REPORT

ON

BIOSAFETY POLICY OPTIONS AND CAPACITY BUILDING RELATED TO GENETICALLY MODIFIED ORGANISMS IN THE FOOD PROCESSING INDUSTRY OF ASEAN

BY

DR. SAKARINDR BHUMIRATANA

June 2002

CONTENTS

		Page
1.	INTRODUCTION	I
2.	BIOSAFETY STATUS OF BRUNEI DARUSSALAM	2
3.	BIOSAFETY STATUS OF CAMBODIA, THE LAO PDR AND MYANMAR	4
4.	BIOSAFETY STATUS OF INDONESIA	6
5.	BIOSAFETY STATUS OF MALAYSIA	10
6.	BIOSAFETY STATUS OF THE PHILIPPINES	14
7.	BIOSAFETY STATUS OF SINGAPORE	17
8.	BIOSAFETY STATUS OF THAILAND	19
9.	BIOSAFETY STATUS OF VIETNAM	24
10.	ASEAN BODIES AND BIOSAFETY ACTIVITIES	26
11.	INTELLECTUAL PROPERTY PROTECTION FOR BIOTECHNOLOGY IN SOUTHEAST ASIA	29
12.	OVERVIEW, ANALYSIS AND RECOMMENDATIONS: REGIONAL PICTURE	30

ANNEXES

1. ASEAN Guidelines on Risk Assessment of Agriculture-Related Genetically Modified Organisms (GMOs)
2. The Provision on Biosfaety of Genetically Engineered Agricultural Biotechnology Products (Indonesia)
3. Draft Government Regulation of the Republic of Indonesia Regarding Safety of Living Organisms and Foods of Biotechnological Products Produced Through Genetic Engineering
4. Draft Law of the Republic of Indonesia Regarding Safety of Living Organisms of Biotechnological Products Produced through Genetic Engineering
5. Release of Genetically Modified Organisms (GMOs) into the Environment (Malaysia)
6. Philippine Biosafety Guidelines (PBG)
7. Rules and Regulations for the Importation and Release into the Environment of Plants Products Derived from the Use of Modem Biotechnology (the Philippines)
8. Singapore Guidelines on the Release of Agriculture-Related Genetically Modified Organisms (GMOs)
9. Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work (thailand)
10. Biosafety Guidelines in Genetic Engineering and Biotechnology For Field Work and Planned Release (Thailand)
11. Biosafety Regulations for GMOs and Their Products in Viet Nam (DRAFT)
12. Names of Officials Interviewed during Country Visits

INTRODUCTION

Man has been making use of biotechnology for centuries, long before the terminology was ever coined, More recently-developed gene technology has now made the word "biotechnology" a household name due to its association with the controversial subject of genetically-modified organisms, GMOs. The reasons that this subject attracts so much public interest are twofold. On the one hand people believe that it may be the much needed solution for more effective healthcare, as well as helping to ensure world food security through high-yield and disease resistant varieties of both plants and animals through the introduction of foreign genes. On the other hand, there is a concern over the safety of these new organisms to consumers and their possible effects on the balance of the environment, The subject becomes complex with certain interest groups implying that genetically modified food is in some way contaminated, the issue of intellectual property and fears that this technology will be dominated by the multinationals at the expense of poorer agricultural countries, as well as the as yet unknown socio-economic consequences for farmers and the possibility of increasing trade harriers.

Traditionally, much of the ASEAN economy has relied on agriculture for centuries. The region is the main exporter of tropical agricultural produce and food products, while at the same time being an importer of some agricultural raw materials. It is thus desirable for countries in the region to harmonize their policies and regulations concerning biosafety issues and GMOs and to collaborate in building up the region's science and technology capacity to support these policies of choice.

For the reasons stated above, a project was initiated by the Sub Committee on Biotechnology (SCB) and the Sub Committee on Food Science and Technology (SCFST), both of which are under the auspices of the ASEAN Committee on Science and Technology (ASEAN COST), to examine these issues and this has resulted in this report. Funding support has kindly been provided by the United Nations Industrial Development Organization (UNIDO) and the International Service for the Acquisition of Agri-biotech Applications (ISAAA). This report contains

- An overview of the structure of the GMO-based food-processing industry in ASEAN member countries.
- A review of the policy and institutional framework at both country and regional levels.
- An analysis of the main emerging issues, challenges and trends relating to GM food and the GMO-based food-processing industry.
- Recommendations on (a) possible policy options to address those issues at regional and national levels as well as (b) viable mechanisms for their implementation with particular regard to capacity building, strengthened coordination and networking.
- Areas that may require external assistance and a draft preliminary proposal concerning the support that could he provided by UNIDO within the framework of a follow-up technical cooperation project.

The consultant team would like to thank UNIDO and ISAAA for their financial support and technical assistance. The team also wishes to acknowledge the interest and help of all the people who shared their information and ideas and who spent time with the team on site visits, in giving interviews and providing hospitality.

BIOSAFETY STATUS **OF** BRUNEI DARUSSALAM

Overview

Brunei Darussalam is a non-agricultural country whose main source of revenue is oil. The country has a population of 340,000 people. Most of the agricultural produce and other processed food is imported, The country is self-reliant in the production of eggs, whole chicken and leafy vegetables.

The industrial and research activities in biotechnology are minimal. Current research carried out at the University Brunei Darussalam is on the transfer of genes into sea bass *(Lutes calcarifer)* and black tiger prawns *(Penaeus monodon).* These studies are limited to a short term of three months.

The current use of GMOs in the food processing industry in Brunei Darussalam is not known. However, it is assumed that the situation is similar to Malaysia and Indonesia in that Brunei Darussalam imports many of the agricultural commodities such as soybean and maize for use in food and feed industries.

Policy and Institutional Framework

During the meeting of the ASEAN Ministers on Agriculture and Forestry (AMAF) in Bangkok in 1997, it was recommended that ASEAN members establish a National Authority on Genetic Modification (NAGM). At the request of AMAF, the Agriculture Department of Brunei's Ministry of Industry and Primary Resources has proposed the formation of National Authority on Genetic Modification to oversee the biosafety aspects of GMOs in 1999. The approval for the establishment of NAGM by the Permanent Secretary of the Ministry of Industry and Primary Resources is pending. NAGM is to be comprised of various related government departments and agencies including academics and relevant government agencies. The mission of the task force is to oversee the development and use of gene technology, advise the government on regulation of GM products and advise the government on the import of GM food into Brunei. Once NAGM is formed, they would be expected to initiate and assist in the drafting of guidelines/regulations on biosafety. One particular concern to Brunei Darussalam and other Islamic nations is the issue of *halal* in GM food.

Emerging Issues, Challenges and Trends

- Public Awareness

The first public awareness program on gene technology and the safety assessment of GM food was held at the ASEAN Science and Technology Week in September 2001. The public awareness program is planned to continue on with the target groups including agricultural entrepreneurs and farmers, food retailers and manufacturers, women's organizations, students and the general public.

- Trade and Industrial Competitiveness

The government of Brunei has incorporated biotechnology in its Sixth (1990-1995) and Seventh (1996-2000) National Plans, which is an indication of the government's interest to diversify the economy. There has apparently been some proposal to establish a Brunei Biotechnology Centre and Japan has approached the Forestry Department on prospective joint studies on Biotechnology. These proposals await further development.

Recommendations

1. Policy options
   - Develop policy on biosafety in accordance to the Cartagena Protocol.
   - Develop legal framework for biosafety.
   - Develop policy on public awareness.
2. Viable mechanisms for their implementation
   - Develop mechanisms for implementation of biosafety regulations.
   - Form network with other ASEAN members sharing information.
   - Implement mechanisms for risk assessment.

External Assistance

- Human capacity development.
- Develop infrastructure for risk assessment of GMOs
- Share information and expertise.

References

1. ***Public Awareness on GMOs in Negara Brunei Darussalam.*** In "Consultation on Creating Public Awareness on Genetically Modified Organisms (GMOs) in ASEAN", by Dr. Zohrah Haji Sulaiman and Hajah Aidan Haji Mohd Hanifah
2. ***Genetic Engineering in Negara Brunei Darussalam: Future Implications*** by Dr. Zohrah Haji Sulaiman
3. GMO-Frequently Asked Questions in Brunei Darussalam (http://www.aseansec.org/)
4. ***Status on Biosafety Regulations in Brunei Darussalam*** by Hajah Normah S.H. Jamil
5. ***Current Status of Biotechnology in Brunei Darussalam*** by Zohrah Haji Sulaiman

BIOSAFETY STATUS **OF** CAMBODIA, THE LAO PDR AND MYANMAR

Overview

Cambodia, the Lao PDR and Myanmar (CLM) do not have regulatory control on importation of GM food or food products. There is no infrastructure set up to regulate the commercialization of GM food. Hence it is entirely possible that the food ingredients such as soybean and maize imported from neighboring countries are derived from genetic engineering. Cambodia imported food and food products worth US$139 million in 2001 (data from the Cambodia Import-Export Inspection and Fraud Repression Department, Ministry of Commerce). However, Article 6 and 12 of Cambodia's "Law on the Management of Quality and Safety of Products and Services" can be used to regulate any products, goods or services deemed harmful to health or safety of consumers. For Myanmar, very little information is obtained on the commercialization of GM food. In the Lao PDR, agriculture still constitutes more than 50% of the gross national product with rice being the major commodity. However, it is believed that the situation is akin to Cambodia in that GM products are available from neighboring countries and there is no regulatory control on the commercial release.

There is no information available on the commercial plantation of GM crops in these countries, but it is believed that if there were any, it would be through seeds pilfered or purchased from neighboring countries, particularly China.

Policy and Institutional Framework

The Lao PDR **is** a signature country to the Convention on Biological Diversity (CBD) and plans to ratify the Cartagena Protocol on Biosafety. The Science, Technology and Environment Agency (STEA) is the competent national authority and the Director General of the Research Institute of Science is the national focal point for the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP). The country has joined the UNEP-GEF Global Project on Development of 100 National Biosafety Frameworks and hopes to set up the National Biosafety Framework in accordance with the Cartagena Protocol on Biosafety. The main elements of the framework are regulatory system, administrative system, decision-making system, including risk assessment and management and mechanisms for public participation and information. The National Biosafety Committee (NBC) has been set up and is composed of the following representatives: Science Technology and Environment Agency, Ministry of Agriculture and Forestry, Ministry of Education, Ministry of Industry and Handicraft, Ministry of Trade and Tourism, Ministry of Foreign Affairs and Ministry of Justice. The NBC is to draft the national guidelines on biosafety to be approved by Prime Ministerial decree.

There has been no institutional framework set up for biosafety policy, guidelines and regulations in Cambodia and Myanmar. As mentioned earlier. Cambodia has developed mechanisms to prohibit the commercial sale of food if deemed unsafe. Myanmar still has not developed such mechanisms yet. In all these countries, the industrial or business structure remains underdeveloped, hence there is no mechanism for their involvement in forming policy.

Emerging Issues, Challenges **and** Trends

CLM being less advanced economically than other ASEAN members, the countries do not yet have the infrastructure necessary for consumer education and protection. Research activity in this area is non-existent. It is likely that some GM crops would be greatly beneficial to agriculture, as the crop yields in these countries are considerably below average compared to their neighbors. Given the developing status of science and technology in these three countries, it seems that GM seeds will have to be imported for distribution to the farmers. The emerging issues for these countries are setting up the regulatory framework and safety assessment infrastructure to accommodate GM crops for planting or food. More importantly, CLM should develop the legal framework to accommodate biosafety legislation and to protect exploitation of their biodiversity.

Public Awareness
Basically, there have been no public awareness programs in CLM and it is assumed that the public *is* poorly educated on GMOs. The poor communication systems and low literacy rate would also hinder public education and awareness campaigns.

Recommendations

1. **Policy**
   - **Establish or develop policy on biosafety.**
   - **Set up legal framework for biosafety, an organized structure, expertise to handle GMOs in policy and decision making process.**
2. Viable mechanisms for their implementation
   - Set up mechanism for approval process.
   - Risk analysis.
   - Set up mechanism for food safety system.
   - Set up training program for human capacity development.
   - Set up infrastructure for regulatory control.
   - Public awareness.

External Assistance
Human resource development.

References

Myanmar

1. ***Status of Biotechnology in Myanmar*** by Mr. Saing Lian Ceu In "Southeast Asian Seminar: Workshop on Public Awareness and Participation in the Implementation of the Cartagena Protocol on Biosafety", 1-3 August 2001, Hanoi, Vietnam.

Cambodia

1. ***Report on GMOs Status in Cambodia*** by Mr. Sin Sideth.
2. ***Law on the Management of Quality and Safety of Products and Services.*** Kingdom of Cambodia Nation Religion King.

Lao PDR

1. ***The Status of Biosafety Regulations and Capacity Building in Lao People's Democratic Republic*** by Dr. Sourioudong Sundara In The Southeast Asian Seminar Workshop: "Public Awareness and Participation in the Implementation of Cartagena Porotocol on Biosafety", 1-3 August 2001, Hanoi, Vietnam.
2. ***Country Paper of Lao P.D.R*** by Phonetip Varavongsa In Proceedings of the SEAN Workshop on "Regulations for Agricultural Products Derived From Biotechnology, 1-2 April 1998, Singapore.

BIOSAFETY STATUS OF INDONESIA

Overview

Indonesia is the first country in Southeast Asia to venture into the commercial production of GM crops with Bt cotton. The approval showed the commitment of Indonesia to maintain sustainable agricultural practice in keeping with rapid population growth. The transgenic crop is being farmed in a control area on an island and the area covers about 4,000 hectares in seven districts in South Sulawesi Province. The GM cotton seed is to be restricted for export only and no remains are *to* be commercially available in the country. The approval has a time limit of one year and renewal is based on the results of the review.

The transgenic Bt DP5690B cotton was field-tested in seven districts of South Sulawesi including Bantaeng, Bone, Bulukumba, Gowa, Soppeng, Talakar and Wajo. The results of the trial undertaken by Hasanuddin University and University of Gadjah Mada (UGM) showed that the GM crop has outperformed its isogenic line, DP5690, as well as the local variety, Ranesia7 in 15 locations tested. The yield of the Bollgard was 2-3 times higher and reduced the use of chemical spraying by more than twice, resulting in almost doubling the average net income. The scientific information was submitted for approval to the Minister of Agriculture and a decree was subsequently in February 2001 allowing limited planting of Bollgard cotton in 7 districts in South Sulawesi for one year.

Multiple location field trials for both soybean and maize have been completed and are next in the pipeline for approval.

Last year Indonesia imported over 826,000 tons of soybean and 1.2 million tons of corn, some of which are believed to be GM variety. About 50% are for the food processing industry and 50% animal feed. The popular traditional Indonesian fermented food, *tempeh* is made from imported soybean coming from the USA, China or Argentina. Over 99% of cotton is also imported.

Indonesia is quite active in research and development and there are GMOs being developed including rice, soybean, corn, sweet potato and peanuts. Perhaps the most advanced is transgenic rice resistant to the Sambola insect.

Policy and Institutional Framework

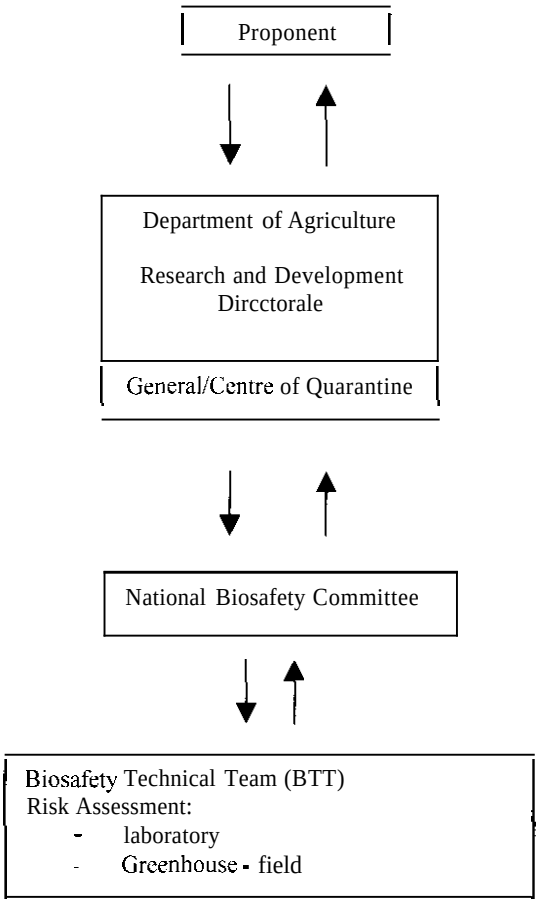
Indonesia is a signatory member of the Cartagena Protocol and a party to the Convention of Biological Diversity. The focal point of the protocol is the Ministry of Environment, while competent national authorities are the Department of Agriculture and the Food and Drug Agency. Indonesian Institute of Sciences is the National Biosafety Clearing House.

The first of the biosafety regulations developed in Indonesia was the laboratory guidelines for genetic engineering research in August 1993 under the Decree of the Ministry of Agriculture No.85/Kpts/hk.330/9/1997. The regulation is used to control research of genetically engineered organisms. The Biosafety Commission (BC) was established in 1997 to implement the Decree. The Commission has the mandate to advise the Ministry of Agriculture on the release of agricultural biotechnology products deemed safe to human health and/or the environment. A Biosafety Technical Team (BTT) was formed to assist the BC to evaluate the applications and carry out further technical studies or tests of genetically engineered agricultural biotechnology products (GEABP) in a biosafety containment or confined field. The BTT formulated a series of guidelines for the release of genetically engineered organisms; general plants, animals, fish and microorganisms and the specific guidelines for each organism.

In 1999, a food safety decree was released by four ministries; Agriculture, Forestry and Estate Crops, Food, and Health to regulate the biosafety and food safety of Genetically Engineered Agricultural Biotechnology Products. The guidelines for risk assessment of genetically modified food and animal feed are expected to be released in 2002.

The procedure for GMO release would require filing an application through the Department of Agriculture and/or the Food and Drugs Agency. The BC will provide recommendations on the safety of environment and human health. Then for plant release, the applicant will have to submit the request to the Plant Variety Release Committee and the next step is to perform a multi-location trial. The general approval steps are: application is tiled at the Department of Agriculture and is sent to the BC. The studies on environmental impact are assessed under supervision. The Plant Variety Release Committee will assist with multiple location plot tests of about 20 seasons. The results are reviewed by the BC and submitted to the Department of Agriculture for approval.

Procedure for Releasing GEABP



Indonesia has enacted a patent law in 1989 and enforced it in 1991. The law was later revised in 1997 to include protection of animals for meat and milk production and crops such **as** rice and corn. The plant breeders' rights (PBR) are not yet in place in Indonesia **as** committed under GATT/TRIPs which requires PBR commitment within a four year period.

The public and semi public research institutes, universities and industrial laboratories play an important role in research and development using gene technology (Table 1). The research funding is mainly from the government.

Crop	Institute	Target Trait
Rice	RDCBt, RIFCB	• Resistance to stem borer
	RDCBt	• Blast • drought
Corn	RIFCB	• resistance to borer
Papaya	RIVC and RIFCB	• viral resistance
Soybean	RIFCB	• resistance to borer
Soybean	BAU	• Viral resistance
Sugarcane	BRUEC	• Drought
	ISRI	• Resistance to borer
Potato	BAU	• Resistance to virus

RDCBt : Research and Development Centre for Biotechnology
RIVC: Research Institute of Vegetable Crops
BAU: Bogor Agricultural University
BRUEC: Biotechnology Research Unit for Estate Crops
ISRI: Indonesian Sugar Research Institute

Key Players/Stakeholders

Apart from the government agencies involved with the release of GMOs, there are demands from farmers for government to provide transgenic seedlings. The current demands are for cotton seed, soybean and corn.

The NGO and consumer groups are also quite active in Indonesia. Recently, they conducted a survey and found GMOs in certain food products. The food products were baby food, soy sauce and potato based products. However, there has not been strong public reaction against GMOs yet.

Emerging Issues, Challenges and Trends

- Public perception and awareness

According to the November 1999 Far Eastern Economic Review Asian Executives Poll, **80%** of Indonesian Executives were concerned to very concerned about food biotechnology. Also in 1999, studies by AFIC showed that up to **80%** of Indonesians were not aware of biotechnology. Only about 20% responded correctly on the question of "Ordinary soybeans don't contain genes but GM soybeans do". Hence there are gaps in knowledge of biotechnology amongst the general population.

The reaction to the field release of Bt cotton received minimum attention from the public. There are some campaigns against gene technology but there are no adverse reactions from the public. However, the government is aware of public outrage and has exercised precautionary principles in approving the release of Bt cotton as evidenced from the limited time of one year, restricted area and acreage of plantation and restriction on the release for export only.

Thus far, there has been no structured public education nor awareness programs on GMOs.

- Trade and Industrial Competitiveness

lndonesia has a population of 220 million with the projection of 400 million in **2036.** In order to achieve self-sufficiency in food production, biotechnology may be one strategic approach in improving yields and reducing production costs. The Indonesian Government seems to favour this approach with the introduction of Bt cotton, and with soybean and corn waiting to be released. The research on major staple crops for Indonesia such as rice (Table 1) would be a significant contribution to Indonesian food security in the future.

- Labeling

Labeling is stipulated in the Indonesian Biosafety Bill but the threshold level has not been decided yet. Given the limitations of the infrastructure and human resources, together with the uncertainties of labeling worldwide, enforcement may be a long way off yet.

Recommendations

1. Policy
   - Establish a legal framework to handle biosafety.
   - Set up public awareness policy.
   - Enhance infrastructure and financial resources to conduct R&D and risk assessment.

2. Viable mechanisms
   - Designate expertise and competent authorities.
   - Develop human capacity.
   - Promote information sharing, networking with others.

References

1. ***Indonesia Now Into GM Crop Production*** by Rudy **A.** Fernandez **(8** May 2001) in The Philippine Star.
2. ***Status on Biosafety Regulations and Capacity Building: The Case of Indonesia*** by Siamet-Loedin, I.H. and Karossi, **A.T.**
3. ***The Current Status of Industrial Biotechology in Indonesia*** by **A.T.** Karossi, Linar, Z. Udin and **S.** Pujiraharti.
4. ***The Current Status of Environmental Biotechnology in Indonesia*** by Harmastini I. Sukiman.
5. ***Regulations for Agricultural Products Derived from Biotechnology in Indonesia*** by S. Moeljopawiro. G. Subarto and Suprahtomo.

BIOSAFETY STATUS OF MALAYSIA

Overview

Biotechnology is one of the five strategic technologies expected to accelerate Malaysia's transformation into a highly industrialized nation by 2020. The National Agriculture Policy 3 (NAP **3)** for 1998-2010, highlights the importance of human resource development in order to generate highly skilled and innovative manpower in new and emerging sciences such **as** food, genetic engineering and biotechnology.

Malaysia signed the Cartagena Protocol on Biosafety at the Fifth Meeting of the Conference of Parties to the Convention in Nairobi, Kenya. Hence any national biosafety legislation will need to be in line with the Protocol.

The Ministry of Science, Technology and Environment (MOSTE) is the lead agency in Malaysia for biosafety matters. Several divisions have been set up to spearhead the development in this area, notably the Science and Technology Division, the International Division, the Conservation and Environmental Management Divisions and the National Biotechnology Directorate (BIOTEK). BIOTEK was set up to propel the development of the country's biotechnology sector.

Like many other ASEAN members, Malaysia has no specific laws addressing the biosafety issues in any holistic way. However, several laws from different governmental sectors do address specific segments such as the Food Act 1983, the Fisheries Act 1963 (revised 1978), the Plant Quarantine Act 1976, the Poisons Act 1979 and the Pesticide Control Act of 1974. The Genetic Modification Advisory Committee (GMAC) was set up under the National Committee on Biodiversity of MOSTE to be the national advisory body. GMAC is currently chaired by Prof. Dr. Mohamad Noor Embi, Deputy Vice Chancellor of the Agricultural University of Malaysia (UKM) and consists of the following members:

1. Prof. Dr. Koh Chong Lek, Institute of Biological Sciences, University of Malaysia.
2. Dr. Low Fee Chon, BIOTEK.
3. Dr. Villasini Pillai, Malaysian Agricultural Research and Development Institute (MARDI).
4. Prof. Dr. Mohd. Sanusi Jangi, Open University.
5. Assoc. Prof. Dr. Nazlan Najimudin, University of Science Malaysia.
6. Representative, Crop Protection and Plant Quarantine Division, Ministry of Agriculture.
7. Representative, Ministry of Primary Industry.
8. Representative, Food Quality Control Division, Ministry of Health.
9. Representative, Attorney's General Chamber, MOSTE.
10. Administrative Secretary, MOSTE.

GMAC has drafted a Biosafety Bill with anticipated approval by Cabinet in June 2002. The Biosafety Bill is a draft law to regulate and manage the import, deliberate the release into the environment, placing on the market and the contained use of genetically modified organisms and products derived from these organisms, in accordance with the Precautionary Principle, the principle of sustainable development, and ethical and cultural norms, so as to protect human, plant and animal health, the environment and biological diversity. The biosafety guidelines for research and development are also included in the draft Bill.

The National Guidelines for the Release of Genetically Modified Organisms into the Environment, formulated by GMAC, set the regulatory framework for biotechnology. The guidelines cover all GMOs at all stages of research and development, use, handling, trans-boundary movement, release and placing in the market of GMOs and products containing GMOs and address biosafety issues in biotechnology such **as** risk assessment, risk management and monitoring. The guidelines were essentially developed using the UNEP Guidelines.

According to the official sources, currently there is no commercial release of GM plants actually growing in Malaysia. To date, only one application for the release of a GMO has been received by the

GMAC, namely glyphosate resistant "Round Up Ready" soybean for food and feed. The environmental impact and the safety assessment of GM soybean was conducted and approved in 1997, as the likelihood of environmental harm was considered very low.

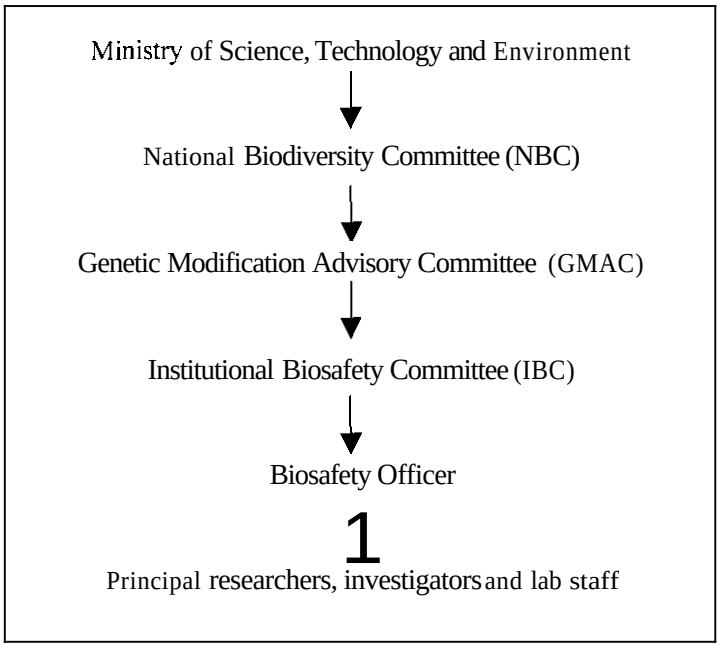
Since there is no regulatory control on importing products of GM crops into the country, it is expected that some of these may he entering the country. However, apart from the Consumer's Association of Penang (CAP), there seems to be no general public pressure from consumer groups or NGOs for regulatory control of GM food entering the country.

There are several ongoing research activities in developing new varieties of both plant and tree crops using gene technology. The most promising varieties to be commercially released into the market are GM rice and shorter-ripening palm.

Policy and Institutional Framework

MOSTE is responsible for the national policy, technical direction and guidance to programs and activities related to conservation and environmental management. GMAC offers technical advice to MOSTE, as well as to private bodies. It is responsible for establishing guidelines for the importation, research, testing, release and utilization of genetically modified organisms (GMOs) and to promote public awareness in biotechnology and biosafety. The Secretariat of GMAC is housed in MOSTE and its members comprise experts from different research fields. All requests for commercial release of GMOs must go directly to GMAC for consideration. Once the request is reviewed by GMAC, then it is submitted to a government-appointed council for final approval. The approval is based on commodity and there is no time limitation. There has also been interest expressed in having a monitoring system for approved-release GM commodities. Thus far, GMAC has released a guideline for "Release of GMOs into the Environment".

The Food Quality Control Division of the Ministry of Public Health has also put up a draft on "Regulation on Genetically Modified Foods (GMF)". The draft is an amendment to the Food Regulations 1985. According to the draft, all GM food must be approved by the Director-General of Health, Malaysia. There is also a labeling provision which states that all food containing genetically modified ingredients greater than 3% of the total ingredients must be so labeled. The wording used in labeling, as well as the manner of labeling, must conform to that specified in the Proposed Amendment



Key Players/Stakeholders

There are several government agencies involved in enforcing and implementing biosafety regulations. Other than those mentioned above, other government agencies involved in detection techniques for GMOs are the Malaysian Agricultural Research and Development Institute (MARDI) and the Agricultural University of Malaysia (UKM). MARDI is also responsible for field trials of GMOs intended for environmental release. The private sector and the consumer groups have shown some interest as either advocates or opponents.

Emerging Issues, Challenges and Trends

- Public Perception and Awareness

The only public survey undertaken on Malaysian perception of GMOs was by AFIC (ASEAN Food Information Centre) in 1999. According to the studies of 300 interviews, about 18% were aware of food biotechnology and about 50% did not know about biotechnology. The responses which illustrated the knowledge of gene technology such as "ordinary soybeans do not contain genes but GM soybeans do"; over 40% of the Malaysians answered "yes" to the question while over 30% responded that they did not know. On the question of "By eating a GM fruit, a person's genes could he changed, nearly 20% of the Malaysians responded "yes" and 30% did not know. The report did not specify the population group of the respondents. The executive's poll surveyed by the Far Eastern Economic Review in November 1999, showed that 75% of the Malaysians who responded as concerned to very concerned regarding genetically modified food. This would indicate that genetically modified food is a sensitive issue as in other countries, when there is awareness of it. However there appeared to he no public pressure on having regulatory control and labeling legislation in place.

- Consumer Protection and Public Awareness

The Riosafety Legislation currently awaiting approval by Cabinet would be one form of consumer protection strategy. Once the legislation is adopted, then guidelines for commercial release must be enforced. Quite a number of non-government consumer protection groups are monitoring developments with GMOs in Malaysia. Frequently asked questions concerning GMOs and biotechnology in general are addressed by the Riotechnology Information Centre on their web-site (http://www.bic.org.my/faqs_body.html). Public funds are available through the National Riotechnology Directorate for workshops and training courses. These can he organized by the Biotechnology Cooperative Centres for Food.

- **Trade and Industrial Competitiveness**

Malaysia is both a major food importer and, largely through being the world's major supplier of palm oil, also a food exporter. Islam is also the official religion, thus the issues concerning GMOs are importation as food, *halal* certification, seed for plantation agriculture, and the need to certify exports. The government has decided that Malaysia should become a major world player in biotechnology and is providing infrastructure funding accordingly. MARDI has recently been reorganized to emphasize biotechnology. GM technology is one strategy the Malaysian Government has taken to enhance industrial competitiveness. The focus may not he so much on agricultural biotechnology, hut more on using plants to produce pharmaceutical products. Currently, three genetically modified crops are close to commercial release; they are genetically modified rice resistant to virus, genetically modified maize and CM oil palm for faster ripening.

- **Labeling**

The Food Quality Control Division of the Ministry of Health (MOH) Malaysia has proposed an amendment to the Food Regulations 1985 for public comment. GM food found not to he equivalent to the corresponding existing food and food ingredients are required to be labeled. The label must provide information on the characteristics or properties ie. composition and/or nutritional value and intended use, making it different from the corresponding existing food and food ingredients. Information on mode of storage, preparation or cooking should be on the label. The threshold level is determined to be more than 3% of the total ingredient content.

Recommendations

1. Policy
   - Set up legal framework to handle biosafety.
   - Set up public education policy.

2. Mechanism for Implementation
   - Human capacity building for risk assessment and GMO detection.
   - Information sharing and networking.

References

1. GMO-Frequently Asked Questions in Malaysia (http://www.aseansec.orei).
2. ***National Guidelines for the Release of Genetically Modified Organisms (GMOs) into the Environment*** by Genetic Modification Advisory Committee (GMAC), Ministry of Science, Technology and Environment, Malaysia.
3. ***Draft Proposed Regulation on Genetically Modified Foods (GMF): Proposed Amendment to the Food Regulations 1985 for Public Comments***. Food Quality Control Division, Ministry of Health, Malaysia.
4. Full text of Regulations on Release of GMOs into the Environment can be found at http://www.hdt.fat.ory.bribinas/Reeulations/fultegs/malaysia/malgmo.html

BIOSAFETY STATUS OF THE PHILIPPINES

Overview

The use of industrial and agricultural biotechnology in the Philippines is well established, mostly focussed on food and alcoholic beverages. Although, there is no record on the use of GMOs in the food processing industry, the Philippines, like other ASEAN countries, imports much of the soybean and corn used for domestic consumption. Many of the imported commodities are likely to be derived from gene technology.

The Philippines was the first ASEAN country to formulate a national policy on biosafety in 1990. The National Biosafety Committee of the Philippines (NBCP) was first established under the Executive Order No. 430 on 15 October 1990 to evaluate and recommend measures on the effective utilization of national resources. To date, there have been two completed field trials of Bt corn in the Philippines. There has not yet been any commercial release of any GM plant varieties.

The Philippine Department of Agriculture recently issued Administrative Order No. 08, Series of 2002, governing the importation and release into the environment of plants and plant products derived from the use of modern biotechnology. Under this Order, the approval process for importation of regulated articles for direct use as food or feed, or for processing is also included.

Research and development has progressed well as the Philippines is home to the International Rice Research Institute (IRRI), hence there is a lot of research in developing better plant crop varieties. Other local research facilities include the Institute of Molecular Biology and Biotechnology, the Philippines Rice Research Institute and the Institute of Plant Breeding at the University of the Philippines, Los Baños.

Policy and Institutional Framework

The functions of the National Biosafety Committee of the Philippines (NBCP) are to identify and evaluate potential hazards involved in genetic engineering experiments and recommend measures to minimize the risks, to formulate and review national policies and guidelines on biosafety and risk assessment of work in biotechnology and to work in collaboration with other quarantine services and institutions to evaluate, monitor and review projects. NBCP's major task is to focus on biodiversity in addition to GMOs as more than 95% of applications filed are related to biodiversity and not to GMOs. The function of NBCP also covers only the experimental use of GMOs, not their commercial use. The authorities of commercial release are specific to the nature of the commodity seeking approval such as the Department of Agriculture for plant crops and the Department of Health for food. None of these agencies have the guidelines for commercial release as yet. The Department of Agriculture is expected to complete its own guideline soon. Hence NBCP has two guidelines for laboratory research approval and environmental release.

The laboratory research approval process involves two steps; the Institutional Biosafety Committee (IBC) and NBCP. IBC will have to approve the project before it can be accepted by NBCP. The IBC is composed of five members, two of whom must be community representatives from where the research was conducted and are independent from the institute. For field trials, IBCs must assess and review the field test proposals for potential hazards, the qualifications and experience of the personnel and the competency and professional practices of project staff.

NBCP also relies on the technical expertise of the Scientific and Technical Review Panel (STRP) for evaluation of the project. Each evaluation involves at least three members of STRP for scientific expertise and experience. NBCP also must evaluate the planned release into the environment or field testing of GMOs. The guidelines cover both GMOs and potentially harmful exotic species. The guidelines in the Philippines also require a public notice and comment period before the NCBP finally takes action on any field test proposal. The Public Information Sheet (PIS) must be posted in the community for three consecutive weeks and published once a week for two weeks in a newspaper of general circulation. The public comment period is 30 days from the date of last posting and the

proponent shall have 15 days to respond. The public notification process is not considered to be the informed consent by the community.

The NCBP "approval" is based entirely on scientific and technical merit, hence the proponent must also comply with other requirements of other relevant agencies who may take the socio-economic factors into consideration.

Key Players/Stakeholders

In the case of the Philippines, there is more public involvement in the experimental phase. This can be seen from the community members in IBC and the public notification procedure. There is no information yet on the positive or negative influence of public participation in the field trials.

In general, the consumer groups in the Philippines are quite active opponents to GMOs and may cause negative bias to the public involved in the process. On the other hand, the involvement can also build confidence to the public as they have input to the experiments.

Emerging Issues, Challenges and Trends

- Public Perception

A survey of awareness and attitudes regarding GM food among students of the University of the Philippines showed that most are hardly or moderately aware of GMOs and *65%* are willing to consume GM food. **96%** want GM food to be labeled and ***66%*** are willing to consume even though they are labeled. The Far Eastern Economic Review survey in November 1999 showed that **80%** of executives are very concerned to concerned with biotechnology. About equal proportion responded correctly as to incorrectly to the statement on "ordinary soybeans don't contain genes but GM soybeans do" and a majority of 70% said that the statement "by eating a GM fruit, a person's genes could be changed" is false. It appears that Filipinos in general have a better understanding of gene technology than other ASEAN neighbors.

- Labeling

The subject is being studied by concerned government agencies. However, there is no government policy on labeling as yet.

- **Trade and Industrial Competitiveness**

It is assumed at the policy level that biotechnology would greatly enhance industrial competitiveness, particularly in agriculture. However, the Philippines has not yet been able to take full advantage of the opportunities offered by the technology.

Recommendations

1. Policy options
   - Set up policy to handle GMOs.
   - Set up legal framework to enforce biosafety.
2. Viable mechanism for their implementation
   - Establish infrastructure and capacity to conduct risk assessment
   - Enhance networking and information sharing.
   - Promote R&D in biotechnology.

References

1. Evaluation of Project Research Proposals in Potentially Hazardous Biological Work (Department of Science and Technology Web Site: http://www.dost.vov.ph).
2. Procedures and Guidelines on the Introduction, Movement and Field Releases of Regulated Materials (Department of Science and Technology Web Site: http://www.dost.gov.ph).
3. ***Survey of Awareness and Attitudes Regarding Genetically Modified Foods Among Students of the University of the Philippines*** by Tuazon, Tejada, Romero, Alcazaren, Fernandez, Roxas and Villanueva.

4. ***Biosafety Regulations in the Philippines: Salient Points and Pending Issues.*** By Ochave, Esq. and Estacio
5. ***The Current Status of Environmental Biotechnology in the Philippines*** by M.A. Tavanlar to the BIOASIA 2000 Workshop, 21-24 November 2000

BIOSAFETY STATUS **OF** SINGAPORE

Overview

Singapore is an industrialized city state where most of the food and agricultural products are imported into the country. Currently, there seems to be minimal control on the importation of GM commodities. The most likely GM products are soybean, maize and canola oil. There has been no formal approval of any GM food products. As for non-food items, the genetically modified blue carnation (cut flower) has been approved for commercial release but not for cultivation.

The regulatory body for biosafety is being centralized at the Agri-Food and Veterinary Authority of Singapore (AVA). The Genetic Modification Advisory Committee (GMAC) was established in April 1999 by AVA and the Agency for Science, Technology and Research (A* Star). GMAC is chaired by Dr. Ngiam Tong Tau, CEO of AVA and comprises members of government statutory boards, ministries and the hospitals. The role of GMAC is to oversee and advise on the research and development, production, use, and release of GMOs in Singapore. Moreover, to ensure that these are done in compliance with international standards, GMAC is to develop and approve biosafety guidelines regarding GMOs, as well as facilitate the harmonization of guidelines with international authorities. GMAC also has the authority to recall any genetically modified organisms approved for release based on its assessment of new information.

At the Institute of Molecular Agro-biology in Singapore, there is a lot of research activity on development of plant varieties for resistance to disease, to produce pharmaceutical products and to obtain higher yields. It is more likely that Singapore will use such transgenic varieties for farming in other countries such as China.

Policy and Institutional Framework

Singapore has invested heavily in biotechnology research and hopes to become the "World Class Life Science Hub". The research is focussed not so much on the end product but mostly to generate intellectual property. Being a food importing state. the GMO policy seems to be open to GM food and food products. The following have been submitted for safety review; Bt corn, potatoes, soybeans, canola and maize. There is also a request for a review of resveratrol producing lettuce.

The biosafety guidelines on agriculture-related genetically modified organisms were developed by the GMAC in July 1999. GMAC consists of representatives from national agencies. The mission of GMAC is to be the central clearing house for GMOs with the main objective to advise and recommend for approval of research and development, production, use and handling of GMOs. Predominantly, the biosafety approval process for research and development at the laboratory level is done at the institutional level. The field trials are undertaken in collaboration with researchers in China and New Zealand. However, research on sensitive issues such as human cloning or stem cell engineering may require approval from the National Bioethics Advisory Panel. Under GMAC, there are four different specialized subcommittees for agricultural products, research, labeling and public awareness.

Singapore has played a leading role in the adoption of ASEAN guidelines on risk assessment and in the harmonization of risk assessment in ASEAN.

Stakeholders

The members of GMAC main-committee are
Dr. Ngiam Tong Tau (Chairman), CEO, AVA Singapore
Prof. Lee Sing Kong, National University of Technology
Prof Chong Tow Chong, Agency for Science, Technology and Research (Science & Engineering Research Council)
Dr. Lam Sian Lian, Health Promotion Board
Dr. Leong Chee Chiew, National Park Board
Mr. Daniel Wang Nan Chee, Ministry of Environment
Mr. Sivakant Tiwari, AG Chambers

Prof. Kong Hwai Loong, Agency for Science, Technology and Research (Biomedical Research Council)
Prof. Edison Liu, Genomics Institute of Singapore, National University of Singapore (NUS)
Prof. Hew Choy Leong, NUS
Prof. Lam Kong Peng, Institute of Molecular and Cell Biology
Mr. Yeo Guat Kwang, Consumers Association of Singapore (CASE)
Prof. Zhang Lianhui, Institute of Molecular Agrobiology, NUS

The stakeholders involved in the drafting of guidelines are mostly from industry, government offices and academicians. The Singapore consumer group, CASE, is also represented

Emerging Issues, Challenges and Trends

- Public Perception and Awareness

GMAC has conducted a public perception survey on GMOs in Singapore and found that the knowledge of the subject is quite limited. However, over 50% appeared to support GM food. There are some negative sentiments but no report of any organized campaign.

- Labeling

There are no labeling provisions for GM food in Singapore to date. The view of GMAC is to wait for international agreement on the issue.

- Trade and Industrial Competitiveness

Singapore has very little land for agriculture where land for farming accounts for only 1.8% of the total area. Biotechnology is therefore utilized in a strategic approach by providing the agricultural industry with tools for intensive farming and to increase productivity.

Recommendations

1. Possible policy options
   - Policy to risk assess GMOs for food and environmental release.
   - Policy on research work using gene technology.
   - Policy on labeling.
2. Viable mechanisms
   - Networking and sharing of information.
   - Develop guidelines for research and labeling.

References

1. ***Regulations for Agricultural Products Derived from Biotechnology in Singapore*** by Lee Siew Mooi and Dawn Chan. In "Proceedings of the ASEAN Workshop on Regulations for Agricultural Products Derived from Biotechnology", 1-2 April 1998, Singapore.
2. GMO-Frequently Asked Questions in Singapore (http://www.aseansec.ore/).
3. Singapore Guidelines on the Release of Agriculture-Related Genetically Modified Organisms (GMOs).

BIOSAFETY STATUS OF THAILAND

Overview

Agriculture continues to contribute a significant proportion of Thailand's gross national product. The country remains a world leader in the production of several commodities such as rice, cassava, canned tuna and canned pineapple. The government view is that for Thailand to maintain its position in world food production, biotechnology will play an important role in increasing the competitive advantage of farmers and agro-industry.

Thailand is one of two ASEAN countries that has yet to sign the Rio de Janeiro Agreement on Convention of Biological Diversity. Guidelines for biosafety were adopted in June of 1992 and a National Biosafety Committee (NBC) established in 1993 by the National Center for Genetic Engineering and Biotechnology (BIOTEC). In order to ensure that the guidelines are effectively implemented at the institutional level, a total of 16 Institute Biosafety Committees (IBC) were set up at academic and research institutes and one private laboratory. Thailand has long experience with field trials of genetically modified plants, starting in 1994 when the Department of Agriculture (DoA) granted permission for seed production of FLAVAR SAVAR tomato in 1994 and Bt cotton in 1995. Field trials of Bt cotton for commercial planting started in March 1996 and have since been completed. However, permission for the commercial release of Bt cotton is still pending by DoA. In October 1999, Thailand's Committee on International Economic Policy issued a guideline for commercial release of seeds and grain derived from genetically modified organisms. It prohibits commercial release and growing of plant seeds derived from gene technology. However, field trial experiments are permissible under the jurisdiction of DoA. The 1964 Plant Quarantine Act and the 1999 amendments have restricted importation of over 70 different varieties of transgenic plants. In addition, GMOs must be proven as safe before they can be permitted for use as food or food ingredients. This food safety issue is to under the jurisdiction of the Food and Drug Administration. Transgenic soybeans and maize have received exemption for use as human food and animal feed.

To provide technical support to various government agencies in risk assessment, NBC established three specialized subcommittees on plants, microorganisms and food. The Sub-Committee for Food Biosafety has issued guidelines for safety assessment of GM food which has since been adopted by the Food and Drug Administration. Under this guideline, transgenic soybean and cotton seed oil have been assessed for their safety.

Thailand is very active in research and development seeking better varieties of plants using gene technology. While no local transgenic plants have been commercially released, there is evidence to suggest that farmers are obtaining GM seed from neighbouring countries, particularly cotton from China. Work on the ring spot virus resistant papaya is probably the closest to commercial development, although food safety assessment has not yet been conducted. There also has been a commercial release for a container-used genetically modified microorganism to produce food ingredients.

Policy Review and Institutional Framework

Thailand has a liberal policy for research and development using gene technology, however the work must be approved at the institutional level or IBC. The government fully supports development and strengthening of capacity in research and production of genetically modified food and agricultural products. However, the government still does not allow commercial release of GM plants due to strong opposition from consumer groups, particularly Greenpeace (Thailand).

Currently, Thailand is in the process of drafting Biosafety Legislation. In the meantime existing regulations are used to try and control the use of GMOs in the country.

The institutional framework for approval of GMOs **is** that the Department of Agriculture is in charge of environmental release, the Department of Livestock Development of commercial release of genetically modified animals and animal feed, the Department of Fisheries of fish and aquatic animals,

the Royal Forest Department of wild animals and the Food and Drug Administration of food and food products. With the establishment of Thailand's Biodiversity Centre in January 2000, the NBC, IBCs and the three subcommittees have been transferred to he under this new centre. TBC is to he responsible for the implementation of biosafety legislation for sustainable utilization of Thailand's natural resources and is the national focal point for the Cartagena Protocol.

Regulations and Legislation

DoA amended the 1964 Plant Quarantine Act in 1999 to include all possible genetically modified plant varieties. Other legislation used in controlling GMOs are shown in Table 1.

Table 1. Legislation in regul ig GMOs in Thailand

Genetically Modified Organisms	Legislation	Government Agencies
Plants	• Plant Quarantine Act B.E. 2507 (1964) amended 1999 • Plant Variety Act B.E.2518 (1975)	Department of Agriculture
Animals	• Animal Disease Control Act B.E. 2505 (1962) • Animal Pathogen and Toxin Act B.E. 2525 (1982)	Department of Livestock Development
r-DNA derived and biotechnological products	• Hazardous Substance Act B.E. 2535 (1992) • Fertilizer Act B.E. 25 I8 (1975)	
Environment Protection	• Enhancement and Conservation of National Environmental Quality Act B.E. 2535 (1992)	
Food	• Food Act	Food and Drug Administration
Technology Transfer	• Copyright Law B.E. 2521 (1978) • Patent Law B.E. 2522 (1979) • Intellectual Property Right Act B.E. 2536 (1993)	Department of Justice

In addition, DoA has issued a declaration and undertaken the following actions to control genetically modified organisms in Thailand:

1. DoA's Declaration on Request for Certification Documents from Exporting of Seeds which are not genetically modified. Issued on 7 January 200 I
2. DoA's declaration on importing of plant breeding materials including seed where certification documents that the material are not derived from genetic modification
3. DoA's declaration on Cultivation of Genetically Modified Cotton, issued on 6th March 2001

Key Players and Stakeholders

The NGO and consumer groups are actively involved in the decision making process of biosafety in Thailand. There are strong public campaigns against gene technology mostly focusing on family-oriented food. The multinational biotechnology companies have been quite vocal in supporting the technology through public forums and mass media.

Emerging Issues, Challenges and Trends

- Consumer Perception and Public Awareness

There is still negative perception against GMOs in Thailand due to strong opposition from consumer groups, many of whom have been transplanted into Thailand from Europe and seem to be deliberately targeting multinational food producers. Greenpeace (Thailand) has conducted analyses on GMO content in food products from supermarkets and found a number of commodities containing ingredients from soy proteins derived from GMOs. The survey focussed the analyses on sensitive food items such as baby food and appears to have been coordinated with similar campaigns elsewhere in the region and internationally. There have also been educational campaigns to provide scientific information on GMOs through the government offices using mass media and publications. However, strong public sentiment against GMOs both domestically and internationally appears to be the biggest barrier for commercial release of GMOs in Thailand.

- Labeling

The Food and Drug Administration has drafted a labeling regulation for food containing ingredients derived from GMOs. The threshold level has been determined to be 5% or the top 3 ingredients. FDA has also conducted a public hearing on GMO labeling and found that most supported the initiative. However, most of the responses received by FDA were from NGOs, not necessarily representative of the general public. The labeling regulation is expected to be signed by the Minister of Health in June 2002.

- **Trade and Industrial Competitiveness**

Biotechnology is vital to the trade and competitiveness of Thai agro-industry. Current research focuses on higher yields, disease and stress resistant crops of local varieties such as Jasmine rice KDML105. It is hoped that once the public realizes the positive benefits of gene technology, Thailand will not have already lost its preeminent position in the agricultural world.

Recommendations

1. Possible policy options
   - Develop Biosafety legislation.
   - Develop a legal framework to handle biosafety.
   - Develop a biosafety clearing house mechanism.
2. Viable mechanisms for their implementation
   - Sharing of information and data sharing among stakeholders.
   - Train technical expertise to conduct risk analysis.
   - Promote coordination among governmental agencies and multi-sectoral participation

References

1. ***Current Status of Biosafety Policy and Regulation in Thailand*** by Banpot Napompeth.
2. ***Genetically Modified Foods: Challenges to Thailand*** by Morakot Tanticharoen and Ruud Valyasevi.
3. Biosafety Guidelines for laboratory work and field release by Thailand National Biosafety Committee.

Appendix 1: Thailand's GMOs Chronology

Date	Events
I983	Inauguration of Thailand's National Center for Genetic Engineering and Biotechnology (NCGEB, now BIOTEC)
1985	Establishment of BIOTEC's Plant Genetic Engineering Unit (PGEU) in Nakhorn Pathom, Thailand
1986	BIOTEC commissioned a status report on the prospects of biotechnology in agriculture stated the need for the country's biosafety regulatory system
I990	A feasibility study on biosafety by BIOTEC
I990	Biosafety Subcommittee was established under BIOTEC
April 1992	BIOTEC appointed an ad hoc subcommittee to draft Thailand's first biosafety guidelines
June 1992	Complete draft of biosafety guidelines (for laboratory and for field test)
January 1993	National Biosafety Committee (NBC) established with BIOTEC as secretariat, followed by establishment of Institutional Biosafety Committees (IBCs) at various research institutes.
1993	First application for importing transgenic plant for field test on seed production (Calgene's Flavr Savr tomato)
1994	A list of 40 prohibited transgenic plants added to the I964 Plant Quarantine Act
1994	Flavr Savr tomato granted permission for field test
1995	Application of Monsanto's *Bt* cotton.
I995	Establishment of DNA Fingerprinting Unit, BIOTEC in Nakhorn Pathom, Thailand
March 1996	***Bt*** cotton field test experiment started in northeastern Thailand.
I997	Establishment of Plant Biosafety Subcommittee under NBC
1998	Establishment of Food Biosafety Subcommittee under NBC
1998	Establishment of Microbial Biosafety Subcommittee under NBC
1999	Trade dispute between Thailand and some EU countries over detention of tuna in oil from Thailand. Other trade dispute cases follow suit.
1999	Subcommittee for Policy on Trade of Biotechnology Products set up under the Committee for International Economic Policy
I999	Amendment of the 1964 Plant Quarantine Act to strengthen regulation of transgenic plants
September 1999	A report "Status of GMOs in Thailand" published by BIOTEC
September 1999	First public hearing on GMOs organized by Department of Agriculture (DOA) held in Bangkok
October 1999	First survey in Bangkok by BIOTEC on public awareness and attitude towards GMOs
December 1999	Inauguration of Thailand Biodiversity Center (TBC) as the potential national focal point for the Cartagena Protocol on Biosafety (Thailand has not yet signed the protocol). NBC's secretariat (including subcommittees) moved to TBC.

Appendix 1. (continued)

Date	Events
2000	Establishment of DNA Technology Laboratory (former part of DNA Fingerprinting Unit), with a mandate to detect GMOs on service basis, among other tasks.
2000	Establishment of two separate GMOs detection laboratories in Department of Agriculture and Department of Medical Science
2000	Thailand Food and Drug Administration (FDA) commissioned a work group to consider labeling method for GM foods
March 2000	Ministry of Agriculture and Cooperatives' declaration on import prohibition of 40 transgenic plants (revised) with exceptions for grains of GM corn and soy bean
April 2000	Trade dispute between Thailand and Kuwait / Saudi Arabia over tuna in oil (suspected to be made from GM soy bean)
October 2000	National Subcommittee on Biosafety Policy proposed to the National Committee on Conservation and Utilization of Biodiversity (NCCUB), with TBC as secretariat office.
January 2001	Trade dispute between Thailand and Egypt over tuna in oil reached its peak. Both party agreed to sign MOU.
February 2001	A draft of GMOs policy approved by the Subcommittee for Policy on Trade of Biotechnology Products
March 2001	BIOTEC starts a series of consultation meeting with stakeholders on GMOs issue

BIOSAFETY STATUS OF VIETNAM

Topics	**Institutes**
1. Rice and vegetables	Institute of Biotechnology, Hanoi
2. Veterinary vaccines	Institute of Veterinary, Hanoi
3. Transformation of *Penecilium* sp.	VINAPHA
4. Plant bioactive compounds	Institute of Biotechnology, Hanoi

Public participation in the development of biosafety regulations in Vietnam has been minimal. There have been no public forums or public education campaigns on biosafety and gene technology. Since a large proportion of the population has low education levels and there is generally a poor communication infrastructure, this becomes the biggest hurdle in getting public involvement. Only when biosafety regulations are adopted and risk assessments implemented will the public be protected. The proposed biosafety regulations also contain a clause on labeling requirements for GM food or their products. Minimal threshold levels have not been decided and given the limited human resources, facilities and infrastructure, it would be very unlikely that labeling will be implemented in Vietnam anytime soon.

Funding for research and development in biotechnology has increased considerably over the last two decades and the government has set the budget priority to increase Vietnam's competitiveness, particularly in the field of agriculture.

The commercial release of GM crops for planting *is* not likely to occur soon, if it did Bt cotton would likely be the first crop. The use of genetically modified microorganisms as factories for producing pharmaceutical products is most likely to be the first commercial release.

Recommendations

1. Possible policy options
   - Develop biosafety policy in line with the Cartagena Protocol.
   - Develop legal framework for biosafety.
   - Develop structured decision making system for biosafety.

2. Viable mechanisms for their implementation (capacity building, strengthened coordination and networking)
   - Risk analysis.
   - Networking and information sharing.
   - Public awareness.
   - One clearing house system.

Areas which may require external assistance

- Human capacity development.

References

1. ***Industrial Biotechnofogyin Vietnam*** by Prof. Nguyen Van Uyen.
2. ***Biopolicy in Vietnam*** by Le Minh Sat and Le Tran Binh.
3. Biosafety Regulations for GMOs and their Products in Vietnam (draft).
4. Status of Biosafety Regulations and Capacity-Building in Vietnam.

ASEAN BODIES AND REGIONAL BIOSAFETY ACTIVITY

The Hanoi Plan of Action, 1999-2004 was conceptualized as a strategy to realize the goals of ASEAN Vision 2020. The first is to identify 10 priority program areas in food, agriculture and forestry, environment and science and technology. This has led to the cooperation among ASEAS members in biotechnology, especially in agriculture, environment and biosafety.

There are 3 ASEAN sectoral bodies that deal with biotechnology and biosafety issues:
1. ASEAS Ministers on Agriculture and Forestry (AMAF)
2. ASEAS Committee on Science and Technology (COST)
3. ASEAS Senior Officials on Environment (ASOES)

AMAF tackles the issues from the perspective of ASEAS trade promotion of food products and food safety. The implementation body for the cooperative programs in food, agriculture and forestry is handled by the Senior Officials Meeting – ASEAN Ministers on Agriculture and Forestry (SOM-AMAF). SOM-AMAF has organized a Task Force on the Harmonization of Regulations for Agricultural Products Derived from Biotechnology. The driving force in setting up the task force is Singapore who would like the ASEAN Free Trade Agreement (AFTA) to be realized as soon as possible.

COST takes the approach towards biotechnology from the perspective of research and technology development and its utilization. The Sub-committee on Biotechnology has been established to oversee the implementation, monitoring and evaluation of joint research and development and training programs in biotechnology.

ASOES deals with biotechnology from the environmental protection perspective. The Working Group on Nature Conservation and Biodiversity takes the issues in the context of international conventions and protocols. An ASEAS Biodiversity Center has been established in the Philippines.

Major Program Areas

SOM-AMAF has been active in trade issues of crops. The recent work included the harmonization of phytosanitary measures and harmonization of maximum residue limits of pesticides for vegetables. In livestock, ASEAN standards for animal vaccines are being developed. There are also some R&D and technology transfer programs to improve agricultural productivity.

COST is involved with the overall development of science and technology capability within the region through joint research and development, human resource development, regional networking of science and technology infrastructure and programs, and promotion of technology transfer. These activities are implemented in economically significant sectors and disciplines such as food science and technology, marine science, non-conventional energy and biotechnology. The priority areas for the Sub-committee on Biotechnology for 2001-2004 are in food and horticultural crops, improvement of livestock production, value-addition to natural products and bioinformatics.

ASOEN is concerned with policy measures and institutional development. These promote the integration of environmental factors into national and regional development planning, establishment of long-term goals on environmental quality and work towards harmonization of environmental quality standards, and joint actions to address common environmental problems in the region.

Quite recently SOM-AMAF and ASOEN have become involved in biotechnology and biosafety as it was agreed to take up Singapore's initiative on the harmonization of regulations for agricultural products derived from biotechnology in 1997. In the same year, ASOEN agreed to develop a common protocol on access to genetic resources and related intellectual property rights. It was at this time that the genetic modification technology moved out of the research laboratories and into agri-business that resulted in the marketing of products derived from genetically modified organisms.

The ASEAN Workshop on Regulations for Agricultural Products Derived from Biotechnology, hosted by Singapore was held to be a venue where baseline data on the various national regulations being imposed by the ASEAN member countries were established as well as where the views of the private sector and civil society groups were heard. The status of biosafety regulation of ASEAN revealed that few member countries (Indonesia, Malaysia, Philippines, Singapore and Thailand) had developed some guidelines for R&D and field releases of genetically modified organisms, none had a comprehensive legal framework to address commercial and consumers' concerns. The key weaknesses were the lack of the force of law, and the standard S&T infrastructure for most operational procedures in risk assessment and risk management was weak. ASEAN still needs to build up the institutional and legal framework, as well as developing the scientific and technical capacity to implement the framework.

In October 1999, the task force was completed and AMAF adopted the ASEAN Guidelines on Risk Assessment of Agriculture-Related GMOs. The guidelines call for the establishment of a National Authority on Genetic Modification in each member country, to oversee the implementation of the guidelines. The task has not accomplished in many ASEAN member countries, particularly the less developed economies.

After the adoption of the harmonized guidelines, SOM-AMAF will proceed with a public awareness program on GMOs. Currently, the national bodies have publications or brochures in the format of FAQs on GMOs, which are readily accessible by Internet.

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

However, COST has the role as the driving force for ASEAN regional cooperation in science and technology to accelerate the capacity building in biotechnology with particular attention to the newer members. At the same time ASOEN could develop regional institutional mechanisms to address biodiversity concerns, including the upgrading of regulatory agencies' capacity to regulate biosafety and establish biosafety clearing house mechanisms.

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

The following recommendations and future steps were proposed at the workshop:

1. Regional cooperation between ASEAN for approaches to biosafety and capacity enhancement.
2. Improve scientific training to conduct independent risk assessment.
3. Legal and institutional expertise for risk management and implementation of biosafety regimes.
4. Enhancement of coordination and cooperation among national government entities in formulating policies and strategies.
5. Increase stakeholders awareness in integrating of existing regulatory mechanisms (The Cartagena Protocol, CODEX, SPS and TBT).
6. Establishment of regional networks for information exchange.

7. Ensure synergism, support, and articulate communication among actors for risk assessment, risk management and decision makers.
8. Promote public awareness and education.
9. Urgent need of adequate financial resources.

On October 3-4, 2001. ILSI SEA Region organized a seminar and workshop on ASEAN Food Safety Standards Harmonization in Singapore for key regulators in ASEAN. ASEAN Guidelines on Risk Assessment of Agricultural Related GMOs was endorsed by AMAF member countries with a common understanding and approach for conducting scientific evaluations for the release of agricultural-related GMOs. The guidelines describe the procedures for notification, approval, and registration of GMOs. Information on approved GMOs is deposited at the ASEAN Secretariat for inclusion in a database and to assist ASEAN member countries with the evaluation of the applications. The guidelines also address the need for each country to establish its own national authority on genetic manipulation along with the roles and responsibilities in regulating ag-GMOs. ILSI, in collaboration with SOM-AMAF, is also organizing a series of four workshops on food-biosafety capacity building in ASEAN.

Much of these ASEAN accomplishments have been largely due to the support from other organizations and financial commitment from member countries. Although there is much more to he done in addressing these needs, progress is slow due to lack of capacity, human resources, financial support and, to a certain extent, the different stages of biosafety development in member countries.

References

1. ***Capacity Development for the Integrated Approaches to Biosafety of Genetically Modified Organisms (GMOs)***. Chairman's Summary. 6-8 November 2001, Jakarta, Indonesia.
2. ***Biotechnology and Biosafety in ASEAN*** by Linda S. Posadas, ASEAN Secretariat.
3. Proceedings of the ASEAN Workshop on ***"Regulations for Agricultural Products Derived from Biotechnology".*** Primary Production Department, Singapore (Ed.), 1-2 April 1998. Singapore.
4. ASEAN Guidelines on Risk Assessment of Agriculture-Related GMOs (http://www.aseansec.org/)

INTELLECTUAL PROPERTY PROTECTION FOR BIOTECHNOLOGY IN ASEAN

Keeping pace with biotechnological development, more legal disputes and challenges concerning intellectual property (IP) protection for biotechnology have been witnessed. Legislators and legal practitioners have developed IP regime and practices in order to accommodate the rapid development of biotechnology. Compared with countries with well-established IP systems, Southeast Asia is still in an embryonic stage of IP development in the area of biotechnology. Current status of IP protection for biotechnology can be seen as follows:

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

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

Institutional level: Few research institutes in this region have been well equipped with skills and knowledge concerning intellectual property management. During the past decade, developing countries have witnessed increasing disputes and cases resulting from the lack of effective intellectual property management. Therefore, certain legal measures have been developed to tackle with IP management. Amongst these are material transfer agreement, confidentiality agreement and IP audit. With assistance from international organizations, a number of intellectual property activities have been introduced in this region. Capacity building is the most urgent and vital activity. Launched in October 2001, SoutheastAsia Network on IP/TT Management is a joint effort amongst biotechnology research organizations in 5 countries and International Service for the Acquisition for Agri-Biotech Applications. The network aims to promote establish cooperation amongst network organizations and other organizations in the area of management of intellectual property and technology transfer.

OVERVIEW, ANALYSIS AND RECOMMENDATIONS: REGIONAL PICTURE

Despite all the controversies, biotechnology has enormous potential, as an enabling tool to solve certain intractable problems and thus to:

a. meet the challenges of hunger, poverty, sustainability, inequity and globalization,
b. bring about sustainable precision agriculture even in small farms, and
c. evolve the green revolution into the ever-green revolution.

With such expectations, recombinant DNA technology has broad application in developing countries and has the potential for very positive impacts on their economies, particularly for the agricultural based ASEAN countries. With the expressed views that rDNA technology might be of greater importance for developing countries than for industrialized countries, developing countries look on rDNA technology as a means of addressing the need to produce sufficient quantities of nutritionally adequate and safe food for their growing populations as well as in enhancing their competitiveness in the globalization process. ASEAN produces a large portion of the world's food crops with large numbers of food processors, thus both ASEAN unprocessed as well as processed food plays a significant role in the global food trade. The benefits from this technology, which are likely to have a direct impact on people at the production level, are extremely important to ASEAN, being a region of small farmers -- the majority of which have a land holding of less than a hectare. However, in order for the technology to have the true impact to the region, local problems must be appropriately addressed. In this context, biotechnology is recognized as an important enabling technology for competitiveness as well as the tool for sustainable development. With the needed infrastructure and the possibility of additional non-tariff trade barriers, ASEAN must apply appropriate policy and management tools to build both technological capacity and management capability. The capacity building is very much a local issue, but regional cooperation can help accelerate the process.

Also of equal importance is the capability to carry out safety assessment. The environmental and food safety assessments of genetically modified organisms requires trained manpower, up-to-date legislation, as well as an efficient food control system. Food safety issues are not bound by national borders, and it is therefore important that countries that have inadequate resources for assessing rDNA technology and products derived from it, make special efforts to obtain these resources through capacity building. Moreover, since globalization interconnects raw material production to processing and consumers of all regions in the world, it is imperative that proper safety assessment of food and food components produced by genetic modification be practiced worldwide. In this context, the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO) announced in March 2002 that a Task Force of the Codex Alimentarius Commission has reached agreement on a final draft of "Principles for the risk analysis of food derived from biotechnology". The Principles will provide a framework for evaluating the safety and nutritional aspects of Genetically Modified (GM) food. They define the need for a pre-market safety assessment of all such food on a case-by-case basis,

Overview of the Structure of ASEAN's GMO-based Food Processing Industry

Up to now only a few ASEAN countries have approved the use of GM food crops as human and animal feed. However, it is anticipated that both soybean and corn are widely used in the region both legally and illegally either as food or food ingredients in the food processing industry. Thailand has approved the use of GM soybean and corn for human food and animal feed. Malaysia and Indonesia have also approved GM soybean. Indonesia imports nearly 900,000 tons of soybean and about 1.2 million tons of corn each year. Most of these imported commodities come from the USA, Argentina and Brazil, where a high proportion of transgenic crops are grown. Most of the soybean destined for human consumption would go to soy cake and *tempeh* manufacturing for Indonesia; soy sauce and soy oil for Thailand, Singapore and Malaysia (Table 1). The imported corn would go into flour, starch and oil. Maize and soy meal also would be used as animal feed.

Table 1. Import by commodity in 2001
(Thousands of US dollars)

Items	Indonesia	Malaysia	Singapore	Thailand	Vietnam
1. Soya sauce	16,404	36,870	556,005	1,179	-
2. Corn (grain)	2,567	50,800	-	106,096	3,423
3. Corn Starch	-	5,463	53,247	-	-
4. Pop Corn			6,732	17,021	-
5. Corn Oil	28,834	236,137	571,500	-	-
6. Corn Flake and prepared food	287	134,454	8,478	220,537	-
7. Corn prepared or preserved by vinegar	-	-	3,875	87,680	

Source: Bureau of Export Trade Promotion in respective countries

*Table 2. Countries of Import by Commodities into **ASEAN** in 2001*
(Tones)

Items	USA	South Africa	Argentina	Brazil
Corn	1,113,733	426,876		
Corn Flour	1,315,946			
Soy bean	85,267,701	-	110,012,000	11,000,286
Soya oil cake	60,469,360	-	168,867,990	60,065,286

Both soybean and corn are important as whole food or food components for the food industry. In many countries such as Thailand, which almost totally relies on imported soybean, it becomes inevitable not to accept GM soybean and corn (Table 2).

Policy and Institutional Framework **of** ASEAN Member Countries

Of the 10 members in ASEAN, at least 4 countries, Indonesia, Malaysia, Philippines and Thailand, have successfully conducted field trials of GMOs. Indonesia is the only country that has approved the environmental release of Bt cotton. However, the release comes with restrictions. First, the farming area is restricted to 7 districts in South Sulawesi Province; the cotton seed is to be exported only and the remaining plant parts must be destroyed. Moreover, the approval came with a time restriction of 1 year subject to review for annual renewal. The Indonesian authorities also have completed the field trials for soybean and corn which would be the next likely candidates for commercial release. Thailand has concluded the 3-year environmental studies of Bt cotton and the genetically modified viral resistant papaya is being field studied. In the past, Thailand has also conducted environmental impacts on several lines of GM food crops such as tomato, rice, corn (see country report). Malaysia has also concluded the environmental assessment of GM soybean. The Philippines also has completed the field trial studies of Bt corn but has not approved it for commercial release yet. Singapore has approved commercial sale of GM blue cut carnation but not for growing. Apart from the field trials being conducted, GM crops are proving to be quite popular amongst the farmers as there have been reports of illegal plantation of GM crops particularly Bt cotton in Thailand, Vietnam and Indonesia.

ASEAN can be classified into two groups based on GMO policy. The first group has not yet developed policy on GMOs. This includes Cambodia, Lao PDR, Myanmar, Brunei Darussalam and Vietnam. Among these countries, the Lao PDR is setting up the National Biosafety Framework and the government has designated the Science, Technology and Environment Agency as the national focal point. Brunei is establishing the National Authority on Genetic Modification (NAGM) to oversee the regulatory control of GMOs. Vietnam has formed a working group (see country report) and drafted the Biosafety Bill which is being approved by the Ministry of Science, Technology and Environment. As for Cambodia, the Cambodian Import and Export Inspection and Fraud Repression Department of the Ministry of Commerce is of the view that, as long as the safety of GM food has been substantiated by scientific evidence, Cambodia sees no need to develop a restriction policy on GMOs. In Myanmar,

due to weak infrastructure and regulatory framework, the government appears not to have taken up the issue yet.

The second group is countries which exercise regulation over GMOs, either through their existing systems or new regulations. Many of these countries; including Indonesia, Malaysia, Philippines and Thailand are expected to have Biosafety Legislation in force of law soon. The Philippines has the Biosafety Guidelines published in 1991. The two guidelines cover laboratory approval and environmental release.

The control of GMOs imported into the country and the commercial release of GMOs for culture and cultivation or for agriculture production are through the existing Acts administered by the Agri-Food and Veterinary Authority of Singapore (AVA), formerly Primary Production Department. Once approval is granted, the product (GMO) will be registered with the Genetically Modified Advisory Committee (GMAC). As for commercial and academic research, the project managers are required to seek clearance from GMAC before any research is done using GMOs and vectors not in the positive list.

Malaysia and Indonesia have the national guidelines for the release of genetically modified organisms into the environment. Both are expected to release the guidelines for safety assessment of GM food in 2002. Indonesia is the only country to have the legal provisions on biosafety of genetically engineered agricultural biotechnology products released under the Ministerial Decree No. 85/kpts/HK330/9/1997. The Decree of the Minister of Agriculture does not have law enforcement power. Furthermore, there are Law No. 5/1994 for the Ratification of the UN Convention on Biological Diversity and Law No. 7/1996 on food. Thailand has released guidelines for laboratory, field trial and safety assessment of GM food. This year, Thailand is expected to revise all three guidelines and release a new guideline for industrial production of chemicals or biological materials using GMOs.

In comparison to that of China, ASEAN member countries have taken cautious biosafety policies. These cautious policies have been strongly reinforced by international market forces and international diplomatic and NGO pressures. China has been less cautious toward GM crops, in part because there is less opportunity in China for international organizations or independent critics of GM crops to challenge the official policy.

Stakeholders/Key Players

The key players for biosafety regulations in ASEAN are relevant government departments. Brunei Darussalam plans to establish the National Authority on Genetic Modification (NAGM) under the Ministry of Industry and Primary Resources. Most other countries, Indonesia, Lao PDR, Malaysia, Thailand and Vietnam, have their biosafety central bodies in the Ministry of Science, Technology and Environment. The Philippines has appointed the National Biosafety Committee of the Philippines (NBCP) as an independent body. Singapore and Malaysia also have GMAC, which operates under a government office. The Philippines and Malaysian systems require local community involvement for the laboratory work and field trials. Singapore also has a consumer group in their GMAC while Thailand's National Biosafety Committee (NBC) and associated subcommittees have some members from industry and civil society or NGOs.

Human Resource

Although there exists government bodies in many ASEAN members working on biosafety, it has been found, mainly from this study, that the development of biosafety is impeded by the shortage of human resources and skills as well as insufficient and poor infrastructure. A few programs have been initiated by international organizations to help alleviate this problem. The International Service for the Acquisition of Agri-biotech Applications Southeast Asia Center (ISAAA *SEAsia*Center) has been instrumental in promoting capacity building at both research and regulatory levels among its five member countries, namely Indonesia, Malaysia, Philippines, Thailand and Vietnam. ISAAA's Papaya Biotechnology Network of SEA Asia project supports capacity building and technology transfer of transgenic papaya. A number of training courses and fellowships for biosafety training have been

provided to its member countries within the past few years. The International Life Science Institute (ILSI), APEC (Asia Pacific Economic Cooperation) and FAO (Food and Agriculture Organization) have also been active in organizing workshops and seminars in the region. Numerous other international agencies, such as the Australian Centre for International Agricultural Research (ACIAR), have selected to work on projects on the applications of biotechnology. **ILSI,** in cooperation with SOM-AMAF and the ASEAN Secretariat, has organized a series of workshops on food biosafety (see section on ASEAN Bodies and Biosafety Activities).

Public Awareness

The recent studies by AFIC Market Research between 1998-1999 in ASEAN (Thailand, Philippines, Malaysia and Indonesia) showed that the public in general, was not very aware of food biotechnology. In Thailand, 12% of the respondents were "very to quite" aware, 38% in Philippines and 8% in Malaysia and Indonesia. The responses to the question of "ordinary soybeans don't contain genes but GM soybeans do" also indicated the limited knowledge in biotechnology in all 5 countries where more than 50% answered either 'yes" or "don't know".

Most countries do not have structured or organized public education programs on GMOs. This is in contrast to the programs and organized campaigns of anti-GMO NGO groups. In Thailand the Thailand Biodiversity Center (TBC) and BIOTEC have conducted several public forums and have several publications available such as cartoons on GMOs and GM food. Thailand's Food and Drug Administration also runs educational programs using mass media. Most countries have information such as frequently asked questions (FAQs) on their websites.

Public awareness and understanding is considered a very important issue for several international organizations. One organization that stands out for supporting such a program in this region is the International Service for the Acquisition of Agri-biotech Applications (ISAAA). ISAAA Southeast Asia supports the establishment of the Biotechnology Information Center (BIC) in its participating countries (Indonesia, Malaysia, Philippines, Thailand and Vietnam) in order to provide information concerning biotechnology to the public. BIC websites are now set up in Malaysia, Philippines and Thailand and can be accessed at **http://www.bic.ora.mv/index.htmI** for Malaysia, http://www.searca.org/~bic/ for Philippines and http://www.safetvbio.com/ for Thailand. BIC in Vietnam is in operation, but not yet formally established as a center. Apart from public information, ISAAA also supports the capacity building in R&D (Papaya Biotechnology Network of SEA Asia) and risk assessment.

UNIDO's Biosafety Information Network and Advisory Service (BINAS) is also an excellent database for information concerning biosafety. BINAS monitors global developments in regulatory issues in biotechnology. The database maintained at the BINAS website (http://binas.uiiido.ore/binas/) includes exhaustive information on national regulation and field trials in several countries as well as news and announcements. With funding support from the Rockefeller Foundation and the Swiss Agency for the Environment, Forests & Landscape, BINAS developed a pilot decision support system for safety assessment of genetically modified crop plants (DTREE). The pilot system is intended to be used as a tool to preserve, disseminate and interpret available data and information regarding releases of genetically modified crop plants into the environment. It is also intended to enhance familiarity with environmental introductions of transgenic crops and provide information support to regulatory authorities, researchers and biosafety officers of public institutions and commercial enterprises. DTREE-Lite, the current version under development, is available for trial at: http://binas.unido.ore/dd.

Many countries have a built-in system of public awareness for field trials or commercial release. Some have public participation in the decision-making level. Indonesia requires the proponents to announce plans for use/release of GMOs in newspapers circulating in the vicinity of the utilization areas upon submission of application or upon receiving directives from the Ministry of Agriculture. Malaysia requires that national authorities, industry and researchers disclose or make available safety information to the public, particularly to the communities where field trials or planting is to take place. In Malaysia, GMAC must inform the local community of planned release and national authorities

should provide appropriate information to the public. The Philippines has similar but more public involvement than Malaysia in that, there must be 2 community representatives in NCBP and in IBCs and public information sheet (PIS) must be posted in target field test site and allow **30** days for public comment. Thailand has a member of civil society and industrial representatives in the policy-making body of NBC. Singapore also has a consumer group in GMAC and decision to inform public of planned release of GMOs is rested with GMAC.

Trade and Industrial Competitiveness

Inevitably, ASEAN relies quite heavily on certain GM crops for its food processing industry. Soybean and corn, including the GM varieties, are imported with minimal restrictions. The trend is towards more GM varieties also not just from imports but soon other ASEAN countries may follow Indonesia using both local and imported GM varieties. The higher yields and the use of less pesticides are the direct benefits to the ASEAN farmers.

Summary **of** Key Points

1. It is apparent that government agencies in ASEAN countries are actively involved in the subject of GMOs. Several programs and activities have been generated. Half of ASEAN's members have biosafety guidelines in place, while a few are in the process of drafting and/or approving same. Training on risk assessment and public awareness programs commonly exist in many member countries.

2. The region is divided into two groups in terms of the policy framework. The advanced group consists of five ASEAN-founding members (Indonesia, Malaysia, the Philippines, Singapore and Thailand), and the less advanced group is the newer ASEAN members.

3. Under ASEAN framework, the subject of GMOs and biosafety are dealt with by three main bodies: SOM-AMAF, ASOEN and COST, from three different perspectives: agriculture, environment and S&T, resulting in a fragmented attempt and a lack of holistic approach. This problem can also be found at the national level.

4. There exists no concrete action plan for systematic monitoring of GMOs

Recommendations **on** Policy Options and Mechanisms for Their Implementation

As policy options, there are five policy areas in which governments of developing countries can either support or discourage GM crops: intellectual property rights, biosafety, trade, food safety, and public research and investment. Concurrent with general acceptance to adopt biotechnology, there are several concerns that restrict application of biotechnology. A striking commonality in issues of concern has been observed. These are primarily related to biosafety, bioethics, environmental conservation, human resources, capital investments, regulatory mechanisms, biosafety protocols, and IPRs, and information sharing. This section provides recommendations on policy options and mechanisms for their implementation in order of relevance to the GMOs in the food-processing industry of ASEAN.

1 **Food** Biosafety Policy: Table **3** shows clearly that ASEAN members are at different embryonic stages of development in biosafety. The countries, Brunei, Cambodia, Lao PDR and Myanmar which have not yet initiated any policy on biosafety, should give highest priority to establish such policies. As for Malaysia, Philippines, Singapore, Thailand and Vietnam, the adoption of biosafety into law should be set as the first priority and then a clear-cut plan of implementation should also be established. The policy on national biosafety legal framework is vitally important and, most if not all ASEAN members do not have laws or lack legal mechanisms to support the protocol. ASEAN needs to focus on capacity building to fully implement biosafety policy. The legal expert must be competent enough to translate protocol into law. As a strategy for consumer protection, it must develop the capacity to conduct risk assessment, risk management and field trials. Many ASEAN countries also do not have the capacity to develop biosafety clearing house mechanisms. ASEAN should quickly develop coordination amongst governments on biosafety, the capacity for data management and information sharing and

strengthen the research network system. Notably absent is any policy and regulations on GMO-related industrial practice which can be of paramount importance to the food industrial sector in such areas as flavors and starter cultures. **ASEAN** should work together and develop expertise to strengthen capacity in the following areas:

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

Table 3. Status of GMOs in ASEAN

Country	GMO		Biosafety Legislation/ Status	Guidelines			Field Trials	GMF Approved	Public Education	Labeling (threshold)
	Planting	Food		Food	Env.	Lab				
Brunei	N	L	N	N	N	N	N	N	N	N
Cambodia	N	Y	N	N	N	N	N	N	N	N
Laos	N	Y	N	N	N	N	N	N	N	N
Indonesia	Y restricted	Y	Y	N	Y	N	Y	Y	Y	Y (not decided)
Malaysia	N	Y	Expected in June 2002	Y	Y	N	Y	Y	N	Y
Myanmar	N	L	N	N	N	N	N	N	N	N
Philippines	N	L	Expected in 1st qtr of 2002	N *	Y	Y	Y	N	Y	N (being studied by gov't agencies
Singapore	N		N (Existing legislations)			N	N	N	Y	N (being studied by gov't agencies
Thailand	I (field trial only)	I	Expected in 2003	I	I	I	I	I	I	I (5%)
Vietnam	N	Y	Expected in 2002	N	N	N	N	N	N	Y

Note: N – no; L – likely and Y - yes
* addressed in the commercial guidelines

2. Human Resource Development: In view of the potential impact of biotechnology on the food industrial sector, there is a clear need for ASEAN to take initiatives to build autonomous capability not only in areas directly related to food safety but to pursue high priority biotechnology research without any further loss of time. In a highly skill-intensive area like biotechnology, training of scientific and technical manpower is a crucial element of any strategy to build local capability. Building local capability in biotechnology is essentially a national effort with strong supportive input provided by mutual cooperation within the region and international agencies. The key to building local capacity is human resource development. The number of scientists involved in biotechnology R&D in the region is still very low, particularly when compared with other regions. Thus, there is a need to increase the number of scientists in the region, particularly in countries such as Brunei Darussalam, Cambodia, Myanmar, and the Lao PDR. Regional collaboration on ASEAN-help-ASEAN can be coordinated through the functional committees and other ASEAN mechanisms. Human resource development should also include training of personnel in the regulatory systems to increase their capability in doing risk assessment and evaluation of GMOs. Political awareness and will **is** needed to make resources available and to facilitate the flow of people across national boundaries for the training and collaborative S&T activities.

3. Information Exchange, Regulation and Harmonization: Not only because information exchange creates better understanding, leads to more active interactions, and thus a stronger region, it is also critical to the success of a harmonization process which is required to allow free movement and facilitate trade within ASEAN under the ASEAN Free Trade Area (AFTA) agreement. Standards and regulations need to be harmonized to reduce any possible friction and ensure fair practice. This is in line with ASEAN Vision 2020 which aims to harness technology to develop a competitive agriculture sector within the AFTA framework. Free intra-ASEAN trade will strengthen the competitiveness of the region's food products while addressing the concerns of these products on health and the environment. In order to harmonize regulations, there is a need for open communication between the various regulatory agencies to ensure that the task can be completed expeditiously. As experience and knowledge on the introduction of GMOs to the environment are limited in this region, together with the fact that technology is changing dynamically, there is a need for exchange of information to understand the requirements of each country and to keep pace with new knowledge and experiences gained; particularly in the areas of environmental safety assessment, food and feed safety assessment, approaches to risk/safety assessment and on potential long-term impacts on environment, biodiversity and human health. There is also a need to speed up the implementation of ASEAN Guidelines on Risk Assessment of Agriculture-related Genetically Modified Organisms. The guidelines in their present form may not be perfect, but improvements can be introduced later as more scientific data becomes available. SOM-AMAF, ASOEN and COST have to invent meaningful schemes and frameworks to work together in this and many other areas. Although very difficult to implement, the success in establishing sectoral or commodity-based technology transfer information networks can be very effective science and technology support services for the region.

It is already apparent that misinformation and the lack of scientific understanding can lead to poor judgment, mismanagement and missed opportunities. ASEAN must work together to increase public awareness and understanding of S&T, and particularly, biotechnology, at all levels. Collaborative efforts in the preparation of documentation and information packages in various forms to meet the needs of different target audiences can reduce duplication of effort and lead to efficiency improvements. The governments should have a structured policy on public education especially in the Philippines and Indonesia, which require public community involvement in field trials.

4. Intellectual Property Rights: Being well endowed with rich biodiversity and rich traditional knowledge in the use of these biological resources, such as in the area of flavors and fermented food, biotechnology-related IPR issues can be of particular importance to the ASEAN food

industry. Most ASEAN countries recognize that IPR protection is crucial for the growth of the biotechnology industry, since huge investment has been made in developing a product. The World Trade Organization (WTO) requires IPR protection. The implication of this to trade, technical investment and access to products puts a lot of pressure on developing countries. ASEAN should think through carefully, especially in the post-genomic era, as to what role would intellectual property rights be playing in order to enhance the progression of the region's food industry so as to scale up the overall economic development and the betterment of science and technology sector. Cultural and traditional practices are being tested and put under various constraints due to globalization forces. ASEAN needs to work together to make the requisite change as painlessly as possible. Also, being a region well endowed with rich biodiversity, ASEAN countries should come together to develop national legislation on protection of indigenous and/or traditional knowledge and on that basis formulate an ASEAN collective position to be advocated at the international level. Countries should develop an inventory and registry of their biological resources and traditional/indigenous knowledge, taking into account the intellectual property implications of such inventories and registries. There should be a network of information exchange and networking among the ASEAN member countries for this purpose. The issue of patentable subject matters is indeed not only the question of law but also the consideration of policy, active national and regional debates should be encouraged. ASEAN should also consider regional mechanisms in working with any integrated IP escrow service, a mechanism which has been suggested by several organizations such as ISAAA, the Strategic World Initiative for Technology Transfer (SWIFTT) and the Consultative Group on International Agricultural Research (CGIAR).

External Assistance

As outlined in the recommendations, there are various areas where UNIDO can be of assistance. These are and not exclusive to:

A. Assist in organizing regular dialogue at the senior policy level to provide political view and support in such areas as:
   - Developing domestic policies for research, production, commercialization, and trade in ag-biotech products.
   - Sharing information on the experiences in consumer information, e.g. role of government in disseminating information of biotech products; breakthroughs in R&D, and science based regulatory structures.
   - Common approaches e.g. capacity building, strengthening public confidence in biotechnology, supporting R&D, and realizing the potential contributions of biotechnology to the growth of food sectors and food security.

B. Assist in developing legal framework for biosafety.

C. Assist in capacity building for risk assessment such as development and delivery of training modules on food and environmental safety.

D. Assist ASEAN in developing coordination among governments on biosafety particularly on data management and information sharing.

E. Assist to upgrade technology and preparedness to implement a biosafety regulatory framework.
   - Assist in developing Biosafety Clearing House Mechanisms which should facilitate cooperation amongst ASEAN members.
   - Provide coordination support and assist in research work on releases of GMOs and sharing of case studies.
   - Assist in the identification of other key issues related to the regulation of biotechnology products, e.g. ethical issues, Cartagena Protocol (meeting requirements of CP on Biosafety), harmonization of standards and protocols, discussion of IPR issues related to research and commercialization.
   - Assist on the development of an internet site for information sharing in best practice guidelines on regulatory communications, list of peer-reviewed information to highlight benefits and potential risks of biotechnology to counteract misinformation, status of R&D/commercialization of products in order to provide context for regulatory

developments in ASEAN, e.g. validation of detection methods, channeling, list of various international organizations that provide internship / training opportunities.

References

1. ***Opening the Biotechnology Toolbox*** by JamesDargie Director, FAO/IAEA Joint Division for Nuclear Techniques in Food and Agriculture. This article is adapted from a paper presented at the European Media Seminar on Global Food Security (Stockholm, 14-16 October 2001).
2. ASEAN Guidelines on Risk Assessment of Agriculture-Related Genetically Modified Organisms (GMOs) (From http://www.aseansec.org/view.asp?file=/economic/nagmguid.htm)

ANNEX 12

Names of Officials Interviewed during Country Visits

INDONESIA

1. Saptowo J. Paradal & Dr.Sutrisno
   Molecular Priology Division
   Research Institute for Food Crop Biotechnology (RIFCB)
   E-mail : rifcb@indo.net.id
2. Dr. Ida Hanarida
   Genetic Resources & Germplasm Division, RIFCB
   E-mail : borif@indo.net.id
3. Dr. Djoko S. Damardjati
   Jln. Ragunan No.29, Pasarminggu
   Jakarta Selatan 12540
   Indonesia
   E-mail : dsdjati@indo.net.id
4. Ir. Sugiono Moeljopawiro, Ph.D.
   RIFCB
   Jalan Tentara Pelajar 3A
   Bogor 16111, Indonesia
   E-mail : sugionom@indo.net.id
5. Ir. Muhammad Herman, Ph.D.
   Molecular Biology Laboratory, RIFCB
   Jl. Tentara Pelajar No. 3A
   Bogor 16111, INDONESIA
   E-mail : mherman@indo.net.id
6. Andi Hasanuddin
   Jl. Merdeka 147 Bogor 16111, Indonesia
   E-mail : crifc1@indo.net.id
7. Prof.Dr.Ir. Dedi Fardiaz M.Sc.
   Deputy for Food Safety and Hazardous Substance Control,
   Jl. Percetakan Negara No.23 Jakarta 10560
   E-Mail : d_fardiaz@,hotmail.com

MALAYSIA

1. Yeoh Quee Lan
   Bio Technology Center MARDI
   P.O.Box 12301, General Post Office
   50774 Kuala Lumpur
   Malaysia
   E-mail : qlyeoh@mardi.my
2. Prof. Nor Muhammad Mahadi
   School of BioSciences and Biotechnology
   University Kebangsaan Malaysia
   43600 UKM Bangi, Selangor, Malaysia.
   E-mail : mahadi@pkrisc.cc.ukm.my
   Normm@pc.jaring.my
3. Nik Shabnam Bt. Mohd. Salleh
   Food Quality Control Division,
   Department of Public Health,
   Ministry of Health Malaysia,
   4th Floor, Block E,
   Office Complex,
   Jalan Dungun, Damansara Heights,
   50490 Kuala Lumpur, MALASIA
   E-mail : shabnam@dph.gov.my
4. Dr. Adib Rahman

Secretariat GMAC
Conservation & Environment Management Division
Ministry of Science, Technology and Environment
Email: adib@mastic.gov.my

VIETNAM

1. Dr. Le Huy Ham
Vice Director, Agricultural Genetics Institute
Tuliem, Hanoi, Vietnam
E-mail : lhham@agi.ac.vn

2. Dr. Truong Nam Hai
Vice Director, Institute of Biotechnology
18 Hoang Quoc Viet Street,
Cau Giay-Hanoi
Vietnam
E-mail : tnhai@hn.vnn.vn

3. Nguyen Duc Thanh, Ph.D.
Institute of Biotechnology
Hoang Quoc Viet Street,
Cau Giay, Hanoi,
Vietnam
E-mail : ndthanh@pcg-ibt.ac.vn

4. Prof. Dr. Vu Duc Quang
Head of Molecular Biology Division,
Agricultural Genetics Institute
TuLiem Hanoi, Veitnam
E-mail : vdquang@hn.vnn.vn

5 Dr. Nguyen Van Son
Vice-Head of International Cooperation Department
Agricultural Genetics Institute
TuLiem Hanoi, Vietnam

6 Ms. Pham Thi Viet
International Cooperation Department
Agricultural Genetics Institute
TuLiem Hanoi, Vietnam

SINGAPORE

1. Pauline Erica Tay
A*STAR
10 Science Park Rd., #01-01/03
Singapore Science Park II, Singapore 117684
E-mail : pauline_TAY@a-star.edu.sg

2. Lee Boon Kwang, Jeffery
A*STAR
10 Science Park Rd., #01-01/03
Singapore Science Park II, Singapore 117684
E-mail : Jeffrey_LEE@a-star.edu.sg

3. Dr. Ngiam Tong Tau
5 Maxwell Rd., #04.00
Tower Block, MND Complex, Singapore 069110
E-mail : NGIAM_Tong_Tau@ava.gov.sg

4. Dr. Er Jwee Chiek
5 Maxwell Rd., #04.00
Tower Block, MND Complex, Singapore 069110
E-mail : ER_Jwee_Chiek@ava.gov.sg

5. Lee Yuen Tong

5 Maxwell Rd., #04.00
Tower Block, MND Complex, Singapore 069110
E-mail : LEE_Yuen_Tong@ava.gov.sg

6. Yeoh Guan Huah
ALSTechnichem
14 Little Rd.,
#07-01 & #08-01
Tropical Industrial Building
Singapore 536987
E-mail : alssg@als.com.sg

7. Hong Yan Ph.D. MBA
1 Research Link, The National University of Singapore
Singapore 117604
E-mail : hongy@ima.org.sg

8. Tan Li-Mien
1 Research Link, The National University of Singapore
Singapore 117604
E-mail : limien@ima.org.sg

9. Dr. Mohan Balasubramanian
1 Research Link, The National University of Singapore
Singapore 117604
E-mail : mohan@ima.org.sg

10. Chee Yen Chin
1 Research Link, The National University of Singapore
Singapore 117604
E-mail : yenchin@ima.org.sg

11. Dr. Audrey Ann Yuen
Singapore Polytechnic
500 Dover Rd.,
Singapore 139651
E-mail : AAYuen@sp.edu.sg

12. Koh Siok Im
Singapore Polytechnic
500 Dover Rd.,
Singapore 139651
E-mail : silk@sp.edu.sg