

No 1013/ **78**



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10 March B.E. 2552 (2009)

Dear Dr. FeeChon Chong-Low,

**Subject: The Report on National Biosafety Frameworks for Thailand and
Final Documents for the Project**

The Office of Natural Resources and Environmental Policy and Planning would like to show our appreciation for your kind support and advice on executing the Project on National Biosafety Framework (NBF) for Thailand. Toward the project closure in December 2007, we have developed and finalized the report on the NBF for Thailand, as well as the draft Biosafety of Modern Biotechnology Act, which would be used as a legislative tool to support implementation of the NBF. However, even though the draft Biosafety of Modern Biotechnology Act was approved by the Cabinet in January 2008, further clarification and Parliament's approval would be needed before the Act could be enacted. The process of enactment might be deferred to the end of 2009 or beyond, due to higher priority set in other areas, such as economic and educational development. As a result, the NBF, which closely link to the Act, still awaits Cabinet's approval.

We, therefore, would like to assure you that once the NBF approved by the Cabinet; we will then submit the full report to you to be put into the system. However, in order to accommodate the closure of the project, we would like to attach herewith an executive summary for the NBF report, which can be temporarily used to refer to the work that had been done under the project. Likewise please find the final documents for the project enclosed as follows:

1. Terminal Report
2. The Seventh Quarterly Expenditure Report

3. A signed copy.../

Dr. FeeChon Chong-Low
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3. A signed copy of Final Inventory
4. The Final Workplan for the project

It has been a pleasure working with you. I would like again to take this opportunity to express our sincere thanks to you and looking forward to working with you in the near future.

Yours sincerely,

S. Bunpapong

(Dr. Sirikul Bunpapong)
Director of Biological Diversity Division
For Secretary-General

- Enclosures:
1. National Biosafety Framework for Thailand: Executive Summary
 2. Terminal Report
 3. The Seventh Quarterly Expenditure Report
 4. A signed copy of Final Inventory
 5. The Final Workplan for the project

EXECUTIVE SUMMARY

REPORT ON THE DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORKS OF THAILAND

A Project Supported by The UNEP-GEF Global Project on the Development of National Biosafety Frameworks (2005-2007)

After the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil in June 1992, most outstanding among several legally binding international instruments under the United Nations Multilateral Environmental Agreements (MEAs) related to biological diversity are the **Convention on Biological Diversity (CBD)** and the **Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CPB)**.

While the Convention on Biological Diversity emphasizes on the conservation, the sustainable use of natural resources, and the fair and equitable sharing of benefits deriving from the use of genetic resources, the Cartagena Protocol on Biosafety help serves as an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing biotechnology industry to enable the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing all potential threats to biological diversity and the environment, taking also into account the risks to human health, focusing specifically on transboundary movement of any **genetically modified organism (GMO)** or **living modified organism (LMO)** resulting from **genetic engineering** or **modern biotechnology** that may have adverse effect on the conservation and sustainable use of biological diversity.

Thailand became a signatory to the CBD after signing it on **12 June 1992** and became a party on **29 January 2004**. Subsequently, Thailand acceded to Cartagena Protocol on Biosafety on **10 November 2005** to become a party to the Protocol on **8 February 2006**. Even though, as a non-party to the CBD until 2004 and the CPB until 2006, Thailand has a policy emphasizing to undertake all relevant CBD- and CPB-related activities by itself not awaiting when the country will become parties to either CBD or CPB. Among all relevant obligations and requirements, biosafety regulatory concerns on the genetically modified organisms (GMOs) or living modified organisms (LMOs) derived from modern biotechnology and the development of the **National Biosafety Framework (NBF)** have been identified and prioritized.

The development of national biosafety framework in Thailand has been initiated since 2001 by the then **National Biosafety Committee (NBC)** having the National Center for Genetic Engineering and Biotechnology (BIOTEC) as the secretariat under the then Ministry of Science, Technology and Environment (MOSTE). When the MOSTE was reorganized to become the Ministry of Science and Technology (MOST) and the Ministry of Natural Resources and Environment (MONRE) in 2002, all biosafety related obligations under the Cartagena Protocol were since then transferred to MONRE having the Office of

Natural Resources and Environmental Policy and Planning (ONEP) under MONRE as the secretariat.

Almost at the completion of the UNEP-GEF NBF Global Project for Development of National Biosafety Frameworks in 2006, Thailand was granted with UNEP-GEF support to help develop the national biosafety frameworks (NBF) of Thailand in the mid 2005 having the Office of Natural Resources and Environmental Policy and Planning (ONEP) under MONRE as the UNEP-GEF Project's National Executing Agency (NEA). ONEP then appointed the **Steering and Advisory Working Group on the Development of the National Biosafety Frameworks of Thailand** on 2 November 2005 to undertake this formidable task which was to be completed by the end of 2006 but was, however, extended until the end of 2007.

The key obligation on this endeavor is "**Biosafety**" which is a term that is used to describe "**The policies and procedures adopted to ensure the environmentally safe application of genetic engineering or modern biotechnology.**" Since the policies and procedures related to biosafety in each country may be diversified and variable with or without proper alignment, a basic national framework covering the policy, technical, administrative, legal, institutional, etc. is necessary and is of a vital importance as a basis upon which the biosafety issues could be effectively and efficiently administered, regulated and managed to ultimately benefit the country.

A **National Biosafety Framework (NBF)** is "**A system which is a combination of policy, legal, administrative and technical instruments or mechanisms that are established and set in place to address safety for the environment and human health in the field of modern biotechnology.**" It often focuses on genetically modified organisms (GMOs) or living modified organisms (LMOs) and GMOs or LMOs intended for direct use as food or feed, or for processing (GMO-FFPs or LMO-FFPs). The national biosafety frameworks vary from country to country but each national biosafety framework will essentially consist of five common elements:

- 1). Biosafety policy,
- 2). Regulatory regime,
- 3). Systems to handle requests covering administrative, risk assessment and management, decision-making,
- 4). Follow-up actions including monitoring, inspection and enforcement, and
- 5). Public awareness, education and participation.

The development of a national biosafety framework is typically an on-going and iterative process in order to establish an adequate level of biosafety. Upon having completed the draft framework, there is a need to implement the draft as well as the continuous evaluation and feedback so as to ensure the legal practicability and the country's needs.

This report consists of 15 chapters. It is divided into three sections. Chapter 1, in Section I (Introduction), paves the pathway to introduction and background related to biosafety and national biosafety frameworks. Chapters 2-7, in Section II (Biosafety-Related Activities Prior to Thailand Becoming a Party to the Cartagena Protocol),

chronicle the background and development on biosafety-related issues prior to Thailand becoming a party to the Protocol on Biosafety on 8 February 2006. Chapters 8 to 15, in Section III (Biosafety-Related Activities Upon Thailand Becoming a Party to the Cartagena Protocol), deal with the obligation under the Protocol and biosafety relevant matters and issues undertaken after Thailand has become a party to the Protocol on 8 February 2006. The report ends with conclusions, and recommendations.

Section I Introduction

Chapter 1 – Introduction provides general background and introduction to biosafety, rationale for the development of the national biosafety frameworks and key elements of the national biosafety frameworks appropriate to Thailand.

Section II Biosafety-Related Activities Prior to Thailand Becoming a Party to the Cartagena Protocol

Chapter 2 – Past Development and Current Status of Biotechnology in Thailand reviews earlier organizational and administrative development of genetic engineering or modern biotechnology in Thailand including research and development, capacity-building, development of appropriate biosafety guidelines, establishment of the national biosafety committee and institutional biosafety committees, laboratory and field trial of genetically modified plants, adaptation and amendment of the existing laws to regulate GMOs or LMOs and GMO-FFPs or LMO-FFPs from 1983 until 2007 with the tentative national biosafety frameworks in Thailand developed by the then National Biosafety Committee in 2001.

Chapter 3 – Policies and Relevant Agencies presents various policies on biotechnology and biosafety under different authorities. The National Biodiversity Strategy and Action Plan (NBSAP) on Policy, Measures and National Plan on the Conservation and Sustainable Use of Biodiversity Resources (1998-2002 and 2003-2007) deal, among other biodiversity issues, also the releases of GMOs into the environment and related biosafety regulations. The Policy Guidelines and Strategy on Commodities derived from Biotechnology of the Committee on International Economic Policy on Production, Export and Import, and Information Dissemination on GMOs (1999) prohibits import of GM seeds for commercial cultivation until proven safe, but import is allowed for research use only. Imports of food, feed and grains, especially corn and soybean, as GMO-FFPs are allowed and regulated by the Ministry of Commerce. Certification and labeling of GMO-FFPs for export is voluntary between the trading partners. The Ninth Five-Year National Economic and Social Development Plan (2002-2006) supported and promoted research and development in biotechnology while the Tenth Plan (2007-2011) emphasizes capacity building in terms of personnel supporting biotechnology, country position on GMOs and formulation and enactment of biosafety law. The development of Thailand's National Biotechnology Policy Framework (2004-2009) was drafted and finalized by the National Biotechnology Policy Committee chaired by the Prime Minister in 2005 with key strategies and measures to meet the six goals for biotechnology development in Thailand. In addition are various occasional decisions by the cabinet on GMO-related issues including a

moratorium of 3 April 2001 prohibiting field trials of GM crops until the enactment of biosafety law, etc.

Chapter 4 – Regulatory Regime Supervising Biosafety deals with biosafety regulatory regimes in existence and in place in the country for the regulation of GMOs and GMO-FFPs such as the development of the Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work and Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release, both of 1992, which were merged to become **Biosafety Guidelines for Work Related to Modern Biotechnology or Genetic Engineering of 2004**, Plant Quarantine Act B.E. 2507 (1964), amended B.E. 2542 (1999), Plant Varieties Protection Act B.E. 2542 (1999), Animal Disease Control Act B.E. 2505 (1962), Animal Pathogen and Toxin Act B.E. 2525 (1982), Fisheries Act B.E. 2490 (1947), amended B.E. 2528 (1985), Consumable Products Control Act B.E. 2495 (1952), Commodity Export and Import Act B.E. 2522 (1979), Confidential Commercial Information Act B.E. 2545 (2002), Food Act B.E. 2522 (1979), and Animal Feed Quality Control Act B.E. 2525 (1882), etc.

Chapter 5 – Systems to Handle Applications for Permit gives details on the existing mechanism to handle GMOs or LMOs, transgenic livestock and aquatic animals, and GMO-FFPs or LMO-FFPs. Under the Plant Quarantine Act B.E. 2507 (1964), amended 2542 (1999), 89 plant species known to have been subject to genetic engineering research and development, laboratory and field trials, and/or developed commercially were declared as being “**Prohibited Materials**” and not allowed for import into the country except for research use with permits issued by Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC). Import of genetically modified livestock and aquatic animals must be approved and be in compliance with the regulations of the Department of Livestock Development (DOLD) and Department of Fisheries (DOF) respectively and is considered by their respective institutional biosafety committees. There is no regulation on the import of GMO-FFPs or LMO-FFPs especially GM corn and GM soybean but their products are subject to the labeling requirements under the ministerial announcement No. 251 B.E. 2545 (2002) issued by the Ministry of Public Health.

Chapter 6 – Systems for Inspection and Surveillance covers the follow-up actions consisting of regulations on both the import and export of transgenic plants, animals and GMO-FFPs or LMO-FFPs by the concerned national competence authorities.

Chapter 7 – Capacity Building on Education, Awareness and Public Participation devotes in particular to the relevant issues on capacity building on education emphasizing **public awareness** and **public participation** including the public hearings of the draft national biosafety frameworks carried out in four representative regions of the country.

Section III

Biosafety-Related Activities Upon Thailand Becoming a Party to the Cartagena Protocol

Chapter 8 – Obligations Undertaken Under the Cartagena Protocol deals with necessary preparation to meet the basic obligation to the Protocol. The **Office of Natural**

Resources and Environmental Policy and Planning (ONEP), as the national focal point for the Cartagena Protocol, in collaboration with other relevant governmental departments and agencies in concerned ministries has established various committees, subcommittees, working groups, etc., in particular, the **Cartagena Protocol Subcommittee** under the National Committee on the Conservation and Utilization of Biodiversity Resources, the **National Focal Point (NFP)** of the Protocol, and the establishment of point of contact as well as the **Biosafety Clearing-House (BCH)**. On the legal and official basis, the Departments of Agriculture, Department of Livestock Development, and Department of Fisheries have been designated as the **Competent National Authorities (CNAs)** in charge of genetically modified plants and microorganisms; genetically modified livestock and genetically modified fodder crops; and genetically modified fish and any GMOs intended for use as food and feed in aquaculture, respectively.

Chapter 9 – National Biosafety Policy Framework rationalizes and gives details on the **National Biosafety Frameworks** of Thailand covering the development of the national policy framework with eight key principles to guide how biosafety legislation and management should be addressed. They are conservation and sustainable use of biodiversity resources, risk categorization, risk assessment and risk management, risk communication, the precautionary principle, freedom of choice, capacity building, and public awareness, education and participation.

Chapter 10 – National Biosafety Legal and Regulatory Framework provides a legal framework including the overall issues, administration and compliance on the handling of GMOs or LMOs and GMO-FFPs or LMO-FFPs to be included in the draft **Biosafety of Modern Biotechnology Act B.E. 2551 (2008)** which has been approved by the cabinet on 23 January 2008. The draft act is now under the scrutinization by the Office of the Council of State for further consideration by the parliament for the enactment and enforcement expected in 2008.

Chapter 11 – National Biosafety Institutional Framework suggests an administrative and institutional framework covering the **National Focal Point (NFP)** of the Cartagena Protocol, the **National Biosafety Committee (NBC)**, **Competent National Authorities (CNAs)**, **Institutional Biosafety Committees (IBCs)** in academic, public and private sectors, their authority, functional mandate, and coordination.

Chapter 12 – National Biosafety Handling Framework outlines the requirements and regulations on LMOs and LMO-FFPs for import, export and in transit, **advance informed agreement (AIA)** procedure, including surveillance and monitoring of their intentional use in the country to minimize the risk, if any, and to ensure safety to the environment, taking also into account risks to human health.

Chapter 13 – National Biosafety Technical Guidelines Framework gives an account on the development of Biosafety Guidelines in Genetic Engineering and Biotechnology For Laboratory Work and For Field Work and Planned Release since 1992 and their revision to become Biosafety Guidelines for Work Related to Modern Biotechnology or Genetic Engineering in 2004 and additional guidelines for transgenic plants and for safe assessment of genetically modified foods. These guidelines were administered by the National Biosafety Committee and 34 institutional biosafety (IBCs).

The technical biosafety committee was also established in 2006 under BIOTEC to help assist the performance of IBCs.

Chapter 14 – Public Participation on Biosafety Matters deals with the participation of general public and the public hearings process involving all stakeholders and NGOs. Meetings and seminars to introduce the NBF development project, public participation procedure and risk communication as well as public hearings were organized in Bangkok and four regional areas of the country at Kamphaeng Saen, Chiang Mai, Khon Kaen and Hat Yai during the latter half of 2007. Delineating in these gatherings were reference to an article on public participation contained in the draft Modern Biotechnology Biosafety Act including the development of database and public information network through the setting up of Biosafety Clearing-House (BCH) via internet (<http://bch-thai.onep.go.th>) by ONEP.

Chapter 15 – Conclusions

This report on the development of **National Biosafety Frameworks (NBF)** of Thailand provides details of various national frameworks in accordance with the context of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It brings together five key national biosafety frameworks consisting of (1) National biosafety policy framework, (2) National biosafety legal and regulatory framework, (3) National biosafety institutional framework, (4) National biosafety handling framework, and (5) National biosafety technical guidelines framework. It also includes a chapter on public participation on biosafety matters.

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

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

Recommendations

It is recommended that this **Report on the Development of National Biosafety Frameworks in Thailand** should be submitted to the **Cartagena Protocol Subcommittee** for preliminary approval and endorsement for further necessary action by the **Committee on Conservation and Utilization of Biodiversity Resources**.

It is further recommended and anticipated that this report will be eventually approved by the government as a **“Key Working Document”**, endorsed and adopted by the concerned and competent national authorities for further consideration in the development of any enabling mechanism to support any action and implementation program of biosafety-related matters derived from modern biotechnology in Thailand.

Furthermore, it is also anticipated that this report be used as an underlying mechanism for any cooperation and collaboration within the country. In addition, this report will also help assist and help accommodate any anticipated upcoming regional and international cooperation and agreements, particularly on regional biosafety regulation alignment and harmonization, if appropriate, within the context of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity within which Thailand is already a contracting party.

Advisory and Steering Working Group on the Development of National Biosafety Frameworks in Thailand

**Office of Natural Resources and Environmental Policy and Planning (ONEP),
Ministry of Natural Resources and Environment (MONRE)**

7 February 2008

Revised and amended by the suggestion of the Cartagena Protocol on Biosafety Subcommittee

29 December 2008