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Thailand

Updated Status and Perspective on Research and Development of Modern Biotechnology and Biosafety Regulation

WHITE PAPER

Second Edition

prepared by
Technical Biosafety Committee (TBC)

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FOREWORD

It is estimated that the world's population will reach 9 billion people by 2015. Despite the enormous advances made in increasing agricultural productivity over the last 25 years, more than 800 million people in the world remain undernourished. Changing demands of diets, global warming, growing populations, and, recently, the need for alternative energy from crops to replace fossil-based fuel are putting tremendous pressures on the ability of countries around the world to feed their citizens. In addition, current energy supplies also fail to meet the daily needs of the world's poor. Over one billion people worldwide lack access to electricity in their homes and continue to rely on wood, straw, dung and other traditional biomass fuels to meet their energy needs.

Modern biotechnology has the potential to address these global concerns about food, energy, environment and health. It can help improve both the quantity and quality of the world's food supply. For example, staple crops with enhanced nutritional values or with desirable traits such as drought resistance could have a significant impact on developing nations.

It is vital that developing countries such as Thailand have access and the ability to use biotechnology

to address these urgent development needs. Thailand recognizes the fundamental role that biotechnology can play in of improving the quality of life for the rural poor as well as providing a much needed source of revenue.

The challenges facing biotechnology in the years ahead are not just scientific and technological but also relate to matters of public policy and public perception. Thailand has put much effort into ensuring that biotechnology is practiced within the Kingdom in a sustainable and safe manner. Through consultations with international partners, it has put in place the required infrastructure and capacity to support a sound, science-based policy and regulatory framework.

Decisions made by the relevant authorities concerning the use of modern biotechnology are being taken with full public participation and scrutiny. The purpose of this paper is to provide the reader with a perspective on key issues and information relating to Thailand's readiness. We hope that this paper will be a valuable contribution to the discussion on the fundamental role that modern biotechnology will play in the years ahead.

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INTRODUCTION

The role of agricultural sector has grown of greater importance and agro-industrial development is increasingly recognized as an important engine for economic growth. For many years Thailand has successfully utilized innovations in agricultural research and technology to develop a vibrant agricultural sector. In order to maintain this drive it is necessary for Thailand to continue support the development and capacity building in research and development of genetically modified organisms and their products to ensure self-reliance, effectiveness and competitiveness while taking into account the safety of consumers.

Research and development in genetically modified organisms is not new to Thailand. In 1992, the country was one of the first in the region to adopt a national biosafety guidelines for both laboratory work and field testing and planned release. The guidelines were initiated by National Center for Genetic Engineering and Biotechnology (BIOTEC), National Science and Technology Development Agency (NSTDA) under Ministry of Science, Technology and Energy (MOST).

Subsequently in 1993, the National Biosafety Committee (NBC) was established while BIOTEC served as the coordinating body and secretariat. Later on, many Institutional Biosafety Committees (IBCs) were established by various research and academic institutes throughout Thailand. NBC has been the host for all technical biosafety matters as technical support to various government authorities in decision-making concerning the safety of genetically modified organisms. This committee functions as technical

advisory group and risk assessment body, working in coordination with relevant government agencies in the approval process.

The first introduction and field testing of genetically modified organism in Thailand was with Flavr Savr tomato. The Department of Agriculture, Ministry of Agriculture and Cooperatives (MOAC) with technical recommendation from NBC, granted permission for the field trial of Flavr Savr tomato in 1994. Additional field trial were also permitted for other goods such as genetically modified cotton with toxin gene from *Bacillus thuringenesis* (Bt) in 1995, *Bt* cotton in 1996 and Bt corn in 1997 etc. However, due to mounting pressure from NGOs, the Cabinet on April 3, 2001 decided to suspend all field-testing of transgenic plants in Thailand. Therefore, all trials conducted for research purposes can only implemented in laboratories or greenhouses setting.

With the establishment of the new Ministry of Natural Resources and Environment (MONRE) in 2002, all biosafety issues related to Cartagena Protocol were then transferred to MONRE which serves as an official national focal point. On February 8th 2006, Thailand became the 128th member country of the Cartegena Protocol on Biosafety. As the central mediator for the Protocol, the Office of The Natural Resources and Environmental Policy and Planning (ONEP) cooperated with related organizations such as the Department of Agriculture, Department of Fisheries, Department of Livestock Development, FDA, BIOTEC, academic institutes and private establishments, in developing a system of biosafety protocols. The system consists of an administrative council and committee to oversee and liaise between parties on important issues, as well as establish and develop the national framework regarding biosafety in Thailand.

National Biotechnology and Biosafety Policy

1. Thailand's National Biotechnology Policy Framework (2004-2009)

Thailand's National biotechnology Policy Framework was formulated to support the government's policy, to promote national self-sufficiency and enhance the country's global competitiveness. The six year framework (for the period 2004-2009) was developed by the National Biotechnology Policy Committee, which is chaired by the Prime Minister and formally approved by the Thai cabinet in 2003.

The six goals for the development of biotechnology in Thailand, as outlined in the National Biotechnology Policy Framework are:

Goal No. 1: Emergence and Development of New Bio- Business
Goal No. 2: Biotechnology Promotes Thailand as Kitchen of the World
Goal No. 3: Thailand Represents Healthy Community and Healthcare Center of Asia
Goal No. 4: Utilization of Biotechnology to Conserve the Environment and to Produce Clean Energy
Goal No. 5: Biotechnology as the Key Factor for Self-Sufficient Economy
Goal No. 6: Development of Qualified Human Resource

With regard to Goal No.2 mentioned, It is recognized that the country needs a clear, transparent and appropriate national policy on the use and management of genetic engineering.

Consequently, National Biotechnology Policy Committee decided in 2004 on an approval of genetic engineering and biosafety policy spelling out "Choice for society". In other words, Thai society shall have an alternative to choose or not choose to use genetically modified organisms which had been assessed as safe for consumers and environments, and taking into consideration together with any traditional uses. To prepare country measures to serve and support the national policy, biosafety legislation was proposed to be developed by Ministry of National Resources and Environment. A crucial national catalyst since then supported to accomplish a draft biosafety act to the government cabinet. Progressively the draft biosafety act has been approved by the government cabinet on 22 January 2008. It is currently scrutinized by the Office of the Council of State, later it is expected to finally be considered by soon (hopefully in 2008).

Draft Biosafety Act

- Rational (according to latest draft April 2007)

The current progress and development of modern biotechnology in using living modified organisms is very promising to several areas and perspectives namely agriculture and human health. Thailand recognizes its significant importance to development and is also aware of safety concerns to the environment, biodiversity and human health. The need to promulgate a legislation to regulate the use of living modified organisms either imported or produced within the country is of crucial concerns. The act will assist all stakeholders to have necessary and appropriate tools and procedures to handle living modified organisms in compliance with international community.

- The draft biosafety act (April 2007) currently consists of 9 chapters enumerating 108 Articles covering all substantial issues;
    - General provisions (Art 1-18)
    - Operational provisions (Art 19-63)
    - Supportive provisions (Art 64-108)

- The draft biosafety act contains;
    - Advanced inform consent
    - Case-by-case and step-by-step approach
    - Risk-based regulation
    - Precautionary principle
    - Socio-economic consideration
    - Public participation and opinion
    - Science-based basis
    - Joint liability and redress

2. Biosafety Policy

Thailand's National Guidelines on Biosafety (draft) follows the principles and rules of the Cartagena Protocol on Biosafety. The draft has been accepted by the Compliance Committee under the Cartagena Protocol on Biosafety on November 7th, 2007.

Principal Concepts of the draft National Biosafety Policy

1. **Public Awareness, Education and Participation:** Requiring the involvement of affected parties in policy-level decision-making on the suitability, advantages and risks of the technology in question.
2. **Sustainability:** Sustainable bioresource management must be taken into account the sustainability of the ecology, preservation of species and genetic pool.
3. **Risk Assessment and Management:** Risk acceptability will be assessed and managed on a case-by-case basis according to the Guidelines on Biosafety which will be base on scientific grounds first and foremost.
4. **Risk Characterization:** Characterizing risks for the management and control of GM materials will depends on the outcome of the risk assessment.
5. **Risk Communication:** Risk communication will be based on basic scientific concepts simplified for the public, in order to lessen the anxiety of affected parties, increase public trust in research results, as well as curb possible panic from sensitive or contradictory information.
6. **Precautionary Principle:** to avoid unnecessary damage from the lack of reliable scientific data on possible effects of GM materials on the conservation and utilization of biodiversity, environment, and health care, this may result from ignorance or inadequate scientific news coverage.

Principal Concepts of the draft National Biosafety Policy (continued)

7. **Freedom of Choice:** In utilizing GM materials for everyone, including consumers, entrepreneurs, academics, farmers, as well as the general public with interested concerns. The state must encourage transparency, accuracy and up-to-date public data for an informed freedom of choice.
8. **Capacity Building:** Capacity-building on the national level for the consistent development of biosafety and modern biotechnology on equal grounds, to increase national strengths in understanding, utilization and management capability for the public, business and general sector via studies and development.

3. R&D Roadmap

The Thailand GMO roadmap was acknowledged and endorsed by the Thailand National Biotechnology Policy Committee. The roadmap outlines Thailand's strategy for building R&D capabilities from research and development to commercialization. Following is the summary of the roadmap:

1. To raise human resource capabilities in technology development to international standard levels. The roadmap emphasizes the development of transformation technology and expression systems for local crops, for use in the genetic modification.

2. Traits improvement should be targeted for plants

that have significant impact on the Thai economy, society and environment.

3. To strengthen biosafety assessment capability as well as regulatory controls of open systems and field trials, to build up public confidence in the regulatory agencies' ability to control and monitor open field trials of genetically modified plants. The roadmap also emphasizes the development of new technologies to support biosafety assessment.

4. Promote public understanding and participation in the decision process, by disseminating accurate information to the public. This will allow the public to make valuable or rational judgments on whether to accept or reject products derived from new technologies.

5. IBC is an important regulatory body at the institutional level. BIOTEC is the national coordinator of these 33 IBCs. One of the important roles of BIOTEC is to strengthen the technical capacity of these IBCs through training and dissemination of information. Moreover, BIOTEC also organize an annual IBC conference as an arena for IBCs to exchange and share their experience.

For the strategic GMO roadmap to be successful, Thailand needs to have a clear policy on field trials, management systems for intellectual property and natural resources, human resource development and infrastructure to support R&D in modern biotechnology and biosafety.

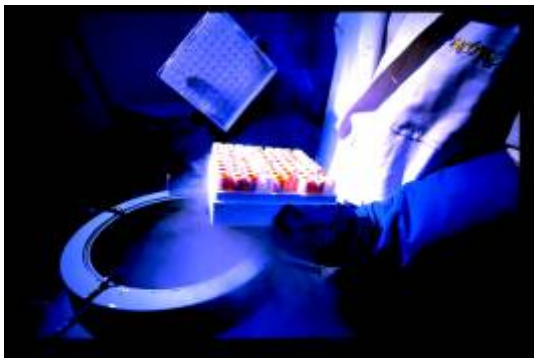
Research and Development in Modern Biotechnology

Research and development on modern biotechnology for agriculture in Thailand is widely performed in a number of government institutions and universities.

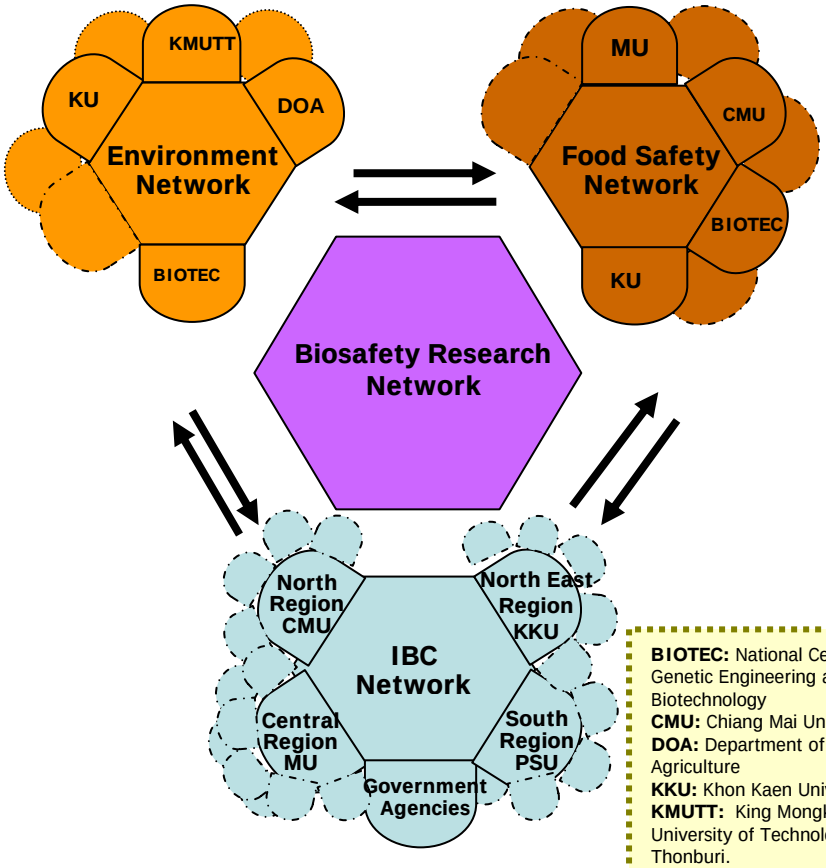
For example, a number of higher plant researches have proceeded such as ringspot virus - PRSV resistant papaya, retardant-ripened papaya, and color-changed orchid, vein-banding mottle virus resistant Chili and Yellow leaf curl virus - TYLCV resistant Tomato etc. Most of them have

progressed up to plant transformation process; many are the model plants ready for biosafety testing.

Research and development on genetically modified microorganisms for industrial uses in Thailand emphasizes on enzymes for feed industry namely phytase, xylanase and cellulose. All are at laboratory scale; not yet at industrial scale. In addition, those are for medicinal uses, Thailand has been performed medical researches using genetically modified organisms namely to develop growth hormones and vaccine (for pandemic influenza).



Those are for food and environments, Thailand has a capacity and readiness in terms of competent experts, however they have not yet cooperated due to a lack of research network and core common research theme. In future, the country needs to continue capacity building of expert pools to serve for research and development.



BIOTEC: National Center for Genetic Engineering and Biotechnology
CMU: Chiang Mai University
DOA: Department of Agriculture
KKU: Khon Kaen University
KMUTT: King Mongkut's University of Technology Thonburi.
KU: Kasetsart University
PSU: Prince of Songkhla University
Government Agencies:DOA, DOF, FDA etc.

Thailand biosafety research network

1. National Focal Point for Cartagena Protocol

- Office of The Natural Resources and Environmental Policy and Planning acts as the national mediator for the Cartagena Protocol.

2. Competent National Authorities

- Ministry of Agriculture and Cooperatives
  - o Department of Agriculture : Responsible for the registration and approval of utilizing genetically modified crops, testing in a controlled environment, intentional leaks into the environment within the permitted zone for agricultural production and research.
  - o Department of Livestock Development, Department of Fisheries: Responsible for all permits for the usage of genetically modified animals, aquatic animal and their subsequent product under controlled conditions.

- Ministry of Public Health
  - o FDA: Responsible for the registration and approval of genetically modified products created for human consumption.

- Ministry of Science and Technology
  - o BIOTEC: Responsible for the registration and approval of genetically modified plants, animals and microorganisms under controlled conditions, for further use in development and non-profit research.

- Ministry of Natural Resources and Environment
  - o Department of Forestry, Department of National Parks, Pollution Control Department of Marine and Coastal Resources: Responsible for the approval of genetically modified plants, animals, or microorganisms intentionally released into the environment outside of the permitted zone.

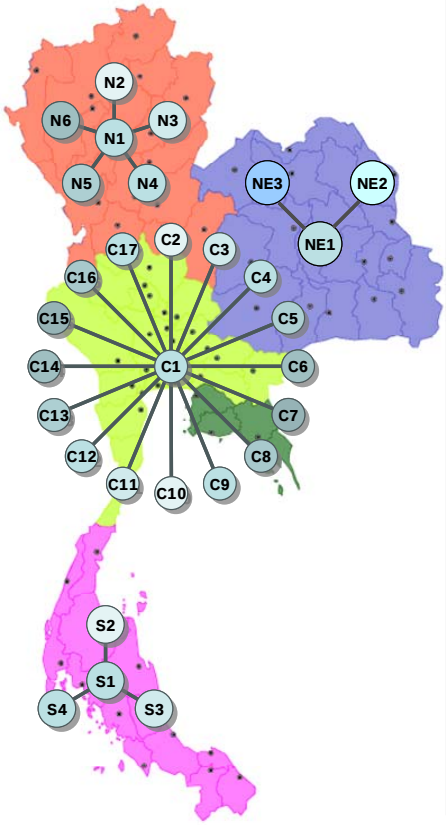
- Ministry of Industry
  - o Department of Industrial Works: Responsible for the registration of genetically modified microorganisms under controlled conditions for industrial production.

- Ministry of Commerce
  - o Department of Foreign Trade: Responsible for the approval of imports or exports involving genetically modified organisms or products.

3. Institutional Biosafety Committee (IBC)

Controlling the safety of genetic engineering research follows the methods outlined in "Guidelines for Biosafety in Genetic Engineering or Modern Biotechnology Research". In practice, an Institutional Biosafety Committee (IBC) is founded in each organization to supervise its internal research processes within the relevant subject, e.g. Ordering, production, transportation, or release of GM materials into the environment. Besides the IBC, the Guidelines also demand the formation of a Technical Biosafety Committee (TBC) to mediate and advise the IBC, or other organizations with genetic engineering research that do not have IBCs of their own

Infrastructure



N – North Region
N1 - Chiang Mai University
N2 - Mae Fah Luang University
N3 - Maejo University
N4 - Uttaradit Rajabhat University
N5 - Reserch Institute for Health Science, Chiang Mai University

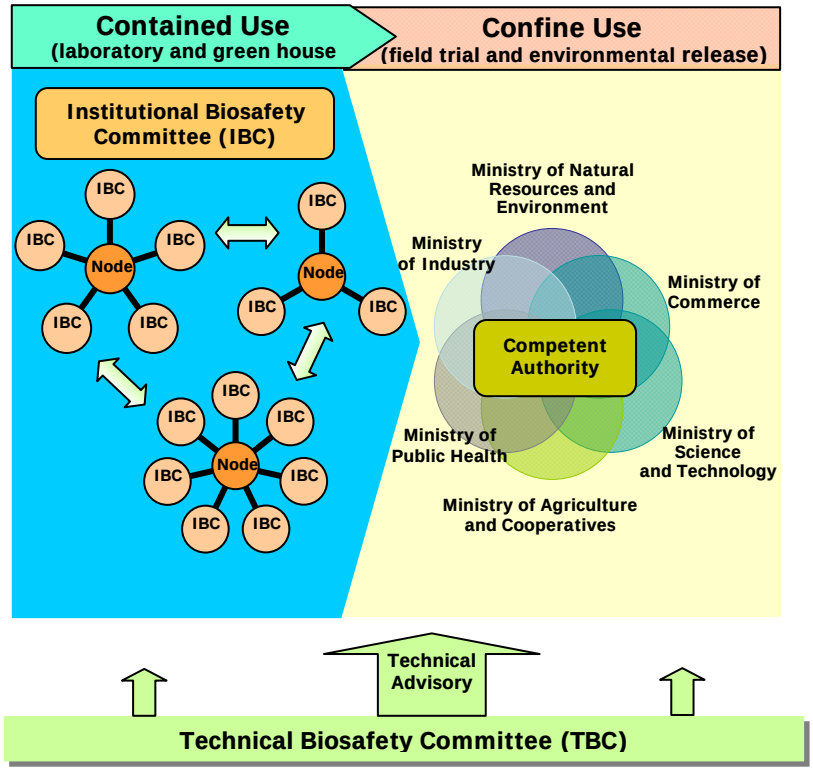
NE – North East
NE1 – Khon Kaen University
NE2 – Suranaree University of Technology
NE3 – Ubon Rajathanee University

C - Central Region
C1 – Mahidol University
C2 – Ajinomoto Co.
C3 – Assumption University
C4 – Burapha University
C5 – Chulabhorn Research Institute
C6 – Chulalongkorn university
C7 – Kasetsart University
C8 – King Mongkut's Institute of Technology Ladkrabang
C9 – King Mongkut's University of Technology Thonburi
C10 – National Center for Genetic Engineering and Biotechnology
C11 – Thailand Institute of Scientific and Technological Research
C12 – Rajamangala University of Technology Thanyaburi
C13 – Ramkhamhaeng University
C14 – Rangsit University
C15 – Srinakharinwirot University
C16 – Silapakorn University
C17 - Thammasat University

S - South Region
S1 – Prince of Songkhla University
S2 – Rajamangala University of Technology Srivijaya Provides
S3 - Thaksin University

IBC network

To date, 34 IBCs have been formed. IBCs are created continually; newly-formed IBCs may not be very strong, therefore, regional IBC networks have been created, divided into the north, northeast, central and south regions respectively. Each region contains a caretaker IBC acting as a node for other IBCs until each is strong enough to function on its own. The IBC network may also organize activities to encourage communication and sharing of experiences between its members annually, such as road shows, workshops, and annual meetings.



Infrastructure

Infrastructures of Biosafety in Thailand

1. Existing Biosafety Related Laws

- **Plant Quarantine Act B.E. 2507 (1964)**

The notifications under this act are promulgated to cover aspects of LMOs issues that are not clearly stated in this act. Eighty nine species of LMOs are prohibited to be imported into and transported across the Kingdom, except for research and development granted by Director-General of Department of Agriculture in compliance with guidelines on import and transit of prohibited materials declared.

- **Plant Variety Protection B.E. 2542 (1999)**

New plant species and the holder of the plant variety right are protectable under this act. Living modified plants capable of registration shall be assessed for potential risks

- **Food Act B.E. 2522 (1979)**

According to this Act, the Minister shall be empowered to promulgate notifications for controlling food by reference to the class and kind of food produced for sale, import for sale, or sale including condition FDA has drafted a labeling regulation for food containing ingredients derived from GMOs. It became the Ministerial Regulation No. 251 B.E.E 2545 (2002) and has been enforced since May 11, 2003. More details of labeling regulation can be summarized as followed:

- o Only soybean, corn and their products (22 items) derived from genetically modified have to be labeled.
- o The threshold level has been determined to be 5% of DNA or protein from each top 3 ingredients and each ingredient should have more than 5% by weight of product.

2. Draft National Biosafety Act

The decision of the Thai Government to become a Party to the Cartagena Protocol on Biosafety addresses bio-safety issues and points to the need to put in place a legislative framework for the entire country. Obligations by the Party under the Cartagena Protocol on Biosafety were synthesized in order to identify components of the country's biosafety laws that should be included so that the Protocol can be effectively implemented for the benefit of the country. The drafting Committee has approved the draft Biosafety Act (issued on April 2007), consisting of 108 Articles in 10 sections. Such a framework would define how Thailand can regulate and promote modern biotechnology at a pace faster than in the past.

3. Biosafety Guidelines

- **Biosafety Guidelines for Research and Development:** a non-binding set of rules proposed and used in 1992 was the first discipline in biosafety that researcher and developers (including plant breeders who involve in genetic engineering) in the country were encouraged to follow.

- **Food Biosafety Guidelines:** based on the concepts used by the Codex Alimentarius Commission, namely: Principles for the Risk Analysis of Foods

derived from Modern Biotechnology, Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms.

- **Biosafety Guidelines for Industrial Application of Genetically Modified Microorganisms:** provide an important framework for entrepreneurs to utilize genetically modified microorganisms in all industrial production.

1. Risk Assessment

Thailand biosafety evaluation and risk assessment of genetically modified organisms and their products are to be carried out on scientifically sound and case-by-case basis particularly in transparent manner procedural basis. Relevant agencies are requested to jointly conduct these tasks using the same measures for imported, domestically produced and exported products. Food and environmental risk assessment require competent and technical-specific, experienced experts. Thailand is consequently building capacity for food and environment risk assessors. A training course and curriculum for regional experts in the country is developed to screen a number of qualified personnel to be listed in a roster of biosafety country experts serving for risk assessment process in the near future.

2. Risk Management

Based on the Cabinet's decision on April 3, 2001, Thailand does not allow importation and production of any transgenic plants for commercial purposes and field

trials except for: (1) processed food; and (2) imports or sales of soybeans and corn for feed use, human consumption, and industrial use. Furthermore, all trials conducted for research purposes must be contained in laboratories or greenhouses.

On December 25, 2007, the Cabinet has approved the Ministry of Agriculture and Cooperatives to prepare for an extension of GM crops within government experimental stations. The plan requires clear definitions of the planting area, the crop, control methods and studies on the effects on the environment and health in nearby locales, as well as gathers public opinion and other interested parties according to Article 67 of the Constitution of Thailand. The study should be integrative and cooperative to reach a mutual agreement before submitting to the Cabinet for each area.

In case of risk assessment of field trial testing, Technical Biosafety Committee under BIOTEC had prepared a specific guideline called “Models for field trial of genetically modified papaya, tomato, pineapple and corn”. The guideline was developed from the Biosafety Guidelines for Work Related to Modern Biotechnology or Genetic Engineering in order to provide public assurance on the released filed trials of 4 targeted genetically modified crops in Thailand.

Realizing the importance of public participation is a strong driving force for progress of modern biotechnology and the public awareness in the technology is a foundation of efficient public participation. Public and private sectors in Thailand have been in cooperation to implement various activity programmes to promote public awareness in science and regulation of genetically modified organisms since 2001. In response to the fact that there are different stakeholders in the public, public awareness programmes in Thailand are strategically planned and implemented in according to interest and concerns of each group of stakeholders. Mainly, the stakeholders are categorized, based on their interest and concerns, into four groups of 1) students and educators, 2) farmers and agricultural extension officers, 3) food producers and 4) general consumers. Awareness in modern biotechnology is then raised and strengthened in each group through different education and communication activities designed to accommodate concerns and interests of each group.

In general, the education and communication activities are to provide information through channels of public seminar and mass media communication such as newspaper, newsletters, radio and television. In addition to information on examples of benefit and risk of

adopting the technology, basic knowledge about DNA, development of genetically modified organisms and biosafety are also provided to the public. This is in order to move forward to develop a knowledge based public participation where the public can compromise concerns with the scientific facts. Public education on complicate science has then been facilitated by translating biotechnology and biosafety information into various forms of nice-and-easy articles and educational materials for broadcasting and publication which includes cartoon books for children. Educational gadgets for learning about DNA, gene transformation, and biosafety were also specially designed and produced to enlighten the learning atmosphere in a learn-and-play manner.

As a lot of personnel are needed to provide information and knowledge to the public at large. The knowledge multiplier training programme has been introduced to generate "technology communicators" in local communities in all four parts of Thailand. Farmers, agricultural extension officers, high school teachers and general consumers who have potential in communication were selected and train in a short course on modern biotechnology and biosafety.

Currently, more than 30 trained technology communicators are serving as an information center in their own community and a linker between local public and academic institutions for update information. The technology communicators also serve as “knowledge multiplier” distributing knowledge to larger scale of public through meetings and seminars that they organize with support from the government. Through these public meetings and seminars, thousands of people have had chance to interactively update information on the technology, discuss their needs and concerns and translate them into sound recommendation to the authorities and the rest of the society. Moreover, those participated in the meetings and seminars can be the next knowledge multiplier delivering information and knowledge they gained to the others in their way of life.

To facilitate the public education in genetic modification and biosafety, three educational media were developed, a cell-DNA-genetic engineering model, particle bombardment toy, and biosafety model. Using the cell-DNA-genetic

Cell-DNA-Genetic Engineering Model

engineering model, instructors can demonstrate cell structure and organelles. A string of DNA can be pulled from nucleus to show DNA structure and how DNA could be cleaved and joined. The particle bombardment toy allows class to try for themselves, as they were in real laboratory; on how the gene is introduced into cells and why selectable marker gene is necessary. And, the biosafety model was designed to demonstrate the tightly control quality and safety assessment process of transformed plants according to regulations and requirements.

All education media were designed to use locally available materials, durable. They are able to function in all possible public educational class since the cell-DNA-genetic engineering and biosafety models do not require power source. The operation of the particle bombardment toy is possible with the aid of either AC electricity or battery.

Particle Bombardment Toy

Biosafety Model

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