisma Tani Blok Podium, Lot 4G1, Precinct 4 Federal Government Administration Centre, Putrajaya Malaysia, 62630 Phone: +6038870 2000, +6038870 2099, +6038870 2102, +6038870 2105 Email: pro@dvs.gov.my	**Ms. Wan Hasmah Wan Mohd** Undersecretary Biodiversity and Forestry Management Division Ministry of Natural Resources and Environment Level 12, Tower Block 4G3 Precinct 4 Putrajaya Malaysia, 62574 Phone: +603 8886 1443 Fax: +603 8890 4021 Email: hasmah@nre.gov.my biodiversity@nre.gov.my	**Mr. Johnny Anak Andrew** Director Corporate and Management Section, Department of Biosafety Ministry of Natural Resources & Environment Level 1, Podium 2, Wisma Sumber Asli No. 25, Persiaran Perdana, Presint 4, Federal Government Administrative Centre Putrajaya, 62574, Malaysia Phone: +603 8886 1780 Fax: +603 8890 4935 Email: johnny@nre.gov.my

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					Url: Official Portal Department of Veterinary Services **National Pharmaceutical Control Bureau** Lot. 36, Jalan Universiti Petaling Jaya, Selangor Malaysia, 46200 Phone: +6037883 5400/ 5409 Email: classification@bpfk.gov.my Url: Official Portal National Pharmaceutical Control Bureau		
Maldives	–	September 02, 2002	–	–	**Ministry of Housing and Environment** Ameeneemagu, Maafannu Male, 20392 Republic of Maldives, Malé Maldives, 20392 Phone: +960 3004300 Fax: +960 3004301 Email: ahmed.saleem@mhe.gov.mv secretariat@mhe.gov.mv Url: http://www.mhe.gov.mv	**Ms. Muhusina Abdul Rahman** Environment Analyst Environment Department/ Biodiversity Conservation Unit Ministry of Environment and Energy Ameenee Magu, Maafannu Male', Kaafu Atoll Maldives, 20392 Phone: +960 3004317 Fax: +960 3004301 Email: muhsina.abdulrahman@environment.gov.mv, muhsina.abdulrahman@gmail.com	**Ms. Muhusina Abdul Rahman** Environment Analyst Environment Department/ Biodiversity Conservation Unit Ministry of Environment and Energy Ameenee Magu, Maafannu Male', Kaafu Atoll Maldives, 20392 Phone: +960 3004317 Fax: +960 3004301 Email: muhsina.abdulrahman@environment.gov.mv, muhsina.abdulrahman@gmail.com
Marshall Islands	–	January 27, 2003	–	–	–	**Mr. Raynard Gideon** Undersecretary for UN / International Affairs Ministry of Foreign Affairs P.O. Box 1349 Majuro 96960 Marshall Islands Tel: +692 625 3181, 3012 Fax: +692 625 4979 Email: mofapol@ntamar.net	**Mr. Bruce Kijiner** Director (CBD Operational Focal Point) Office of Environmental Planning and Policy Coordination (OEPPC) P.O. Box 975 Majuro 96960 Marshall Islands Tel: +692 625 7944, 7945 Fax: +692 625 7918 Email: kijinerb@gmail.com bruce.kijiner@ntamar.net
Micronesia	–	–	–	–	–	–	**Hon. Mr. Peter M. Christian** Secretary Department of Resources and Development P.O. Box PS–12 Pohnpei FM 96941, Palikir, Micronesia (Federated States of) Phone: +691 320 5133 320 2646, 320 2620

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							Fax: +691 320 5854 +691 320 2079 Email: fsmrd@fsmrd.fm Url: http://www.fsmgov.org/ngovt.html
Mongolia	–	22 July 2003	January 26, 2012	May 21, 2013	**Ministry of Nature and Environment** Government Building No. 3 Baga Toiruu–44 Ulaanbaarar 11 Mongolia Phone: +976 11 312 269 Fax: +976 11 321 401 **National Biosafety Committee** Government Building II, United Nation's street 5/2 Ulaanbaatar–15160 Ulaanbaatar Mongolia, 976 Phone: +976–51–26–4627 +976–99049896 Fax: +976–51–264166 Email: biosafety@mne.gov.mn bayarkhuu@mne.gov.mn **Institute of Public Health** Sukhbaatar district Sansar Street 5/4 Building 10, Mongolia Ulaanbaatar, Mongolia, 976 Phone: 976–99762000 Fax: 976–11–454620 Email: jobileg@magicnet.mn	**Mr. Altangerel Enkhbat** Director Ecologically Clean Technology and Science Division Ministry of Environment and Green Development 15160 Government Building 2 United Nation's Street 5/2, Chingeltei district Ulaanbaatar Mongolia Email: enkhbat@mne.gov.mn aenkhbat@mbox.mn	**Mrs. Sandagdorj Bayarkhuu** General Secretary National Biosafety Committee Ministry of Environment and Green Development 15160 Government Building 2 United Nation's Street 5/2 Chingeltei district Ulaanbaatar Mongolia Phone: +976 51 26 46 27 Email: bayarkhuu@mne.gov.mn
Myanmar	11 May 2001	13 February 2008	–	–	–	**Mr. Tin Tun** Director General Planning and Statistics Department Ministry of Environmental Conservation and Forestry Bayintnaung Road, West Gyogone Nay Pyi Taw, Myanmar Phone: +95 67 405009 Fax: +95 67 405012 Email: dgpsmof@mptmail.net.mm minber1978@gmail.com	**U Tin Htut Oo** Director General Agriculture Planning Department Ministry of Agriculture and Irrigation Myanmar Phone: +95 67 410106 Fax: +95 67 410119 Email: dap–hq@mptmail.net.mm

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Nepal	2 March 2001	–	–	–	–	**Mr. Braj Kishor Yadav** Joint Secretary and Chief Environment Division Ministry of Forests and Soil Conservation P.O.Box 3987, Singha Durbar Kathmandu Nepal Phone: +977 01 4211814 Fax: +977 01 4211868 Email: bkyadav@mfsc.gov.np environmentdivision@mfsc.gov.np	**Mr. Braj Kishor Yadav** Joint Secretary and Chief Environment Division Ministry of Forests and Soil Conservation P.O.Box 3987, Singha Durbar Kathmandu Nepal Phone: +977 01 4211814 Fax: +977 01 4211868 Email: bkyadav@mfsc.gov.np environmentdivision@mfsc.gov.np
New Zealand	May 24, 2000	February 24, 2005	–	–	**Ministry of Agriculture and Forestry** Wellington New Zealand Phone: +64 4 894 0100 Fax: +64 4 894 0720 Email: Carolyn.Hini@maf.govt.nz **Environmental Protection Authority** 215 Lambton Quay Private Bag 63002 Wellington New Zealand Phone: +64 4 916 2426; Fax: +64 4 914 0433 Email: neworganisms@epa.govt.nz **Food Standard Australia New Zealand** Url: http://www.foodstandards gov.au/contactus/	Ms. Wendy Jackson Ministry of Foreign Affairs and Trade 195 Lambton Quay Private Bag 18 901 Wellington, 5045 New Zealand Phone: +64 4 439 8462 Fax: +64 4 439 8517 Email: wendy.jackson@mfat.govt.nz	Asela Atapattu Applications Manager (New Organisms) Applications and Assessment Environmental Protection Authority Level 10, 215 Lambton Quay Private Bag 63002 6140 Wellington New Zealand Tel: +64 4 474 5463 Email: asela.atapattu@epa.govt.nz
Niue	–	July 08, 2002	–	–	–	**Ms. Christine Ioane** Director Cabinet and Parliamentary Services Office for External Affairs Premier's Department, Alofi Niue, P.O. Box 40 Phone: +683 4200 Fax: +683 4206 Email: christine.external@mail.gov.nu, external@mail.gov.nu	**Mr. Sauni Tongatule** Director Department of Environment PO Box 80 Alofi, Niue Phone: +683 4021 Fax: +683 4010 Email: biodiversity.ca@mail.gov.nu, tongatules@mail.gov.nu

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						Mr. Sauni Tongatule Alofi Niue Director Department of Environment PO Box 80 Tel: +683 4021 Fax: +683 4010	
Pakistan	4 June 2001	2 March 2009	–	–	**Pakistan Environmental Protection Agency (Pak–EPA)** 311, Margalla Road, F–11/3 Islamabad, Pakistan, 44000 Phone: +92 51 9235142 +92 51 9267627 Fax: +92 51 9267622 Email: pakepa@isb.compol.com, greenlib@isb.paknet.com.pk Url: Pakistan Environmental Protection Agency	**Mr. Syed Mahmood Nasir** Inspector General of Forests Ministry of Climate Change LG & RD Complex G 5/2 Islamabad Pakistan Phone: +92 51 924 55 89 Fax: +92 51 924 55 90 Email: mnasirn@yahoo.com	**Mr. Syed Mahmood Nasir** Inspector General of Forests Ministry of Climate Change LG & RD Complex G 5/2, Islamabad Pakistan Phone: +92 51 924 55 89 Fax: +92 51 924 55 90 Email: mnasirn@yahoo.com
Palau	May 29, 2001	June 13, 2003	–	–	**National Coordinating Committee on Biosafety** P.O. Box 7086 Koror Palau, 96940 Phone: +680 488–6950 Fax: +680 488–8638 Email: debbiemarks614@hotmail.com, ERCPalau@hotmail.com **Office of Environmental Response and Coordination** P.O. Box 6051 Koror Palau, 96940 Phone: +680 488 8681 +680 488 5435 Fax: +680 488 8638 Email: debbiemarks614@hotmail.com	**Mr. Fernando Sengebau** Director Bureau of Agriculture Ministry of Natural Resources, Environment and Tourism P.O. Box 6051 Koror 96940 Palau Tel: +680 767 5435, 3125 Fax: +680 767 3380 Email: ffms@palaunet.com	**Mr King Sam** Special Assistant to Minister/ Programme Manager Protected Areas Network Ministry of Natural Resources, Environment and Tourism P.O. Box 6051 Koror 96940 Palau Tel: +680 767 5435, 3125 Fax: +680 767 3380 Email: esuroi1@gmail.com
Papua New Guinea	–	October 14, 2005	–	–	**Department of Environment and Conservation** Somare Foundation Building PO Box 6601 Boroko, Port Moresby, NCD Papua New Guinea Phone: +675 325 0195	**Dr. Wari Iamo** Secretary Department of Environment and Conservation P.O. Box 6601 Boroko Port Moresby	**Dr. Wari Iamo** Secretary Department of Environment and Conservation P.O. Box 6601 Boroko Port Moresby

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Peoples Republic of China	August 08, 2000	June 08, 2005	–	–	**Ministry of Environmental Protection of the People's Republic of China** No. 115, Xizhimenei Nanziaojie St Beijing, China, 100035 Phone: +86 10 66556323 Fax: +86 10 66556329 Email: zhu.guangqing@mep.gov.cn Url: Ministry of Environmental Protection of the People's Republic of China **Ministry of Environment Protection** No. 115, Xizhimenei Nanziaojie Beijing, China, 100035 Phone: +86 10 6655 6309 Fax: +86 10 6655 6329 Email: zhang.wenguo@sepa.gov.cn Url: State Environmental Protection Administration	**Ms. Jieqing Zhang** Director, Division of International Organizations and Conventions Department of International Cooperation Ministry of Environmental Protection 115, Xizhimennei, Nanxiaojie Beijing, 100035 China Phone: +86 10 6655 6520 Fax: +86 10 6655 6513 +86 10 6655 6494 Email: zhang.jieqing@mep.gov.cn	**Mr. Wang Jie** Senior Programme Officer, Biosafety Management Officer CBD and Biosafety Office, Department of Nature and Ecological Protection State Environmental Protection Administration No.115 Xizhimennei, Nanxiaojie Beijing China, 100035 Phone: +86 10 6655 6325 Fax: +86 10 6655 6329 Email: wang.jie@mep.gov.cn
Philippines	May 24, 2000	October 05, 2006	–	–	**Department of Science and Technology** General Santos Avenue Bicutan Taguig City, Philippines, 1631 Phone: +632 8372071 Fax: +632 8372937 Email: ftdp@dost.gov.ph jfle@dost.gov.ph Url: DOST Biosafety Committee Website **National Committee on Biosafety of the Philippines** Gen. Santos Ave. Bicutan Taguig City, Philippines, 1631 Phone: +632 837–2937 Fax: +632 837–2937 Email: mgmontejo@dost.gov.ph Url: DOST	**Mr. Jesus R.S. Domingo** Assistant Secretary Office of United Nations and Other International Organizations (UNIO) Department of Foreign Affairs 2330 Roxas Blvd., Pasay City Metro Manila Philippines, 1300 Phone: +632 834 4890 +632 834 4814 Fax: +632 833 1322 +632 832 0683 Email: unio.div2@dfa.gov.ph	**Ms. Julieta Fe L. Estacio** Project Development Officer IV, Office of the Undersecretary for R&D and Head of the NCBP Secretariat Department of Science and Technology (DOST) DOST Building, Gen. Santos Avenue Bicutan, Taguig City Metro Manila Philippines, 1630 Phone: +632 837 2930; +632 837 2943 Fax: +632 837 2930 +632 837 2943 Email: estaciojulietafe@gmail.com, zen0555@yahoo.com

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					Department of Environment and Natural Resources Visayas Avenue Quezon City Philippines, 1100 Phone: +632 925–2329 +632 920–4352 Fax: +632 920–4301 Email: osec@denr.gov.ph Url: DENR,PAWB **Department of Health** San Lazaro Compound, Sta. Cruz Manila Philippines Phone: +632 651 7801 +623 651 7800 Fax: +632 743 1829 Email: etona@co.doh.gov.ph Url: DOH Website **Department of Agriculture** Elliptical Circle, Diliman Quezon City Philippines, 1100 Phone: +632 928–8762 to 65 loc. 2210/2214/2254 +632 920–4369 Fax: +632 920–3986 Email: spja_osec@da.gov.ph Url: DA		
Qatar	–	14 March 2007	–	–	**Supreme Council for the Environment and Natural Reserves** P.O. Box 7634 Doha Qatar Fax: +974 4415246 +974 4583310 Email: gamohammad@qatarenv.org.qa	**Mr. Ghanim Abdulla Mohammad** Director Department of Wildlife Conservation and Development The Supreme Council for the Environment and Natural Reserves P.O. Box 7634 Doha, Qatar Phone: +974 458 3635 +974 435 8417 Fax: +974 441 5246 +974 458 3310 Email: gamohammad@qatarenv.org.qa Url: www.qatarenv.org	**Mr. Ghanim Abdulla Mohammad** Director Department of Wildlife Conservation and Development The Supreme Council for the Environment and Natural Reserves P.O. Box 7634 Doha, Qatar Phone: +974 458 3635 +974 435 8417 Fax: +974 441 5246 +974 458 3310 Email:gamohammad@qatarenv.org.qa Url: www.qatarenv.org

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Republic of Korea	September 06, 2000	October 03, 2007	–	–	Ministry of Trade, Industry and Energy 402 Hannuri–daero Sejong–si Republic of Korea, 339–012 Phone: +82–44–203–4390 Fax: +82–44–203–4738 Email: sc292@motie.go.kr Url: MOTIE **Rural Development Administration (RDA)** Suin_ro, 150th, Gwonseon–gu Suwon, Gyeonggi–do Republic of Korea, 441–707 Phone: +82 31 299–2200 Email: jowon007@rea.go.kr Url: RDA **Ministry of Food and Drug Safety (MFDS)** Osong Health Technology Administration Complex, 187 Osongsaengmyeong2(i)–ro Osong–eup Cheongwon–gun, Chungcheongbuk–do Republic of Korea, 363–700 Phone: +82 2 380–1332~4 Email: kye2020@korea.kr Url: MFDS	**Mr. Donghwan Choi** Consul General and Ambassador Permanent Representative to the Council of ICAO Consulate General of the Republic of Korea in Montreal and Permanent Mission to ICAO 1250 René–Lévesque Boulevard West Suite 3600 Montreal QC H3B 4W8 Canada Tel: +1 514 845 2555 Fax: +1 514 845 1119 Email: montreal@mofa.go.kr dhchoi77@mofat.go.kr Web: http://can–montreal.mofat.go.kr/english/am/canmontreal/main/index.jsp **Mr. Tong–q Lee** Director Climate Change and Environment Team Ministry of Foreign Affairs and Trade 37 Sejongno, Jongno–gu Seoul 110–787 Republic of Korea Tel.: +82 2 2100 7794 Fax: +82 2 2100 7991 Email: environment@mofat.go.kr	**Mr. Ho–Min Jang** Director (Ph.D.) Korea Biosafety Clearing House Korea Research Institute of Bioscience & Biotechnology (KRIBB) 52, Eoeun–Dong, Yuseong–gu Daejeon Republic of Korea, 305–333 Phone: +82 42 879 8300 Fax: +82 42 879 8309 Email: kbch@kribb.re.kr, hmjang@kribb.re.kr
Russian Federation	–	–	–	–	–	**Ministry of Industry, Science and Technologies** Twerskaja st.11 Moscow 103905 Russian Federation Tel: +7 495 229 9653 Fax: +7 495 229 1674 Email: nat–step@yandex.ru	**Ministry of Industry, Science and Technologies** Twerskaja st.11 Moscow 103905 Russian Federation Tel : +7 495 229 9653 Fax: +7 495 229 1674 Email: nat–step@yandex.ru
Samoa	May 24, 2000	May 30, 2002	–	–	–	**Mr. Aiono Mose Pouvi Sua** Chief Executive Officer Ministry of Foreign Affairs and Trade P.O. Box L1859 Apia Samoa	**Mr. Aiono Mose Pouvi Sua** Chief Executive Officer Ministry of Foreign Affairs and Trade P.O. Box L1859 Apia Samoa

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Saudi Arabia	–	August 09, 2007	–	–	–	**Dr. Yousef S. Al–Hafedh** Chairman, National Committee on Biosafety; Director, Center of Excellence for Wildlife Research King Abdulaziz City for Science and Technology P.O. Box 6086 Riyadh Saudi Arabia, 11442 Phone: +966 14 81 36 04 Fax: +966 14 81 38 11 Email: yhafedh@kacst.edu.sa	**Dr. Yousef S. Al–Hafedh** Chairman, National Committee on Biosafety; Director, Center of Excellence for Wildlife Research King Abdulaziz City for Science and Technology P.O. Box 6086 Riyadh Saudi Arabia, 11442 Phone: +966 14 81 36 04 Fax: +966 14 81 38 11 Email: yhafedh@kacst.edu.sa
Singapore	–	–	–	–	–	**Mr. Marcus Ong Chun Chuan** Assistant Manager Agri–Food & Veterinary Authority Ministry of National Development 5 Maxwell Road, #04–00 Tower Block MND Complex Singapore Singapore, 069110 Phone: +65 6325 7529 Fax: +65 6220 6068 Email: marcus_ong@ava.gov.sg	**Mr. Marcus Ong Chun Chuan** Assistant Manager Agri–Food & Veterinary Authority Miinistry of National Development 5 Maxwell Road, #04–00 Tower Block MND Complex Singapore Singapore, 069110 Phone: +65 6325 7529 Fax: +65 6220 6068 Email: marcus_ong@ava.gov.sg
Solomon Islands	–	July 28, 2004	–	November 05, 2012	**Environment and Conservation Division** Honiara Solomon Islands Phone: +677 28611 Fax: +677 28735 Email: mbiliki@gmail.com	**Mr. Joe Horokou** Director Environment and Conservation Division Ministry of Environment, Climate Change, Disaster Management and Meteorology P.O. Box 21 Honiara Solomon Islands Phone: +677 23 031 +677 24 215, +677 88 481 Fax: +677 28 054, +677 24 660 Email: horokoujoe@gmail.com	**Mr. Joe Horokou** Director Environment and Conservation Division Ministry of Environment, Climate Change, Disaster Management and Meteorology P.O. Box 21 Honiara Solomon Islands Phone: +677 23 031 +677 24 215 +677 88 481 Fax: +677 28 054 +677 24 660 Email: horokoujoe@gmail.com

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Sri Lanka	May 24, 2000	April 28, 2004	–	–	**Ministry of Environment and Natural Resources** 82, "Sampathpaya" Rajamalwatte Road Battaramulla, Sri Lanka Phone: +94 11 2877290 Fax: +94 11 2877292 Email: forest@sri.lanka.net **Department of Wildlife Conservation** 18, Gregory's Road Sri Lanka Phone: +94 11 2695043 +94 11 2698086 Fax: +94 11 2698556 Email: director@dwlc.lk **Department of Animal Production and Health** 1120, Kandy Road Peradeniya, Sri Lanka Phone: +94 081 2388195 Fax: +94 081 2388619 Email: dgaphamara@sltnet.lk **Department of Fisheries and Aquatic Resources** New Secretariat, Maligawatte Colombo, Sri Lanka Phone: +94 11 2449170 +94 11 2442187 Fax: +94 11 2449170 Email: depfish@diamond.lanka.net **Department of Agriculture** Peradeniya, Sri Lanka Phone: +94 081 2388157 Fax: +94 081 2388333 Email: dgagri@sri.lanka.net **Department of Health Services** 385, Suwasiripaya Colombo 10, Sri Lanka Phone: +94 11 2698543 +94 11 2694860 Fax: +94 11 2693869	**Mr. B.M.U.D. Basnayake** Secretary Ministry of Environment and Renewable Energy 82, Sampathpaya Rajamalwatta Road Battaramulla Sri Lanka Phone: +94 11 2877290 +94 11 2877291 Fax: +94 11 2877292 Email: secoffice@menr.lk biodiversitysl@gmail.com	**Mr. B.M.U.D. Basnayake** Secretary Ministry of Environment 82, Sampathpaya Rajamalwatta Road Battaramulla Sri Lanka Phone: +94 11 2877290 +94 11 2877291 Fax: +94 11 2877292 Email: secoffice@menr.lk

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					Ministry of Industries, Tourism and Investment Promotion 1/73, Galle Road Colombo 03 Sri Lanka Phone: +94 11 2343937 +94 11 2327554 Fax: +94 11 2432783 Email: misec@sltnet.lk		
Syrian Arab Republic	–	April 01, 2004	–	–	**Ministry of State for Environment Affairs** 29th May Damascus Syrian Arab Republic Phone: +963 11 2321305 Fax: +963 11 2320885 Email: belalalhayek@gmail.com **Ministry of Agricultural and Agricultural Reform/ General Commission for Agricultural Scientific Researches** Doma City /Job Damascus **Ministry of Economy and Trade** Damascus **Ministry of Health** Alhamraa st. Damascus **Atomic Energy Commission** Damascus countryside, Dobaia Damascus Url: Atomic Energy Commission **Biological Technology Commission** Damascus– Masaken Barzah–Abu jarach farmings Damascus Syrian Arab Republic, 31902 Phone: +963–11–5130104 Fax: +963–11–5130104 Email: gcht@mail.sy	**Eng. Belal Alhayek** Director Direcotrate of Biodiversity, Land and Natural Reserves Ministry of State for Environment Affairs Yousef Azmah sq. Salhia Box 3773 Damascus Syrian Arab Republic Phone: +963 11 232 1305 Fax: +963 11 232 0885 Email: bilalalhayk@yahoo.com blalhayek75@gmail.com	**Eng. Belal Alhayek** Director Direcotrate of Biodiversity, Land and Natural Reserves Ministry of State for Environment Affairs Yousef Azmah sq. Salhia Box 3773 Damascus Syrian Arab Republic Phone: +963 11 232 1305 Fax: +963 11 232 0885 Email: bilalalhayk@yahoo.com blalhayek75@gmail.com

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Tajikistan	–	February 12, 2004	–	–	**National Biodiversity and Biosafety Center** 44 Aini Str., Dushanbe, 734025 Tajikistan Phone: +992 37 2274490, +992 37 2215351 +992 37 2218978 Fax: +992 37 2218978 Email: NSafarov@biodiv.tojikiston.com biodiv@biodiv.tojikiston.com Url: National Biodiversity and Biosafety Center	**Dr. Neimatullo Safarov** Head National Biodiversity and Biosafety Center, 47 Shevchenko street Dushanbe, 734024 Tajikistan Phone: +992 93 527 86 15, +992 44 600 25 53 Fax: +992 37 2218978 Email: NSafarov@biodiv.tojikiston.com, biodiv@biodiv.tojikiston.com	**Mr. Dilovarsho Dustov** National Biodiversity and Biosafety Centre 47 Shevchenko street Dushanbe, 734025 Tajikistan Phone: +992 37 221 89 78 Fax: +992 37 221 25 46 Email: ddustov@gmail.com biodiv@biodiv.tojikiston.com
Thailand	–	November 10, 2005	March 06, 2012	–	**Department of Agriculture** Phahonyothin Rd., Ladyao, Chatuchak, Bangkok Thailand, 10900 Phone: +66 2 579 0151–8 Fax: +66 2 579 0151–8 Email: office@doa.go.th Url: Department of Agriculture **Food and Drug Administration** Tiwanon Rd., Muang District Nonthaburi, Thailand, 11000 Phone: +66 2 590 7175 Fax: +66 2 591 8460 Email: food@fda.moph.go.th Url: http://www.fda.moph.go.th **Department of Fisheries** Kasetklang, Chatuchak Bangkok, Thailand, 10900 Phone: +66 2562 0600–15 Fax: +66 2940 6203 Email: genetic@dof.in.th Url: Department of Fisheries **National Center for Genetic Engineering and Biotechnology** 113 Thailand Science Park, Phahonyothin Rd., Klong 1, Klong Luang, Pathumthani, Thailand, 12120 Phone: +66 2564 6700 Fax: +66 2564 6703 Email: biosafety@biotec.or.th Url: http://www.biotec.or.th	**Ms. Praopan Tongsom** Biodiversity Division Office of Natural Resources and Environmental Policy and Planning 60/1 Soi Phibun Wattana 7 Phayathai Rama 6 Bangkok, 10400 Thailand Phone: +66 2 2656637 Fax: +66 2 2656637 Email: ga_prao@hotmail.com	**Ms. Dalad Senthong** Biodiversity Division Office of Natural Resources and Environmental Policy and Planning 60/1 Soi Phibun Wattana 7 Phayathai Rama 6 Bangkok Thailand, 10400 Phone: +66 2 2656637 Fax: +66 2 2656637 Email: D_senthong@hotmail.com

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United Arab Emirates	–	–	–	–	–	**Mr. Sultan Abdulla Sultan Bin Al–Wam** Assistant Undersecretary, External Audit Deputy Minister for Water Resources and Natural Protection Ministry of Environment and Water P.O. Box 1509 Dubai United Arab Emirates Phone: +971 4 214 8493 +971 4 214 8321 Fax: +971 4 214 8597 +971 4 256 5822 Email: sasultan@moew.gov.ae cooperation@moew.gov.ae	**Eng. (Mr.) Saif Mohammed Al Shara** Undersecretary Water Resources and Nature Conservation Affairs Ministry of Environment and Water P.O. Box 1509 Dubai United Arab Emirates Phone: +971 4 214 8331 +971506295050 Fax: +971 4 265 5822 Email: smalshara@moew.gov.ae cooperation@moew.gov.ae Url: http://www.moew.gov.ae
Uzbkistan	–	–	–	April 23, 2014	–	–	**Mr. B. Abdusamatov** Chairman State Committee for Nature Protection 5, Mustakillik Sq. Tashkent 100017 Uzbekistan Tel: +998 71 239 11 71, +998 71 239 43 42 Fax: +998 71 239 14 98 Email: chairman@uznature.uz international@uznature.uz Web: http://www.uznature.uz
Vanuatu	–	–	–	–	–	–	**Mr. Albert Abel Williams** Director Department of Environmental Protection and Conservation Ministry of Lands and Natural Resources

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Source: CBD (2014) National Contacts and Competent Authorities. Available at: http://bch.cbd.int/database/compiled-national-contacts; accessed on July 15, 2014.

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.

APAARI has the Mission to promote the development of national agricultural research systems in the Asia-Pacific region through facilitation of intra-regional and inter-institutional, and international partnership.

The overall Objective of APAARI is 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 human resource development of agricultural biotechnology in its broad sense 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 intellectual property rights, sui generis systems, bio-safety, risk assessment, harmonization of regulatory procedures, and benefit sharing in order to address various concerns relating to adoption of agricultural biotechnology.
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.