

# **BIOTECHNOLOGY POLICY-MAKING, REGULATIONS AND DEVELOPMENT IN THE ASEAN REGION**

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# ASEAN Background

- ASEAN (Association of Southeast Asian Nations) was established on 8 August 1967 in Bangkok, Thailand
- Founding member countries (5): Indonesia, Malaysia, Philippines, Singapore and Thailand
- Other member countries (5): Brunei Darussalam (1984), Vietnam (1995), Lao PDR (1997), Myanmar (1997) and Cambodia (1999)

# ASEAN Declaration

“The aims and purpose of the Association are to accelerate economic growth, social progress and cultural development in the region and to promote regional peace and stability through abiding respect for justice and the rule of law in the relationship among countries in the region and adherence to the principles of the United Nations Charter”

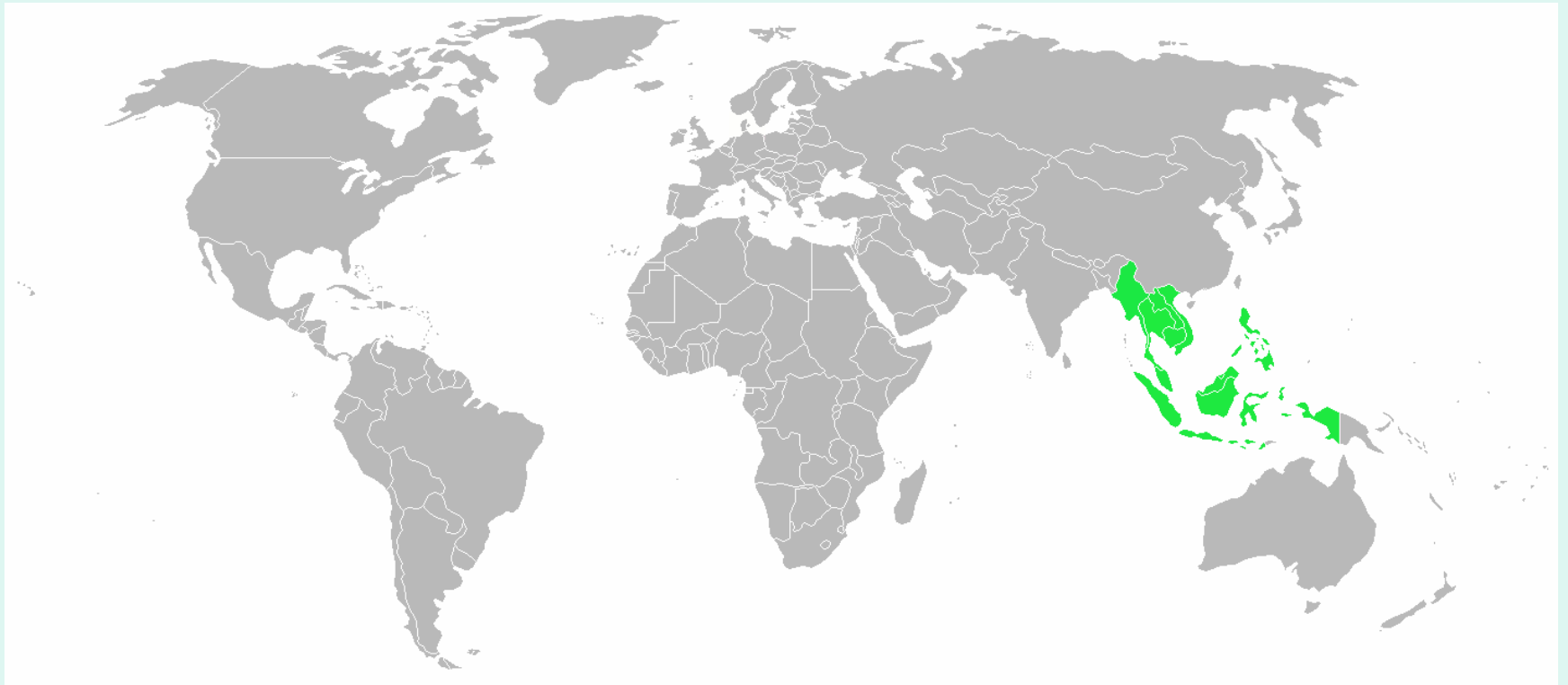
# ASEAN Logo



# ASEAN Flag



# ASEAN Geographical Location



# ASEAN Biodiversity and Geography

- ASEAN countries form one the world's mega biodiversity centers
- Continental ASEAN countries:  
Cambodia, Lao PDR, Malaysia, Myanmar, Thailand and Vietnam
- Insular ASEAN countries:  
Brunei Darussalam, Indonesia, Philippines and Singapore

# ASEAN Geography





# ASEAN Member Countries



# ASEAN Countries and the Convention on Biological Diversity and the Cartagena Protocol on Biosafety

- All ASEAN countries are parties to the Convention on Biological Diversity (CBD)
- All ASEAN countries, except Brunei Darussalam and Singapore, are also parties to the Cartagena Protocol on Biosafety (CPB)

# ASEAN Countries Participating in UNEP-GEF National Biosafety Frameworks (NBF) Development Project

- 2002-2004: Cambodia, Indonesia, Lao PDR,  
Philippines and Vietnam
- 2003-2005: Myanmar
- 2006-2008: Thailand
- Brunei Darussalam, Malaysia and Singapore  
not participating

# Typical Agencies Responsible for Biotechnology/Biosafety Policy Formulation in each Country

- National focal point
- National competent authority
- Ministries and departments concerned
- Environmental agency
- Implementing and enforcement agencies
- Other relevant agencies

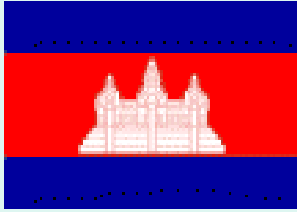


## Brunei Status on Biotechnology/Biosafety Policies

### **BRUNEI DARUSSALAM**

- Not a party to the Cartagena Protocol yet
- Not participating in UNEP-GEF NBF development project
- Not agricultural country
- Biotechnology activities are at minimal level in Department of Agriculture and University of Brunei Darussalam
- No legislation specific to GM foods
- Required to comply with Public Health (Food) Act 1998 and Public Health (Food) Regulation 2000

- Emphasis made that Brunei should have its own regulatory body to regulate and manage genetically modified products
- National Authority of Genetic Modification (NAGM) to be established to oversee the development and use of GM technology and to initiate and draft national biosafety guidelines
- Need capacity building, biosafety framework, infrastructure and facilities to evaluate the presence and biosafety of GMOs
- Brunei Biotechnology Center is being proposed



## Cambodia Status on Biotechnology/Biosafety Policies

### **CAMBODIA**

- NBF under UNEP-GEF Project developed in 2004
- Strictly an agricultural country
- Modern biotechnology is in an infancy stage
- Recognizes biotechnologies as a part of the strategic triangle in developing the country: economic growth, social development and sustainability
- Not capable of developing any GMO in the near future but most likely to be a user of GM products
- Competent national agency: National Biodiversity Steering Committee (NBSC) under Ministry of Environment

- Main policy goals are:
  - To develop biotechnology education while preventing or minimizing environmental risks and health hazards associated with the use and release of GMOs, and
  - To protect indigenous biodiversity from adverse impacts resulting from introduction and use of GMOs
- Fill the gaps in technical, infrastructure and human resources and institutional capacities
- National Biosafety Law and Sub-decree on the Management and Control of Living Modified Organism drafted and pending approval





## Indonesia Status on Biotechnology/Biosafety Policies

### **INDONESIA**

- National biosafety policy established in 1997
- In the form of Ministry of Agriculture decree on the Provisions for Biosafety of Genetically Engineered Agricultural Biotechnology Products 1997
- To include food safety aspect it was revised in 1999 to become a Joint Decree of Four Ministries (Agriculture, Forestry & Estate Crops, Health, and Food & Horticulture) on Biosafety and Food Safety of Genetically Engineered Agricultural Products
- Needs to include Ministry of Environment, the national focal point of the Cartagena Protocol

- National Committee for Biotechnology established since 1985 by Ministry for Research and Technology
- NBF under UNEP-GEF project developed in 2004
- Country adopts genetic engineering to improve national capacity on food security
- Country believes in the potential of genetic engineering for food production, medicine development and human health
- Development of agricultural biotechnology began in 1993 for food production and import substitution

- Biosafety Act promulgated in 2005 to monitor activities relating to GMOs and GMOs-FFP
- Biosafety Committee formed and Guidelines for the Release of GMOs formulated
- Guidelines for Biosafety Assessment of Genetically Engineered Products developed:
  - General Guidelines
  - Guidelines for Plants
  - Guidelines for Food, and
  - Guidelines for Feed

- Examples of some research on GM crops:
  - Transgenic T1 rice developed from drought & salinity tolerant (DST) IR64
  - Potato resistant to late blight
  - Tomato resistant to tomato leaf curl virus & cucumber mosaic virus
  - Sugarcane resistant to drought
  - Citrus resistant to greening disease
  - Amylose-free cassava
  - Bt rice

- In 2001 Bt cotton (Bollgard) was approved for temporary field release on a yearly basis in 7 districts and to be extended to 9 districts in 2003 in Sulawesi
- However, it was withdrawn in 2002 due to controversy between stakeholders and inadequacy in the regulation
- All GM crop research in experimental phase and under confinement
- Country needs capacity building in terms of human resources and infrastructure, GMO detection and identification, monitoring of quality GMO products, and public awareness, education and participation



## Lao PDR Status on Biotechnology/Biosafety Policies

### **LAO PDR**

- NBF under UNEP-GEF Project developed in 2004
- Modern biotechnology is still in an infancy stage
- National policy on biotechnology and biosafety established to promote biotechnology R&D in accordance with the CBD and the CPB on biosafety regulation, risk assessment and management, notification, movement and management of GM products, public awareness, education and participation
- National competent authority: Science, Technology and Environment Agency (STEA)

- NBC and IBCs established with biosafety officers (BSOs)
- Biosafety guidelines being drafted by NBC
- Anticipating a partial progress in R&D in modern agricultural biotechnology
- Needs timely and adequate external technical and financial assistance especially from other ASEAN countries
- Unauthorized GM cotton being cultivated



## Malaysia Status on Biotechnology/Biosafety Policies

### **MALAYSIA**

- Not participating in NEP-GEF NBF development project
- National Biotechnology Directorate (BIOTEK) established in 1995 with 7 Biotechnology Cooperative Centers (BCC) on plant, food, animal, molecular biology, medical, environment, and industry & bio-pharmacy
- Genetic Modification Advisory Committee (GMAC) established in 1996 under National Committee on Biodiversity (NCB) as technical advisory committee to MNRE on risk assessment and GM technology and its application



- “BioValley Malaysia” was established to become a hub with research institutes on agricultural, genomics & molecular, and pharmaceutical & nutraceutical biotechnology
- Other agencies working in GM:
  - MARDI on rice, papaya, chili, orchids
  - Malaysian Palm Oil Board on oil palm
  - Rubber Research Institute on rubber
  - Institute of Medical Research on local & herbal medicine

- Biotechnology receives strong support and commitment, earmarked under 8<sup>th</sup> & 9<sup>th</sup> Malaysian Plans (2001-2010)
- Country is supported by UNDP Project on Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety (2007-2010)
- To enable the country to implement National Biosafety Act, to develop national capacities to carry out risk assessment, to implement activities on risk management, to evaluate and strengthen the legal and regulatory frameworks, etc.
- Executed by Ministry of Natural Resources and Environment and implemented by Department of Chemistry, Department of Agriculture and Department of Health

- Ministry of Natural Resources & Environment is the body responsible for environmental management and biosafety guidelines
- National Biosafety Act passed in July 2007 states that before LMOs or its products can be imported, prepared, placed in the market, shall go through a scientific assessment before its approval by the National Biosafety Board (NBB)
- National Guidelines for the Release of GMOs into the Environment was also formulated to set the regulatory framework for GMOs by GMAC and included in the Biosafety Act 2007

- Institutional Biosafety Committees (IBCs) established by research agencies to meet requirements in biosafety guidelines:
  - IBC on GM plants – Department of Agriculture, Ministry of Agriculture (MoA)
  - IBC on transgenic animals – Department of Veterinary Services, MoA
  - IBC on Fish – Department of Fisheries, MoA
  - IBC on food – Ministry of Health (MoH)

- GM food is controlled under Food Quality Control Division, MoH, under Food Act 1983
- GMAC found R&R soybean is not different from conventional one and safe to import for food and feed
- Food Labeling Law is being drafted

- Future of GM technology:
  - Plan to increase R&D budget allocation for biotechnology
  - Government bills to provide incentives for researchers doing R&D work with commercial potential
  - Urgent need for human resources and infrastructure development
  - Need laboratories for monitoring and detecting GM plant products and GM food



## Myanmar Status on Biotechnology/Biosafety Policies

### MYANMAR

- NBF under UNEP-GEF Project developed in 2004
- Modern biotechnology is in an infancy stage
- National policies related to modern agricultural biotechnology being formulated are to:
  - Promote a safe and sustainable application and equitable access of biotechnology
  - Integrate biotechnology into environmental and sustainable planning, and
  - Ensure an adequate level of biosafety, and public participation in decision-making process

- No law or regulation specific for biotechnology/biosafety
- Some existing laws are relevant such as
  - Pesticide Law of 1990
  - Plant Pest Quarantine Law of 1993
  - Science and Technology Development Law of 1994
  - National Food Law of 1997
- Biosafety Law is being drafted under which NBC will be formed
- Unauthorized GM cotton being cultivated



- Biotechnology R&D activities are being developed and in progress at the laboratory level in research agencies and universities
- There is an urgent need in technical assistance in modern agricultural biotechnology and biosafety from the more advanced GMS countries and ASEAN countries



## Philippines Status on Biotechnology/Biosafety Policies

### **PHILIPPINES**

- NBF under UNEP-GEF Project developed in 2004
- 2008 World 11<sup>th</sup> mega-biotech country (growing GM crop 50,000 ha or more) with 0.4 million ha of Mon 810 GM corn (ISAAA)
- National Policy: Promote the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment, and industry development

- 1992 – President issued Executive Order No. 430 Series #1 & #3 of Committee on Biosafety of the National Committee on Biosafety of the Philippines (NCBP) 1992, under Dept. of Science & Technology, to regulate laboratory experiment and field tests of GM crops
- 1997 – Republic Act 8435 (Agricultural & Fisheries Modernization Act of 1997) to modernize agricultural and fisheries industry by transferring them from a resource-based to a technology-based sector
- 2002 – DoA Administrative Order No. 8 of 2002 (Rules and Regulation on the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology)

- GM crops under R&D:
  - Rice (Philippine Rice Research Institute - PhilRice)
  - Papaya, sweet potato, eggplant, tomato, coconut (University of the Philippines at Los Banos - UPLB)
  - Corn (private industry)
- GM corn approved for commercial cultivation:
  - MON 810 corn (corn borer resistant), (Monsanto (2002))
  - NK 603 corn (herbicide tolerant), Monsanto (2005)
  - Bt 11 corn (stacked insect resistant & herbicide tolerant), Syngenta (2005)

- All applications for field test and applications for release for propagation of GM crops are through Bureau of Plant Industry (BPI), Department of Agriculture
- BPI coordinates and collaborate with other concerned agencies to the final decision, “approved” or “denied”

- Public hearing mechanism:
  - Technology developer shall publish a Public Information Sheet (PIS) in two newspapers for the public to comment on the safety of GM crops
  - IBC ensures safety to human health and Environment in the conduct of field trials and to inform the communities for the planned release of GM crops

- Future Needs:
  - Capacity building in risk assessment risk management & risk communication
  - Public awareness
  - Human resources and infrastructure development
  - Regional harmonization of biosafety regulation



## Singapore Status on Biotechnology/Biosafety Policies

### **SINGAPORE**

- Not participating in UNEP-GEF NBF development project
- Not a party to the Cartagena Protocol yet
- Not agricultural country
- Does not have any legislation specific for GM technology regulation
- GMAC (Genetic Modification Advisory Committee) established to oversee and advise on the research and development, production, use and handling of GMOs



- GMAC Subcommittees on:
  - Release of Agriculture-related GMOs
  - Research on GMOs
  - Labeling
  - Public awareness
- Guidelines:
  - Singapore Guidelines on the Release of Agriculture-Related GMO (1999)
  - Singapore Biosafety Guidelines for Research on GMOs (2006)

- Competent national agencies:
  - Agri-food and Veterinary Authority of Singapore (AVA)
  - Ministry of Health (MOH)
  - Ministry of Manpower (MOM)
  - National Environmental Agency (NEA)

- Institutions, companies or organizations involving in biotechnology are required to:
  - Establish an IBC (Institutional Biosafety Committee)
  - Provide resources and facilities necessary for safe work in laboratories, and
  - May consider making compliance with the GMAC Guidelines



## Thailand Status on Biotechnology/Biosafety Policies

### THAILAND

- National policy is to adopt science & technology as tools for value-addition and long term economic development
- National Center for Genetic Engineering and Biotechnology (BIOTEC) established since 1983
- Biosafety guidelines developed and implemented since 1992, revised in 2004
- BIOTEC prepared the National Biotechnology Policy Framework 2004-2009
- Ministry of Agriculture & Cooperatives (MOAC) completed a Development of Agricultural Biotechnology Plan (2006-2009) including a road map for public participation on GMO issues

- National Biosafety Committee (NBC) appointed since 1993 with 4 subcommittees on plants, microorganisms, food, and socioeconomic issues
- NBC ceased its function at the end of 2004 awaiting the enactment of biosafety law
- Institutional Biosafety Committees (IBCs) initiated since 1993, 33 IBCs in 2009

- Office of Natural Resources & Environmental Policy & Planning (ONEP) under the Ministry of Natural Resources & Environment (MONRE) mandated as the national focal point for CBD and the Cartagena Protocol on Biosafety as well as the Biosafety Clearing House (BCH) of the Cartagena Protocol
- NBF under UNEP-GEF Project developed in 2008

- Several national and domestic legislation applicable for regulating biotechnology are in place but need proper inter- as well as intra- agency coordination and enforcement
- A moratorium banning field trials of GM crops until the biosafety law is in place was issued by the cabinet, as a result of demand by the anti-GMO pressure groups in April 2001
- Draft Biosafety Law is in the process of enactment by the parliament in 2010

- GM crops approved for field trials by NBC:  
(No GM regulation before 1994):
  - Transgenic corn (August 1992), not done
  - Virus resistant cantaloupe and squash (Sept 1992), not carried out
  - Altering ripening tomato (March 1993), not carried out
  - Seed production of FLAVR SAVR tomato (August 1993), completed



- Plant Quarantine Act 1964 regulations in 1994 and 2003 prohibit import of 89 plant species known to undergo GM except for study and research and permits by DOA are required
- GM crops approved by NBC and DOA for research in containment, small and large scale field trials and possible deregulation in 2000:
  - Transgenic tomato (1)
  - Transgenic cotton (4)
  - Transgenic corn (10)

- Locally developed GM crops approved for trials by NBC & DOA:
  - Transgenic squash, DOA (1996)
  - Transgenic papaya, DOA (1996)
  - Transgenic rice, DOA (1997)
  - Bt cotton, papaya, chili pepper, tomato, Kasetsart University
  - Transgenic papaya, Mahidol University
  - Transgenic pineapple, Rajamangala University

- GM corn and GM soybean import and placing in the market allowed
- Labeling is required by FDA, MOPH if the first three ingredients in the product contain more than 5 %
- Labeling enforced for large manufacturers only and not for small vendors
- Over 80 % of commercial cotton cultivation in the country are unauthorized Bt cotton dubbed as the “Iron Boll” cotton
- Growers use non-GM cotton varieties as “refuge”



## Vietnam Status on Biotechnology/Biosafety Policies

### **VIETNAM**

- National policy for biotechnology is to encourage application of biotechnology for agricultural production
- NBF under UNEP-GEF Project developed in 2004
- Modern biotechnology development is advancing at a rapid rate
- A strategic Master Plan for Biotechnology to the year 2020 is being developed and coordinated nationwide
- Government to increase budget for R&D programs and to invest in biotechnology infrastructure development

- Biosafety regulation promulgated in 2005 to cover scientific research, technology development, production, trading and usage, import, and export of GMOs and GMOs-FFP
- Biosafety Guidelines approved in 2005
- National Biosafety Committee (NBC) under Ministry of Natural Resources & Environment consists of representatives from Ministries of Agriculture & Rural Development, Aquaculture, Science & Technology, Public Health, and Trade

- There is no policy on the introduction of GMOs for direct use as food, or feed, or for processing yet
- National plant quarantine systems being utilized to check any inadvertent introduction of GMOs and hazardous microorganisms into the country and field trials of GM crops

- GM crops being developed: rice, maize, cotton, soybean, papaya, cabbage, cassava, sweet potato, potato, tomato, sugarcane, ornamental flowers (carnation, chrysanthemum, gladiolus) and forest trees
- Unauthorized GM maize, soybean, cotton being grown unofficially
- GM soybean and maize imported but GM food labeling regulation with mandatory threshold of 5% is still in the process

- Future needs:
  - Capacity building in terms of human resources & infrastructure development
  - Expertise in GMO detection, handling, identification and monitoring, risk assessment and risk management
  - Public awareness and participation





## ASEAN Policy-Making Mechanism

- In 1999 ASEAN Ministers for Agriculture and Forestry (AMAF) endorsed ASEAN Guidelines on Risk Assessment of Agriculture-related Genetically Modified Organisms (GMOs)
- Followed by Training Workshops on Safety and Risk Assessment of Agriculture-related GMOs in Singapore, Kuala Lumpur, Bangkok and Jakarta in 2001, 2002, 2003 and 2004, respectively
- ASEAN Genetically-Modified Food Testing Network established in 2004 led by Singapore

- ASEAN Committee on Science and Technology (COST) to oversee, implement, monitor and evaluate joint R&D and training programs in biotechnology with a Subcommittee on Biotechnology
- ASEAN Senior Officials on Environment (ASOEN) with a Working Group on Nature Conservation and Biodiversity to look at the matter in the context of international conventions and protocols such as CBD and CPB
- Harmonized Guidelines on Risk Assessment of Agriculture-Related GMOs to be adopted and called for the establishment of a National Authority on Genetic Modification (NAGM) in each member country

## Other Policy-Making Mechanism in the ASEAN Region

- UNEP-GEF NBF Development Project (2002-2006): All ASEAN countries, except Brunei Darussalam, Malaysia and Singapore, participated
- FAO Regional Project on Capacity Building in Biosafety of GM Crops in Asia (2003-2005): Participating countries were Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand and Vietnam; Cambodia, Lao PDR and Myanmar not participating
- Asian Development Bank (ADB) Project on Strengthening Capacity and Regional Cooperation in Advanced Agricultural Science and Technology in the Greater Mekong Subregion (GMS) (2005-2007): Participating countries were Cambodia, China (Yunnan Province), Lao PDR, Myanmar, Thailand and Vietnam

# CONCLUSIONS



- ASEAN countries are highly diversified in terms of R&D, human resources development, basic infrastructure, facilities, etc. and capacity building mechanism is urgently needed in the whole region
- It is most obvious that all ASEAN countries are, to a very large extent, aware and technically concerned with the development and advance in modern agricultural biotechnology going on globally and within the region

- There is a need on the alignment and synergies of the existing policies under different national competent authorities in each ASEAN country
- Where appropriate, there is a need to harmonize biotechnology/biosafety regulations within the region and taking into account similar attempt being made under the ASEAN flagship
- Cooperation, collaboration, linkages and networking in modern biotechnology/biosafety among the ASEAN countries need to be initiated and strengthened

Muchas Gracias!



Thank You So Much for Your Attention!



