Biosafety Guidelines in Genetic Engineering and Biotechnology

For Field Work and Planned Release

Prepared by :

Ad Hoc Biosafety Sub-Committee

National Center for Genetic Engineering and Biotechnology
National Science and Technology Development Agency
Thailand

2nd Print

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ISBN 974-7575-94-9

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RFID Lab NECTEC, STKS

PREFACE

During the past decade substantial progress and development have been achieved in R&D in biotechnology, especially the use of r-DNA technology or genetic engineering. Such achievements have been obvious in several areas including agriculture, industry, medicine and public health. r-DNA-derived products and research extend to various research institutes, universities and private research laboratories located both in the developing and developed countries. Genetically modified organisms (GMOs) (transgenic plants, animals and microorganisms) have been produced and commercial exploitation achieved after meeting necessary requirements in terms of biosafety under laboratory conditions as well as small-and large-scale field trials under different ecological regimes.

As a rule, an investigation on GMOs is undertaken by competent researchers or a research team, taking into consideration good laboratory practices and the acceptable safety of releasing the GMOs into the environment. Nevertheless, such progress and accomplishment has, at the same time, evoked tremendous concerns among researchers themselves as well as the public at large. Such concerns are centered around the release of transgenic organisms into the open environment, biosafety precaution and preventative measures; the fear that certain transgenic organisms may be harmful or become pathogenic to economic plants, animals and human beings; and the unanticipated virulence of manipulated genes or gene products that may disperse uncontrolled and freely in nature.

At the regional and international levels, a number of countries, developing and developed, have prepared or adopted biosafety guidelines for both laboratory investigation and field applications of R&D attempts involving r-DNA. The main objective is to ensure safety and minimize all the risks which are likely to occur, encountered or subsequently generated beyond expectation. Such guidelines may differ from one country to another however the principles are essentially more or less similar. In many cases, acceptable guidelines in developed countries are used as references, subjected to consideration and then modified or amended to be appropriate and in compliance with the existing related laws and regulations within respective countries. At the international level, efforts have been made by UNIDO, FAO, WHO

and other international agencies to prepare biosafety guidelines with contributions from international experts to help assist developing countries to formulate their own biosafety guidelines.

As far as Thailand is concerned, there exists an immediate need for national biosafety guidelines to help foster the development of r-DNA technology in the country. These guidelines are important and extremely essential, not merely for researchers within the country, but also for various cooperative and collaborative ventures between national institutions and overseas research partners interested in laboratory testing or additional field trials of GMOs in Thailand. This is one of many rationales upon which the Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work and for Field Work and Planned Release were developed by the National Biosafety Committee under the National Center for Genetic Engineering and Biotechnology (BIOTEC) of the National Science and Technology Development Agency (NSTDA).

The objective of these guidelines, prepared by the Ad Hoc Biosafety Subcommittee, BIOTEC is not to enforce stringent regulations such that they will impair related R&D activities in the development of biotechnology within the country. At the same time, the objective is also not to be too lenient to allow unintentional safety discrepancies and negligence leading to misuse and irresponsibility by certain researchers or laboratories.

The scope of these guidelines embraces all work related to gene manipulation employing r-DNA technology for all purposes including the development of transgenic plants, animals and microorganisms, production of vaccines, commercial and industrial manufacturing of r-DNA derived products, and releases of transgenic materials and products into the environment.

The preliminary draft guidelines have been under preparation by the Ad Hoc Biosafety Subcommittee since January 1991. They are for laboratory work as well as for field work and planned release. After the Thai version of the guidelines became available in 1992 the National Biosafety Committee considered it desirable to have an English version of the guidelines for the obvious purpose of international collaboration.

With suggestions and guidance of the National Biosafety Committee, several research agencies and universities in Thailand have established their own Institutional Biosafety Committee to oversee r-DNA research activities in their respective institutions and to coordinate their activities in close consultation with the National Biosafety Committee.

The National Biosafety Committee also realizes that these guidelines are still far from complete and future amendments and revision are unavoidable. The Committee welcomes all advice, suggestions, comments and criticism from all concerned in order to incorporate them and render the present guidelines more feasible and supportive of the overall development of r-DNA technology in the country.

Banpot Napompeth
Chairman
National Biosafety Committee
BIOTEC

INTRODUCTION

With awareness of possible adverse effects resulting from deliberate release of genetically modified organisms (GMOs) on human health and environment, biosafety guidelines in Thailand were developed and the draft completed in June 1992. The National Center for Genetic Engineering and Biotechnology (BIOTEC) PUBLISHED THE GUIDELINES FOR THE FIRST TIME IN Thai language. Since more and more cooperation in biosafety development has been made in the region and at the global level, English translation of the guidelines was undertaken and published in 1996.

The National Biosafety Committee (NBC) IS responsible for implementing the biosafety guidelines with BIOTEC as its Secretariat. An Institutional Biosafety Committee (IBC) has been established at each research agency to take care of biosafety measures and to coordinate work with NBC. These Guidelines should be useful for all scientific workers, project supervisors and administrators in conducting genetic manipulation work.

The Guidelines consist of two parts; the first one concerns transgenic work in laboratories and the second on field testing. However, both parts have common guidelines as follows:

1. The classification of work relating to GMOs according to level of risk and safety (Chapter 2). There are 3 categories: 1) work bearing no risk, 2) work bearing low risk, and 3) work with high risk. It is quite important to have such classification so that risk management and control could be made in three levels accordingly (details are in appendices 7-14)

2. Institutional arrangement in monitoring and control of risk (Chapter 3). There are three groups of personnel and organizations concerned: 1) Principal Investigator and researchers, 2) Institutional Biosafety Committee (IBC), and 3) National Biosafety Committee (NBC). Chapter 3 gives details on roles and responsibilities of these persons and committees.

Thailand Biosafety Guidelines are considered to be a soft law based on voluntary action. However, one part has been combined into an existing Plant Quarantine Act. In 1994 the Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives, has made a "Ministerial Declaration" under the "Plant Quarantine Act" and that all transgenic plants are prohibited imports into the country, unless permission is granted by the Director General (DG) of DOA and only for experimental purpose. The applicants could obtain information on the importation of transgenic plants and application for field testing from BIOTEC (as NBC Secretariat) at the following address:

The NBC Secretariat
National Center for Genetic Engineering and Biotechnology (BIOTEC)
National Science and Technology Development Agency Building
73/1 Rama VI Road, Bangkok 10400
Thailand
Tel : 66-2-644-8150-4
Fax: 66-2-644-8107

These Guidelines are to be used and followed by all researchers and institutes conducting genetic manipulation work. It is anticipated that the Guidelines will be modified periodically for more effective and efficient implementation. Therefore, any suggestion for modification and improvement from all agencies involved would be highly appreciated.

NBC Secretariat
August 1996

Table of Contents

Appendices

Chapter 1 Coverage of Guidelines for Field Work and Planned Release

These Guidelines cover all research work involved in the field test/trial of genetically manipulated plants and microorganisms. As a standard practice, genetically manipulated organisms from laboratory work must be field tested before planned commercial application or planned release into the environment. Such genetic manipulation field work is meant to address the following, underlying objectives:

1. To Confirm the observations made during laboratory work, and the results from tests conducted at the laboratory level
2. To Gather accurate information/data on the stability, transmission/heredity and expression of transgenes under field conditions
3. To Assess the viability (e.g. survival, propagation, competitive ability) of genetically manipulated organisms under field conditions
4. To Assess the adaptive or evolutionary potential of genetically manipulated organisms under changing environmental conditions

Inherently, laboratory work must precede field trials. So as to conform with guidelines for the latter*, for the purposes of these Guidelines, *regulated material* shall likewise refer to all genetically manipulated material (DNA and RNA preparations, viroids, viruses, cells and organisms, modified or constructed through genetic engineering), derivatives thereof and the wastes or by-products of genetic engineering practices (containing viable organisms or otherwise).

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* *Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work*, Nov. 1993

Chapter 2 Categories of Plants and Microorganisms for Field Work

2.1 Genetically Modified Plants

Field work with genetically modified plants must first take into consideration the nature or character of the biological system, as follows:

2.1.1

For experimental plants, considered to have a history of safe use in field work as follows, let work proceed in accord with the basic standards appropriate to the particular plant.

A. Modified plants that result from conventional breeding practices (e.g. selective breeding, mutagenesis, protoplast fusion or embryo rescue)

B. Genetically modified plants, having inherent characteristics typical of modified plants from conventional breeding practices.

C. Plants, with genetic inserts that are known to be harmless and inoffensive to the environment.

2.1.2

For experimental plants which do not meet the conditions of 2.1.1, let work proceed under the appropriate containment level and criteria, as presented in Chapter 3. Said measures of containment must be effective, if any one of the following conditions is met, or is to be adopted:

A. There is no cross-hybridization.

B. There are arrangements to contain the dispersal of plants and plant materials.

C. Introduced gene expression is stable, and does not fluctuate with changing environmental conditions.

2.1.3

In the notable case of plants which *do not* have a history of safe use in field work under the conditions of 2.1.2, let work proceed with a preliminary risk assessment to determine the full range of possible environmental effects;

A. Effects on the ecology, at the trial site
    - Heightened resistance to diseases and pests
    - Propensity for weediness
    - Harm to other target and non-target organisms
B. Effects on the ecology, in the open environment
    - Potential for cross-hybridization
    - Promotion of, and stimulus for the growth and development of weeds
    - Invasion of feral Populations, beyond the trial site
C. Effects on other elements of the surroundings.

2.2 Genetically Modified Microorganisms

Field work with genetically modified microorganisms must first take into consideration the nature or character of the biological system, as follows:

2.2.1

For experimental microorganisms, considered to have a history of safe use in field work as follows, let work proceed in accord with the basic standards appropriate to the particular microorganism.

A. Microorganisms from a strain that has been involved in previous, documented field work.
B. Microorganisms which perform the same functions as strains that have been involved in previous, documented field work.
C. Microorganisms which are confined to sites and surroundings that resemble .previous field conditions.

2.2.2

For experimental microorganisms which do not meet the conditions of 2.2.1, let work proceed under the appropriate containment level and criteria, as presented in Chapter 3. To be effective, said measures of containment must observe any one (or more) of the following conditions:

A. There is appropriate biological containment, where:
    - microorganisms are made 'inviable' before being field tested; or

- arrangements are in order to inactivate microorganisms; or
- modifications are done to limit the survival of microorganisms outside, and to confine microorganisms within target areas.

B. Genetic inserts and constructs may be exchanged or transferred to other microorganisms only in a restricted circle.

C. There are physical arrangements to contain the dispersal of microorganisms within the target areas or site of trial.

2.2.3

In the notable case of microorganisms which *do not* have a history of safe use in field work under the conditions of 2.2.2, let work proceed with a preliminary risk assessment to determine the full range of possible environmental effects. Some microorganisms recognized as 'problematic', include:

A. Microorganisms engineered for the sustenance and nourishment of plant species, may provide nutrients in excess and disrupt the chemistry of associated plants.

B. Microorganisms for bioremediation (e.g. destruction of toxic residues) may prompt secondary ill-effects (which may likewise, be toxin-related)

C. Microorganisms for biological control (e.g. control of plant pests) may overwhelm target species and may produce toxic or pathogenic metabolites, spreading ill-health in wild populations at the trial site.

Chapter 3 Regulation and Containment

3.1 Field Tests of Genetically Modified Plants

3.1.1 Experimental Plants with a History of Prior Field Work

Field testing experimental plants with a history of prior field work, still requires for submission to the Institutional Biosafety Committee (IBC), a project notification or proposal form. The IBC shall evaluate the proposed ambient working conditions through to the accredited containment resources, in determining the sufficiency of biosafety provisions. Measures for the control and containment of field work should observe relevant past regulations and address the particular plant(s) under study.

Only after receiving IBC endorsement may work begin. The IBC must forward all proposals and the committees, assessments thereof, to the National Biosafety Committee (NBC) for records and information.

3.1.2 Experimental Plants with No History of Prior Field Work

Field testing experimental plants with no history of prior field work should proceed under the advice, counsel and direction of the IBC and NBC. In both cases, committee recommendations and the command of work, shall be grounded on the biosafety concerns that may be gathered from the written proposals submitted. The project supervisor is prohibited from initiating work before consent is granted directly by the NBC.

Considering the risks involved with 'raw' or untested experimental plants, measures for the control and containment of field work at this level must set aside provisions for the following, assorted interests:

A. Contained tests may be conducted in conservatories or plant glasshouses, on site. The scale and period of contained cultivation is appropriate to both the nature of the investigation, and the nature of the particular plant.

B. The site chosen is befitting of (or made to suit) the particular plant under study. Test plots are fenced in and isolated from feral populations. "No Entry" signs are put up at regular intervals around the perimeter.

C. Arrangements are made collect, burn and destroy experimental plants and plant materials at the conclusion of work.

D. The cultivation of plants is surveyed and directed by the IBC, at regular intervals, as appropriate to the growth or developmental patterns of the particular plant.

E. Other interests, which the NBC or IBC deems suitable.

3.2 Field Tests of Genetically Modified Microorganisms

3.2.1 Experimental Microorganisms with a History of Prior Work

Field testing experimental microorganisms with a history of prior field work, still requires for submission to the IBC, a project notification or proposal form. The IBC shall evaluate the proposed ambient working conditions through to the accredited containment resources, in determining the sufficiency of biosafety provisions. Measures for the control and containment of field work should observe relevant, past regulations and must address the particular microorganism(s) under study.

Only after receiving IBC endorsement may work begin. The IBC must forward all proposals and the committees, assessments thereof, to the NBC for records and information.

3.2.2 Experimental Microorganisms with No History of Prior Field Work

Field testing experimental microorganisms with no history of prior field work should proceed under the advice, counsel and direction of the IBC and NBC. In both cases, committee recommendations and the command of work, shall be grounded on the biosafety concerns that may be gathered from the written proposals submitted. The project supervisor is prohibited from initiating work before consent is granted directly by the NBC.

Considering the risks involved with 'raw' or untested experimental microorganisms, measures for the control and containment of field work at this level must set aside provisions for the following, assorted interests:

A. The medium for testing experimental microorganisms (e.g. soil, water, or air) is regulated and contained, at levels directed by the NBC.

B. The boundaries of testing areas need to be clearly demarcated, and posted with "No Entry" signs. Use of testing areas is strictly regulated.

C. The dispersal of experimental microorganisms is monitored closely with a reliable and effective technique, approved by the NBC.

D. Arrangements are made to destroy/inactivate experimental microorganisms, at the conclusion of work.

E. Other interests, which the NBC or IBC deems suitable.

Chapter 4 Roles and Responsibilities of Pertinent Authorities

The drafting and implementation of safety precautions in genetic engineering and biotechnological work should be supervised and directed by various committees and individuals, representative of all of the following three authorities: The National Biosafety Committee (NBC), the Institutional Biosafety Committee (IBC) and the Project Supervisor.

The various authorities retain different powers and responsibilities in accordance with their respective affiliations (sections 4.1 through 4.3), yet are bound by the common objectives of enforcing and preserving the integrity and the intent of national guidelines.

4.1 The National Biosafety Committee

The National Biosafety Committee (NBC) was established on January 22, 1993 and its members were appointed by the Minister for Science, Technology and the Environment (Appendix 5) following recommendations from the Board of Directors of the National Center for Genetic Engineering and Biotechnology (BIOTEC), which recognized both the promise and the risks of research and development in this field of science and saw to the need to ensure a standard of safety within the discipline. The BIOTEC, through the NBC Ad Hoc Biosafety Sub-Committee (Appendix 6), prepared national biosafety guidelines for work involving genetically manipulated elements, with the safety of personnel, the community and the environment as a paramount concern. The NBC conducts on and furthers the interests of the BIOTEC, and serves to command and harmonize the direction of genetic manipulation work with the protocols laid down throughout, and with the pretenses underlying these Guidelines.

4.1.1 Authorities and Functions

A. Ensure that ambient conditions surrounding genetic manipulation work reflect and adhere to the specifications of national guidelines for the safety of personnel, the community and the environment exposed to the risks borne by the study.

B. Cooperate with the Customs Department and with other relevant authorities overseeing the import of live organisms to formulate guidelines for the identification, inspection and regulation of transgenic species, exotic and otherwise.

C. Review and direct the bearings of research methodologies in genetic engineering.

D. Identify, characterize and assess the hazards associated with innovative genetic manipulation techniques or research for which the risks are as yet uncertain.

E. Warn the authorities and individuals who are involved with, or who may be afflicted by genetic manipulation experiments, of potential hazards throughout the conduct of work.

F. Recommend, instruct and lend specialist technical expertise to various research institutions and regulatory agencies in setting up appropriate experimental conditions for work with specific regulated material.

G. Facilitate all levels of supervision of genetic manipulation work by establishing, and assisting other regulatory bodies in establishing pertinent codes, disciplines and guidelines for the appraisal of biohazards and the management of biosafeguards.

H. Coordinate efforts to inform and educate the public on biosafety issues and on proposed national policies..

- Forge ties with foreign biosafety committees and relevant agencies overseas to ensure that genetic manipulation practices in Thailand address international biosafety concerns and observe universal codes of conduct.

In addition to the authorities and functions listed, the NBC recognizes that no authority can foresee all conceivable developments in the domain of genetic engineering and biotechnology and reserves *the right to consult with the BIOTEC, the various biosafety committees,* state authorities and concerned individuals in amending national biosafety policies and pertinent legislation to suit the incipient needs of this discipline.

The NBC shall see to the constitution of Ad Hoc Sub-Committees as necessary to undertake the various tasks concomitant with the extensive responsibilities of the committee.

4.1.2 Responsibilities in Field Research

To ensure that genetic manipulation field work conforms to the regulations circumscribed within these Guidelines, the NBC must address the following charges:

A. Provide advice and assistance to the IBC on the consideration of work falling under sections 2.1.2 and 2.2.2—or, if necessary, on the consideration of other work bearing various levels of risk.

B. Suggest practical alternatives, if any, to high-risk field procedures.

C. Prepare and provide to IBCs, the various notification and assessment forms, biosafety guidelines, related documents and assorted signs for facilities.

D. Alert the various institutions and offices, either state or private, engaged in genetic manipulation field work, to new developments in biosafety so as not to expose laboratory personnel, the community or the environment to undue risks.

E. Coordinate efforts between pertinent state agencies and private organizations to maintain safety levels in genetic manipulation facilities and to prepare for biological emergencies.

- Protect and restrict access to information of commercial significance, not in the public domain, that researchers have provided in project proposals but wish nonetheless to keep private. On the written proposals submitted, researchers will mark such information, "Commercial-In-Confidence."

4.1.3 Endorsement of Proposals

The NBC shall assume the direct responsibility for evaluating and endorsing proposals for work, falling under sections 2.1.2 and 2.2.2 of these Guidelines. The NBC shall likewise be responsible for any later complications in subsequent assessment proceedings, and will provide advice or counsel, as necessary. The supervising IBCs must follow closely all affairs through these initial proceedings and thereupon throughout the conduct of work. The NBC reserves the right to survey and investigate field work at all times, without prior notice.

4.1.4 NBC Contact (postal address)

National Biosafety Committee

National Center for Genetic Engineering and Biotechnology (BIOTEC)

The 5th Floor, National Science and Technology Development Agency Building

Rama VI Road, Rajthevee

Bangkok 10400 THAILAND

Telephone: (066)-2-6448150-4

Facsimile: (066)-2-6448107-8

4.2 The Institutional Biosafety Committee and the Biological Safety Officer

Institutions and organizations, either state or private, engaged, or with the intent to engage, in the purchase, construction, propagation or field release of genetically modified organisms or components must each arrange for the establishment of an Institutional Biosafety Committee (IBC) to serve as the administrative board on matters of biosafety and on compliance with these Guidelines. To grant the IBC freedom to exercise the full extent of its powers in undertaking all of its functions and responsibilities, the parent institutions and organizations must appoint appropriate and capable individuals to the IBC (section 3.2.2) and prepare to support the needs and demands of the committee. In addition to the IBC, institutions and organizations, particularly those engaged in industrial-grade or other large-scale work, are encouraged to recruit a Biological Safety Officer (BSO) to work in conjunction with various biosafety committees.

Small research institutions, which may encounter difficulties in constituting an IBC, may alternatively request non-affiliated IBCs to shoulder the responsibility for monitoring and supervising the biosafety aspects of their work. Agreements of this nature must be formalized between the parties involved and the NBC must be notified of the proceedings. A representative of the smaller institution requesting assistance must maintain close ties with the *now*-affiliated IBC or more desirably, serve as an acting or honorary member of the committee.

4.2.1 NBC Certification

For the IBC to receive formal endorsement from the NBC, the parent institution must submit to the NBC for review a completed notification form, detailing the academic and professional history, faculty and qualifications of each member appointed to the committee. Subsequently, copies of a second form to be completed and submitted may be obtained from the NBC Secretariat detailing operations within the institution. On the latter form, the NBC will specifically request the following information:

(for genetic manipulation field work...)

- IBC membership (indicate Chairperson, Secretary and organizational structure)
- designated Biological Safety Officer, where applicable
- an exhaustive list of current field work projects supported by the institution (indicate the experimental organism field tested and detail results of risk assessment)
- a catalogue of the contingencies and occupational hazards affecting the health of personnel, the community or the environment—reasonably and directly attributed to genetic manipulation practices—through the time of establishment.

If requested information is lacking for any reason, the NBC shall return the applicable documents and forms to the institution for specific amendments. On the other hand, the institution may wish and should feel free to provide additional information which may influence certification and should thus be brought to the NBC's attention.

4.2.2 IBC Composition

With hindsight, these Guidelines are meant, above all, to simply help and provide a framework for institutions, engaged in genetic manipulation work, to consider issues of risk assessment and biosafety. Inasmuch as the intent of these Guidelines should always be respected, the primary responsibility for maintaining various standards and ensuring biosafety rests with the institutions and the researchers concerned, and should never be wholly dependent upon national guidelines or upon the NBC. The IBC, in particular, represents the most integral element in the domain of biosafety—whether the specifics involve supervising genetic manipulation work, attending to the health of personnel, etc.—and therefore should comprise members of high

caliber and considerable experience to assume the functions and responsibilities. In addition, the Chairperson of the IBC should retain a responsible position under the parent institution to ensure the swift adoption of committee recommendations.

To supervise genetic manipulation field work, the IBC shall comprise no less than five members, with the following minimum, recommended composition:

- An individual with the faculties and the resources to evaluate, assess and advise genetic-manipulation work for the institution. Ideally, such an individual should be a respected authority in the particular field of research supported by the institution (e.g. plant genetics, human physiology, virus life-history, etc.)
- An ecologist, specializing in the type of organism to be field tested.
- An engineer with the necessary expertise and practice to examine and assay the integrity of facilities, instruments and tools governing ambient biosafety conditions.
- A Biological Safety Officer, where applicable.
- An individual, not affiliated with the institution, and representing the interests of the community with regards to biotechnology and biosafety.

Recognizing that biosafety issues evoke many disciplines, the IBC should also consider the prospect of establishing working arrangements with individuals—knowledgeable in such areas as law, economics, social work, ethics, community attitudes, and the environment—who can serve as consultants-on-call.

The institution should acknowledge and appreciate the critical role assumed by the supervising IBC and should thus support and grant principal authority on biosafety concerns to the committee—such that the committee may exercise the full extent of its powers in undertaking all of its responsibilities and offer criticism and advice without contest or conflict.

4.2.3 Authorities and Functions

A. Assist researchers in undertaking risk assessment, organizing training programs and generally in harmonizing experimental conditions with national guidelines.

B. Determine additional biosafeguards and draft supplementary operating procedures for work supported by the institution, in line with and addressing the specific risks and concerns uncovered.

C. Evaluate the qualifications of researchers involved in biotechnological projects and assess whether each retains a thorough understanding of good microbiological practices necessary for the supervision of students, assistants and junior personnel.

D. Monitor all regulated work under progress within the institution and counsel the proponents on issues of biosafety and on compliance with national guidelines on a regular basis, or as requested. The IBC should set apart time for researchers and for laboratory and field personnel to approach the committee with questions, disputes or concerns.

E. Where appropriate, bridge the gap between the NBC and the research teams, and serve as a throughway for the flow of information, ideas and opinions between the two parties.

- Maintain and update a directory of all personnel engaged in activities at every biosafety level, and instruct new personnel on the correct laboratory and/or field practices, emergency procedures and equipment operations at the relevant level.
- Attend to the health of laboratory and field personnel regularly or as necessary, considering test results from baseline serum samples and absentee records.

4.2.4 Responsibilities in Field Research

To ensure that genetic manipulation field work within the institution conforms to the regulations circumscribed within these Guidelines, the IBC must address the following charges:

A. Assess all project proposals referred to the committee, and on the basis of the information provided and the risks forecast, determine the conditions of the proposal and whether to endorse the work proposed.

B. Endorse proposals which fall under the conditions of sections 2.1.1 and 2.2.1

C. Give advice to the proponents of field work which fall under the conditions of sections 2.2.1 and 2.2.2

D. Maintain records of approved project proposals for genetic manipulation field work and the committee's assessments thereof.

E. Forward copies of all project proposals submitted for IBC notification, and the committee's assessments thereof, to the NBC for records and information—or for direct endorsement in the case of proposals falling under the conditions of sections 2.2.1 and 2.2.2.

F. Undertake risk assessment, in cooperation with the research teams as necessary, to determine the appropriate containment and biosafety conditions, operating procedures and emergency safeguards for work with 'raw' organisms.

G. Prepare, in conjunction with the research teams, specific contingency plans after undertaking risk assessments and reviewing project proposals.

H. Suggest practical alternatives, if any, to high-risk laboratory procedures.

I. With particular emphasis on work with 'raw' organisms, enforce NBC and committee recommendations, and ensure that NBC and committee comments have been acknowledged and promptly addressed.

J. Visit testing sites from time to time; survey and direct field work regularly, providing advice to project supervisors and responsible officers.

4.2.5 The Biological Safety Officer (BSO)

Institutions and organizations involved in genetic manipulation work should appoint a Biological Safety Officer to the IBC. Alternatively, institutions affiliated with an IBC yet without the services of a BSO may opt to transfer the responsibility of securing a biosafety officer over to the committee. For larger institutions contracting the services of multiple BSOs, the NBC requires that one representative shall be designated and shall serve as the NBC contact or relations officer. BSOs on leave of absence must arrange for competent replacement to take up the forsaken responsibilities.

To meet the objectives of these Guidelines, BSOs should have considerable experience with pertinent biosafety issues and emergency counter-measures. The BSOs are expected to have undergone rigorous

training on biosafeguards in order to participate in the training and instruction of personnel to review (in conjunction with the IBC, and on a regular basis) operating procedures and biosafety records, and to assay the integrity of containment facilities and safety equipment/ utilities.

The BSO and the Chairperson of the IBC shall assume direct advisory positions to the head of the institution on all matters pertaining to risk and biosafety, the health of personnel, contingencies at work and infractions of national guidelines. As with the IBC, the BSO shall set apart time for researchers and for laboratory and field personnel to approach the officer with questions, disputes and concerns.

4.2.6 Personnel Care and Management

Institutions and organizations, contracting personnel for work in genetic engineering and biotechnology must ensure, through the IBC, that all personnel have been instructed on applicable codes of conduct and are conscious of the risks and hazards involved in their line of work. Personnel should receive supplementary training and instruction on laboratory and/or field procedures, emergency safeguards and equipment operation relevant to their line of work from time to time. The IBC, the BSO or the project supervisor may administer tests without prior notice to gauge the faculties and the caliber of each individual. No one shall be allowed to work under high-hazard or high-risk situations unless they have consistently exhibited good microbiological practice and a requisite understanding of operational routines.

Whether or not, and what measure of, health insurance is provided by the institution remains as a matter of deliberation between the labor organizations concerned and the management. Institutions engaged in microbiological genetic research, however, are strongly encouraged to collect and store baseline serum samples from all personnel at risk at regular intervals for future reference—in the event of contingencies whereby individuals are overtly or unduly exposed to regulated material, and fall sick from unusual or unexplained causes. Institutions which do not effect such practices should institute a program immediately, to be supervised by the IBC, especially where work involves toxic, pathogenic or infectious determinants. Provisions for serological monitoring, general health surveillance and medical treatment must be given due consideration.

Personnel with questions and concerns regarding any issue of biosafety or operational routines should feel free to approach the BSO or the Chairperson of the IBC, among other authorities.

4.2.7 Accidents and Emergencies

The IBC, in conjunction with the BSO and appropriate divisions of the institution, shall adopt a system for reporting laboratory accidents, occupational hazards and personnel exposures, through to the emergency procedures observed in dealing with such incidents. Additionally, the IBC or BSO should maintain complete records of any subsequent absenteeism attributed to the contingencies reported. Where deemed necessary, full-fledged investigations should be launched into these matters.

In the event the Chairperson of the IBC believes any incident (e.g. deliberate attempt to circumvent these Guidelines) to be of gravity, solemnity or of the potential for major repercussions to the community or the environment, the Chair should present the deliberations of the committee to both the NBC and the head of the institution. The various authorities may then cooperate on instituting further measures to deal with the problems uncovered, if need be.

4.3 The Project Supervisor

The project supervisor or head researcher should possess requisite thorough understanding of the codes, regulations and laws applicable to genetic engineering and biotechnological work and exhibit an appreciation for the biosafety concerns that underlie the need for such provisions.

As the officer-in-charge, much of the responsibility of the project supervisor rests in the initial stages of originating proposals and obtaining IBC approbation, where necessary. For genetic manipulation field work, the project supervisor should assess the nature of the research and determine whether the work proposed falls within the scope of these Guidelines. Uncertainty and doubt should be addressed by submitting a detailed proposal of the experimental conditions to the IBC for endorsement or clearance before any work is under way. If work is indeed regulated under these Guidelines, the project supervisor must submit a completed project proposal form (including requests for exempt status) to the supervising IBC for consideration and recommendation, and inform the committee of any notable intents (e.g.

plans to import regulated material). Field work may begin after authorization from the IBC or from the NBC (depending on whether conditions of proposed work are consistent with sections 2.1.1/2.2.1 or 2.1.2/2.2.2). As directed by the IBC, the project supervisor may be required, from time to time, to provide additional details of the research for the various evaluation and monitoring activities of the committee.

The project supervisor should sincerely enforce the provisions and adhere to the intent of these Guidelines through the duration of research work, with special emphasis on the following charges:

A. Submit new project proposals to the IBC for consideration and recommendation before adopting radical operating procedures or substantially amending any parameter of the work (especially approaches to physical and biological containment) which may introduce novel risks, delimit new biosafety levels or warrant change of classification.

B. Establish and maintain working conditions appropriate to the level of biosafety as approved and advised by the NBC and the IBC.

C. Ensure that students, junior personnel, co-investigators and other persons entering controlled areas realize the nature and degree of the risks involved and have been properly instructed on applicable codes of conduct.

D. Liaise closely with the IBC and BSO in carrying out various tests and safety audits, for instance, inspections of containment equipment and personnel examinations.

E. Report all personnel developments, including extended absenteeism, replacements and unusual illnesses, to the IBC.

- Relay to the IBC, details of all contingencies and the emergency procedures instigated to deal with such incidents.

Chapter 5 Movement of Regulated Material

5.1 Movement of Regulated Material Within or Between Institutions

Extreme care must always be observed in moving regulated material within and between institutions. Genetically modified material* must be transported in securely-sealed, double-containment units, each comprising a primary container for holding the organism(s) or culture/preparation, enclosed in a durable, shock-absorbing secondary container which may be readily decontaminated. These units should ideally be placed within sturdy outer shipping containers—soundly packaged and appropriately labeled and addressed to facilitate inspection, to allow for swift delivery to the intended destination and to ensure that relevant authorities are contacted in case of emergencies. Movement of wastes and by-products from genetic engineering practices require comparable packaging and container specifications.

5.1.1 Transport of genetically modified microorganisms

The essential restriction on the transport of viable genetically modified microorganisms allows for only those arrangements which ensure that transgenic species in transit will not be harmful to the community or the environment if the packaging or container integrity becomes compromised *en route*. Species recognized as benign to humans and the environment may be transported within basic packaging and container requirements. Microorganisms, pathogenic, infectious or hazardous to the environment in one way or another, shall only be moved provided that the mode of transport offers exceptional and suitable decontamination features.

5.1.2 Transport of transgenic plants and animals

The transport of transgenic plants and animals should be supervised by an ecologist or biologist skilled and with considerable experience, in handling transgenic species and in initiating population control programs in the event of unforeseen contingencies. Stringent and selective containment must be adopted as necessary—taking into

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* including, transgenic plant and animal materials (e.g. cuttings, seeds, eggs, tissue samples)

account, to the greatest extent possible, various contingencies which may be encountered—so as to minimize the potential for escape and to prevent transgenic species from interbreeding freely with and becoming established in wild populations. Proper arrangements should be made to identify and account for individual animals, plants or containers in transit.

As to the transport of transgenic plants, it is recommended that whole plants be netted and deflowered beforehand and that plants which have set seed not be moved.

5.1.3 IBC Arrangements

The IBC may impose additional security precautions as it sees fit, to address the specific risks and concerns of any transport at hand. Furthermore, the IBC may feel obligated to personally survey and inspect the preparations for transport of transgenic species, to ascertain whether standard requirements and additional precautions, if any, are being attended to.

5.2 Distribution and Receipt of Genetically Manipulated Material

Researchers distributing genetically manipulated material to scientists and institutions, local or abroad, must provide recipients with reviews of the physico-chemical and biological containment measures, safety precautions and any special guidelines for work involving the material circulated. Researchers should also detail the origin of regulated material distributed, to serve as terms of reference for each recipient. In the event of a local beneficiary without previous links to, or background in genetic engineering and biotechnology, the distributor has a further responsibility to ensure that the recipient is made aware of the national guidelines regulating work in this discipline.

Distribution and receipt of genetically manipulated material must be reported beforehand to the appropriate director of the institution for legal purposes.

5.3 Import and Export

Individuals who wish to import viable microorganisms, plants or animals, genetically modified or constructed, must proceed in accordance with the relevant guidelines presented herein and are

strongly encouraged to consult with the IBC regarding the specifics of their intent. Import of live or whole organisms of another nature is regulated directly by the various orders and enactments presented under Appendix 4.

On the other hand, international postage or export of regulated material must strictly comply with the revised provisions and requirements of *The Non-Infectious* and *The Infectious Perishable Biological Substances Services* as agreed to by the International Postal Union (IPU).

Import and export of pathogens must observe the terms of the *Diseases and Animal Toxins Act of 1982*.

Import of transgenic plants of any form must observe the terms of the Plant Quarantine Act 1964 and its additional Ministerial Declaration.

Chapter 6 Sanctions

Scientists who, and institutions which, fail to enforce the provisions or adhere to the intent of these Guidelines may be penalized by the withdrawal of applicable or all government research grants. In addition, non-compliance on the part of private organizations awarded special incentives (e.g. funding from the government or tax incentives) for contributing to biotechnological research and development may result in the withdrawal of said privileges.

Scientists and institutions can be held accountable for all the evident consequences (accidents, medical emergencies and disturbances to the community or the environment) of their failure or neglect to comply with the terms and principles of national biosafety guidelines.

The National Biosafety Committee shall update and inform the Prime Minister on all issues pertaining to the violations of these Guidelines. The Prime Minister reserves the authority to issue public statements on any such issues of infraction, deliberate or otherwise.

Appendix 1

References and Some Related Documents

(for recommended/supplementary reading...)

1. Good Development Practices for Small Scale Field Research with Genetically Modified Plants and Microorganisms: A Discussion Document. 1990. Organisation for Economic Co-Operation and Development (OECD).
2. Safety Considerations for Biotechnology: Scale-Up of Crop Plants. 1993. Group of National Experts on Safety in Biotechnology. OECD.
3. Guidelines for the Release into the Environment of Genetically Modified Organisms. 1991. Inter-American Institute for Cooperation on Agriculture (IICA):
4. An International Approach to Biotechnology Safety. 1990. United Nations Industrial Development Organization (UNIDO).
5. Available List of Authoritative Statutes and Guidelines: Draft of a Voluntary International Code of Conduct for the Release of Organisms into the Environment. 1991. UNIDO.
6. Field Testing Genetically Modified Organisms: Framework for Decision. 1989. National Research Council (NRC), USA.
7. Economidis I. Biotechnology Research and Development in the European Community: Risk Assessment. 1990. (Commission of the European Communities)
8. Miller, H. *et al.* "Risk-Based Oversight of Experiments in the Environment," *Science*. 1990. 250: 480-491.

Appendix 2 Framework of the Project Proposal Form

Project proposal forms may be obtained from the NBC Secretariat at the following contact (postal address):

National Biosafety Committee
National Center for Genetic Engineering and Biotechnology (BIOTEC)
The 5th Floor, National Science and Technology Development Agency Building
Rama VI Road, Rajthevee
Bangkok 10400 THAILAND
Telephone: (066)-2-6448150-4
Facsimile: (066)-2-6448107-8

The *Project Proposal Form for Assessment of Genetic Manipulation Field Work* (along with all attachments and supplements) will serve as the principal source of reference for the IBC and the NBC in the initial consideration and approbation of research work regulated under these Guidelines. On the basis of information provided in, and of risks/concerns that may be inferred from these proposals, the IBC shall classify research work and determine additional biosafety measures to be adopted/implemented as necessary, including site relocation and procedural amendments. Proposals shall also be reviewed by the NBC, and whatever details provided will constitute the framework for NBC assessment and recommendations. The NBC shall assume direct responsibility for endorsing project proposals, falling under sections 2.1.2 and 2.2.2 of these Guidelines.

Recognizing that IBC and NBC activities, in these initial stages of genetic manipulation practice depend on the written forms submitted, researchers should be thorough yet concise and clear as to their intentions, so that the committees may readily and fully understand the nature of proposed work. All important details should be included and as many additional sheets/pages may be attached as necessary. Notable and exceptional intent should be stressed, ideally in the title or under the objectives. Particular care must be observed regarding phrasing—approval will be restricted to the *specific* experimental procedures and biological system components identified so descriptions should be broad enough (though *never vague*) for the purposes of the research.

Project Proposal Form for Assessment of Genetic Manipulation Field Work

Section A - Authorities and Outlook

1. Name and Institutional Address of Project Supervisor submitting proposal
2. Names of other Supervisors, Co-Investigators or Program/Section Leaders
    - Indicate institutional addresses where different from (1).
3. Affiliations
    - Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.
4. Project Title
5. Project Objectives
6. Anticipated Future Release and/or End Use

Section B - Materials and Methods

7. Site of Field Work
    - Specify the location of trial and how plots are to be arranged on site.
    - Provide details of the physical environment and ecology.
    - Identify the facilities available on site.
    - Give reasons for the choice of location.
8. Scale of Field Work
    - Indicate the approximate number of organisms involved and the size of test plots.
9. Methodology and Protocol
    - Provide thorough yet concise descriptions of the main experimental procedures.
    - Indicate the developmental stages involved, and identify the control, test and challenge groups.
    - Include a timetable of activities.

10. Precautions and Safeguards

(please describe in full)

- Measures for containment of test plots and experimental organisms
- Arrangements for the disposal of experimental organisms, and for the clean up of organic residues, at the completion of work
- Contingency plans

11. Results from Laboratory Tests of the Biological System

11.1 Characterization of Genetic Modification

- Stability of Introduced Genetic Traits
- Heredity of Genetic Inserts
- Level of expression and regulation of transgenes
- Traces of recombinant vectors in the final construct (where applicable)

11.2 Effects of Genetic Modification

- Changes in Phenotype and Novel Physiological Traits

11.3 Evolutionary Potential

- Competitive or Selective Advantage, conferred by genetic modification
- Potential for Mutation and/or Adaptation to field conditions

11.4 Noxious or Harmful Characteristics

- Nature of the Harmful Agent
- Known and/or Likely Modes of Transmission

11.5 Ecological Context (Auto-Ecology)

- Viability in Open Environments
- Known predators and parasites
- Natural Crossing Possibilities to Related Species
- Propensity for Transfer of Genetic Inserts

12. History of Prior Field Work

(with the experimental organism(s) or with related biological systems)

13. Assessed Course of Work

- Anticipated direct, and indirect ecological effects
- Possible secondary genetic effects

14. Intended Date of Commencement; Expected Date of Completion

Section C - Personnel Involved with Research Work Proposed

15. Details of Personnel
    - Name, Qualifications and Experience
    - Responsibilities and Duties
    - Medical History
16. Signature (of Project Supervisor) and Date

Instructions for Completion of the *Project Proposal Form for Assessment of Genetic Manipulation Field Work*

The project supervisor must submit two typed, completed project proposal forms to the supervising IBC (one of which shall be forwarded to the NBC for information) and should retain a copy for records and reference. For work supported by two or more institutions, all IBCs of authority must be notified.

Project proposal forms must be signed and dated by the project supervisor to be received by the IBC and the NBC. For research work employing multiple project supervisors or head researchers, the name and professional address of the supervisor preparing and submitting the proposal should be indicated under heading (1). Said individual shall sign and date both proposals before submission to the IBC of authority.

As many additional sheets/pages may be attached as necessary. Incomplete proposals will delay IBC endorsement as further information is sought.

Important Directive

Researchers must procure a copy of the corresponding *Project Proposal Form for Assessment of Laboratory Genetic Manipulation Work*, which precedes the initial genetic engineering of this biological system to be field tested. Attach this form to the back page of the *Project Proposal Form for Assessment of Genetic Manipulation Field Work* before submission to the responsible IBC. Some information on the latter form is critical to IBC and NBC assessment.

Commercial-In-Confidence

Researchers who wish to restrict access to information of commercial significance (e.g. trade secrets or confidential business reports) provided to the IBC and NBC in project proposals, should mark the relevant material or portions "Commercial-In-Confidence."

Appendix 3

Framework of the IBC Assessment Form

The *IBC Form for Assessment of a Proposal to carry out Genetic Manipulation Field Work* serves, above all, to guide the Institutional Biosafety Committees in the consideration and evaluation of project proposals. These forms are meant to provide a framework for IBCs in assessing the experimental parameters of proposed research—leading up to the decision on whether to endorse the work at hand and culminating in the preparation of amendments and provisions to be adopted as necessary. The IBCs must be clear in their evaluation of each component of the experimental system identified in the assessment form. Additionally, the committees should be thoughtful and thorough in drafting the various amendments and provisions to ensure an acceptable standard of biosafety for field work under consideration. Special attention should be paid to determine which issues require direct NBC endorsement. Completed IBC assessments shall be submitted to the NBC, together with corresponding project proposals, and the efforts of the committee, will assist the NBC in reviewing the work proposed, as required.

Institutional Biosafety Committee

Form for Assessment of a Proposal to carry out Genetic Manipulation Field Work

Section A - IBC Assessment of Project Proposal

1. Name and Institutional Address of Project Supervisor who submitted the proposal
2. Affiliations
    - Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.
3. Project Title
4. Experimental Parameters
    - Indicate whether approved, not approved or inconclusive (insufficient information provided); and
    - Include a concise explanation for IBC's position on each of the following.

    4.1 Project Objective and Methodology

    4.2 Biological System

    4.3 Site or Location of Trial

    4.4 Timing and Period of Work

    4.5 Safeguards and Contingency Plans

    4.6 Details of Personnel

    - Experience and Expertise
    - Training and Instruction
    - Health
    - Other (please specify)

Section B - Results of Assessment and IBC Recommendations (where applicable)

5. Experimental Plants are recognized as

    [ ] 5.1 ...genetically modified species with a history of safe use in field work.

    (let work proceed in accord with the standards appropriate to the particular plant, and as has been)

[ ] 5.2 ...not falling under condition 5.1, precedent.

(let work proceed under the advice or counsel of the IBC and NBC)

(where applicable)

6. Experimental Microorganisms are recognized as

[ ] 6.1 ...genetically modified species with a history of safe use in field work.

(let work proceed in accord with the standards appropriate to the particular microorganism, and as has been)

[ ] 6.2 ...not falling under condition 6.1, precedent.

(let work proceed under the advice or counsel of the IBC and NBC)

7. The project proposal form attached has been reviewed by the IBC and as assessed above, the committee

[ ] *endorses* the research work proposed (results of assessment are found to be consistent with conditions 5.1 or 6.1, precedent).

[ ] *does not endorse* the research work proposed (direct NBC endorsement is sought and required).

8. The following special provisions must be adopted and implemented in conjunction with the BIOTEC *Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release*, 1993 during the conduct of research work.

9. Signature (of IBC Chairperson) and date

Section C - NBC Assessment of Project Proposal

10. The project proposal form attached has been reviewed by the NBC and as assessed above, the committee

[ ] *endorses* the research work proposed, unconditionally.

[ ] *endorses* the research work proposed, on the following conditions:

[ ] *does not endorse* the research work proposed, for the following reasons:

11. Signature (of NBC Chairperson) and Date

Instructions for Completion of the *IBC Form for Assessment of a Proposal to carry out Genetic Manipulation Field Work*

The IBC must submit a typed, completed assessment form to the NBC, attached to the corresponding project proposal, and should retain a copy for records and reference. Assessment forms must be signed and dated by the IBC Chairperson to be received by the NBC. Where appropriate, IBC advice and copies of the completed assessment form should be sent to those regulatory agencies duly constituted to manage the planned release of genetically modified organisms, or with the legal responsibility to approve the end use of such organisms.

A clear and concise explanation is required for the IBC's position on each of the experimental parameters identified in the assessment form. The NBC shall expect some justification on IBC decisions to approve or not to approve of the various components of the experimental system proposed. Where inconclusive, the IBC must indicate what information is lacking. As appropriate, references should be made to the relevant sections of the NBC *Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release*, 1993.

Details of personnel need to be checked by the IBC but the relevant attachments should not be forwarded to the NBC.

Some Specific Provisions

Proposals for work consistent with conditions 5.1 or 6.1 (of the IBC assessment form)

The IBCs may authorize or commission research work immediately, upon endorsement of the project proposals. Measures for the control and containment of field work shall observe the rudimentary standards, in current or past practice, as appropriate to the particular organism under investigation. IBC assessments should be attached to the top sheet of the corresponding project proposals and submitted to the NBC for information.

Proposals for work which fall outside conditions 5.1 and 6.1

IBC assessments should be attached to the top sheet of the corresponding project proposals and submitted to the NBC at the earliest possible. The NBC shall assume direct responsibility for endorsing such proposals, and for preparing any terms of approval, additional to IBC recommendations. Measures for the control and containment of field work must comply with NBC and IBC advice/instruction and with the relevant criteria presented in Chapter 3 of the *Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release*.

Appendix 4 Statutes on the Import of Whole Organisms

1. Infectious/Communicable Diseases Act, 1990
2. Order of the Department of Livestock Development, § 161/2531 (1988),
   Re: Movement of Animals and Animal Carcasses within the Kingdom
3. Diseases and Animal Toxins Act, 1982
4. Plant Quarantine Act, 1964

Appendix 5 Constitution of the National Biosafety Committee

Order of the National Science and Technology Development Council

§ 4/2538 (1995)

Re: Constituting the National Biosafety Committee

Following the 2nd deliberation of the National Science and Technology Development Council for the year 1995, on March 8, 1995 (the meeting of 2/2538), a resolution was in favor, passed for the constitution of a National Biosafety Committee; as such

To actualize the above resolution, by virtue of the powers vested in the council under clause 10 of the Science and Technology Development Act of 1992, the National Science and Technology Development Council does hereby order the constitution of the National Biosafety Committee, consisting of the following individuals:

Membership:

1.	Bunpot Napompeth	Chairman
2.	Sutat Sriwatanapongse	Deputy Chairman
3.	Sakol Panyim	Member
4.	Sakarindr Bhumiratana	Member
5.	Jinda Jan-Orn	Member
6.	Pichit Tosukhowong	Member
7.	Supat Attathom	Member
8.	Patanan Sangkatawat	Member
9.	Wichai Kositaratana	Member
10.	Skorn Mongkolsuk	Member
11.	Poonsook Atthasampunna	Member
12.	Representative from Office of Environmental Policy and Planning	Ex officio member
13.	Director of Food Control Division, The Food and Drug Administration or Representative	Ex officio member
14.	Director of Agricultural Regulatory Division, Department of Agriculture or Representative	Ex officio member

15.	Director of Biological Products Division, Department of Medical Sciences or Representative	Ex officio member
16.	Director of Disease Control Division, Department of Livestock Development or Representative	Ex officio member
17.	Deputy Director of the National Center for Genetic Engineering and Biotechnology	Ex officio member and Secretary
18.	An officer of the National Center for Genetic Engineering and Biotechnology	Ex officio member and Assistant to Secretary
19.	An officer of the National Center for Genetic Engineering and Biotechnology	Ex officio member and Assistant to Secretary

The National Biosafety Committee shall have the following authorities and functions:

A. Ensure that ambient conditions surrounding genetic manipulation work reflect and adhere to the specifications of national guidelines for the safety of personnel, the community and the environment exposed to the risks borne by the study.

B. Cooperate with the Customs Department and with other relevant state authorities overseeing the import of live organisms to formulate guidelines for the identification, inspection and regulation of transgenic species, exotic and otherwise.

C. Review and direct the bearings of research methodologies in genetic engineering.

D. Identify, characterize and assess the hazards associated with innovative genetic manipulation techniques or research for which the risks are as yet uncertain.

E. Warn the authorities and individuals who are involved with, or who may be afflicted by genetic manipulation experiments, of potential hazards throughout the conduct of work.

F. Recommend, instruct and lend specialist technical expertise to various research institutions and regulatory agencies in

setting up appropriate experimental conditions for work with specific regulated material.

G. Facilitate all levels of supervision of genetic manipulation work by establishing, and assisting other regulatory bodies in establishing pertinent codes, disciplines and guidelines for the appraisal of biohazards and the management of biosafeguards.

H. Coordinate efforts to inform and educate the public on biosafety issues and on proposed national policies.

I. Forge ties with foreign biosafety committees and relevant agencies overseas to ensure that genetic manipulation practices in Thailand address international biosafety concerns and observe universal codes of conduct.

The Term of the membership is two years.

All told, to be effected henceforth and cancel the Order of the National Science and Technology Development Council § 1/2536 (1993), dated 22 January 1993 of Constituting the National Biosafety Committee.

Done on the 23rd of March, 1995

(Mr. Suwaj Liptapallop)

Minister of Science, Technology and Environment; and
Chairperson of the National Science and Technology Development Council

Order of the National Science and Technology Development Council

§ 1/2536 (1993)

Re: Constituting the National Biosafety Committee

Following the 9th deliberation of the National Science and Technology Development Council for the year 1992, on December 9, 1992 (the meeting of 9/2535), a resolution was in favor, passed for the constitution of a National Biosafety Committee; as such

To actualize the above resolution, by virtue of the powers vested in the council under clause 10 of the Science and Technology Development Act of 1992, the National Science and Technology Development Council does hereby order the constitution of the National Biosafety Committee, consisting of the following individuals:

Membership:

1.	Bunpot Napompeth	Chairman
2.	Poonsook Atthasampunna	Member
3.	Sakol Panyim	Member
4.	Jinda Jan-Orn	Member
5.	Pichit Tosukhowong	Member
6.	Supat Attathom	Member
7.	Patanan Sangkatawat	Member
8.	Wilai Noonpakdee	Member
9.	Skorn Mongkolsuk	Member
10.	Representative from Office of Environmental Policy and Planning	Member
11.	Director of Food Control Division, The Food and Drug Administration or Representative	Member
12.	Director of Agricultural Regulatory Division, Department of Agriculture	Member
13.	Director of Biological Products Division, Department of Medical Sciences	Member
14.	Director of Disease Control Division, Department of Livestock Development	Member

15. Director of the National Center for Genetic Engineering and Biotechnology	Ex officio member and Secretary
16. Deputy Director of the National Center for Genetic Engineering and Biotechnology	Ex officio member and Assistant to Secretary

The National Biosafety Committee shall have the following authorities and functions:

A. Ensure that ambient conditions surrounding genetic manipulation work reflect and adhere to the specifications of national guidelines for the safety of personnel, the community and the environment exposed to the risks borne by the study.

B. Cooperate with the Customs Department and with other relevant state authorities overseeing the import of live organisms to formulate guidelines for the identification, inspection and regulation of transgenic species, exotic and otherwise.

C. Review and direct the bearings of research methodologies in genetic engineering.

D. Identify, characterize and assess the hazards associated with innovative genetic manipulation techniques or research for which the risks are as yet uncertain.

E. Warn the authorities and individuals who are involved with, or who may be afflicted by genetic manipulation experiments, of potential hazards throughout the conduct of work.

F. Recommend, instruct and lend specialist technical expertise to various research institutions and regulatory agencies in setting up appropriate experimental conditions for work with specific regulated material.

G. Facilitate all levels of supervision of genetic manipulation work by establishing, and assisting other regulatory bodies in establishing pertinent codes, disciplines and guidelines for the appraisal of biohazards and the management of biosafeguards.

H. Coordinate efforts to inform and educate the public on biosafety issues and on proposed national policies.

I. Forge ties with foreign biosafety committees and relevant agencies overseas to ensure that genetic manipulation practices in Thailand address international biosafety concerns and observe universal codes of conduct.

All told, to be effected henceforth.

Done on the 22nd of January, 1993

(Mr. Phisan Moonlasartsathorn)

Minister of Science, Technology
and Environment; and
Chairperson of the National Science and
Technology Development Council

Appendix 6 Constitution of the Ad Hoc Biosafety Sub-Committee

Order of the National Science and Technology Development Council

§ 13/2535 (1992)

Re: Constituting the Ad Hoc Biosafety Sub-Committee

Following the 5th deliberation of the National Science and Technology Development Council for the year 1992, on April 9, 1992 (the meeting of 5/2535), a resolution was in favor, passed for the constitution of an Ad Hoc Biosafety Sub-Committee; as such

To actualize the above resolution, by virtue of the powers vested in the council under clause 10 of the Science and Technology Development Act of 1992, the National Science and Technology Development Council does hereby order the constitution of the Ad Hoc Biosafety Sub-Committee, consisting of the following individuals:

Membership:

1.	Bunpot Napompeth	Chairman
2.	Sakarindr Bhumiratana	Vice chairman
3.	Pornchai Matangkasombut	Advisor
4.	Poonsook Atthasampunna	Member
5.	Sakol Panyim	Member
6.	Jinda Jan-Orn	Member
7.	Sonthi Vannasaeng	Member
8.	Pichit Tosukhowong	Member
9.	Supat Attathom	Member
10.	Patanan Sangkatawat	Member
11.	Wilai Noonpakdee	Member
12.	An officer of the National Center for Genetic Engineering and Biotechnology	Ex officio member and Secretary
13.	An officer of the National Center for Genetic Engineering and Biotechnology	Ex officio member and Assistant Secretary

All told, to be effected henceforth.

Done on the 10th of April, 1992

(Mr. Sanga Sabhasri)

Minister of Science, Technology
and Environment; and
Chairperson of the National Science and
Technology Development Council

Glossary

Aerosol	Suspension in air of finely dispersed solids or liquids.
Amphotropic retrovirus	A retrovirus that will grow in the cells from which it was isolated and also in cells from a wide range of other species.
Autoclave	A device in which materials are sterilized using steam under high pressure.
Biological safety cabinet, biosafety cabinet	Specially constructed cabinets that are designed to protect workers and the environment from dangerous agents, especially bacteria and viruses.
Cell	The smallest structural unit of living organisms that is able to grow and reproduce independently.
Chromosome	A structure in the cell, consisting of DNA and proteins, that carries the organism's genes.
Clone	As a noun: a group of genes, cells, or organisms derived from a common ancestor and genetically identical. As a verb: to generate replicas of DNA sequences or whole cells using genetic manipulation techniques.
Conjugative plasmid	A plasmid that codes for its own transfer between bacterial cells by the process of conjugation (mating).
Construct	As a noun: genetically manipulated DNA.
Containment	Prevention of the spread of genetically manipulated organisms outside the laboratory. Physical containment is accomplished by the use of special procedures and facilities. Biological containment is accomplished by the use of particular strains of the organism that have a reduced ability to survive or reproduce in the open environment.

Containment level	The degree of physical containment provided by a laboratory, which depends on the design of the facility, the equipment installed, and the procedures used. Physical containment levels are numbered from one to three, three being the highest level.
Decontamination	Physical or chemical process that kills or removes unwanted infectious agent (does not necessarily result in sterility).
DNA	Deoxyribonucleic acid, the molecule that carries the genetic information for most organisms; consists of four bases and a sugarphosphate backbone.
Donor	The organism or cell from which DNA is derived for insertion into another organism (the host).
Ecotropic retrovirus	A retrovirus that will grow in cells of the species from which it was isolated, but to a very limited or undetectable level in cells of other species.
Effluent	Liquid (or gaseous) industrial waste.
Embryo-rescue	The process in plant breeding whereby tissue from young embryo plants is excised and propagated in vitro for subsequent growth as differentiated plants.
Escherichia coli (E. coli)	A bacterium that inhabits the intestinal tract of humans and other animals.
Escherichia coli K12	A strain of E. coli that has been maintained in culture in laboratories for many years. It has lost the ability to colonized the intestinal tract of humans and animals, is well-characterized genetically, and is often used for molecular cloning work.
Eukaryotic	Belonging to the group of organisms whose cells contain a true nucleus. Eukaryotic organisms include animals, plants, and fungi.

Expression	Manifestation of a characteristic that is specified by a gene: often used to mean the production of a protein by a gene that has been inserted into a host organism.
Fusion	Joining of the cell membranes of two cells to create a daughter cell that contains the genetic material from both parent cells.
Gamete	A reproductive (egg or sperm) cell.
Gene	A hereditary unit of nucleic acid that specifies the structure of a protein or RNA molecule.
Gene therapy	The replacement of a defective gene in a person or other animal suffering from a genetic disease.
Genetic engineering	See **genetic manipulation.**
Genetic manipulation	A technology used to alter the genetic material of living cells or organisms in order to make them capable of producing new substances or performing new functions.
Genome	The total genetic complement of a given organism.
Growth factor	A protein that stimulates cell division when it binds to its specific cell-surface receptor.
GMAC	Genetic Manipulation Advisory Committee.
Helper virus	A virus that, when used to infect cells already infected by a defective virus, enables the latter to multiply by supplying something the defective virus lacks.
HEPA filter	High efficiency particulate air filter with trapping efficiency greater than 99.99 percent for particles of 0.3 micrometers in diameter.
HIV	Human immunodeficiency virus (a retrovirus).

Host	A cell or organism into which foreign DNA is introduced to enable production of proteins or further quantities of the DNA.
Host range	For a virus, the range of species that can be infected by that virus.
Host-vector system	Combination of host and the vector used for introducing foreign DNA into the host.
Hybridoma	A hybrid cell used in production of monoclonal antibodies that is produced by fusing an antibody-producing cell (B lymphocyte) with a tumor cell.
Infectious	Capable of invading a susceptible host, multiplying in it, and causing an altered host reaction ('disease')
in vitro	Literally in glass; performed in a test tube or other laboratory apparatus.
in vivo	In a living organism.
IBC	Institutional Biosafety Committee.
LD50	The dose of a toxin or infectious agent that will kill half of a population of organisms.
Microorganism	An organism that can be seen only with the aid of a microscope.
Monoclonal antibody	An antibody that is derived from a single clone of hybridoma cell and recognizes only one antigenic site.
Oncogene	An activated (modified) cellular gene that causes normal cells to become cancerous.
Oocyte	A cell that divides to form the female reproductive cell.
Packaging	In the process of virus replication, the assembly of the components of the virus to form the complete virus particle.
Pathogen	An organism that causes disease.
Phenotype	The observable properties of an organism as distinguished from its genetic makeup (the genotype)

Physical containment level (PC)	The degree of physical containment provided by a laboratory, which depends on the design of the facility, the equipment installed, and the procedures used. GMAC physical containment levels for large scale facilities are numbered PC2-LS to PC4-LS, corresponding to the Australian Standard for Safety in Laboratories, Part 3: Microbiology (AS 2243.3-1994) and indicating increasing levels of risk for work with particular groups of microorganisms.
Planned release	Intentional release of a genetically modified organism into the open environment.
Plasmid	A small, self-replicating molecule of DNA that contains a specific origin of replication. Plasmids are often used as cloning vectors.
Promoter	A DNA sequence, located in front of a gene, that controls expression of the gene. It is the sequence to which RNA polymerase binds to initiate transcription.
Protein	A molecule composed of amino acids.
Protoplast	A plant or bacterial cell that has had the outer cell wall removed.
Receptor	Cell-surface protein to which molecules, such as hormones and growth factors, bind to exert their effects on the cell, or to which viruses bind to gain entry to the cell.
Recombinant	Organisms, cell, viruses, and the like that contain recombinant DNA.
Recombinant DNA	DNA formed by joining in vitro segments of DNA from different organisms.
Recombination	The occurrence or production of progeny with combinations of genes other than those that occurred in the parents.
Replication	Reproduction.

Retroviral vector	A retrovirus that is used to introduce foreign DNA into animal cells, usually by replacing part of the viral genome with the foreign DNA of interest.
Retrovirus	A virus that uses the enzyme reverse transcriptase to copy its RNA genome into DNA, which then integrates into the host cell genome.
RNA	Ribonucleic acid, a molecule similar to DNA whose function include decoding the instructions for protein synthesis that are carried by the genes; comprises the genetic material of some viruses.
Somatic cell	Any cell of a multicellular organism other than germline cells.
Sterilization	Act or process that kills or removes all infectious agents; applied particularly to bacteria and molds, their spores, and viruses.
Tissue culture	In vitro growth of tissue cells in nutrient medium.
Toxin	A poisonous substance, produced mainly by microorganisms but also by some fungi, plants, and animals.
Transgenic (organism)	An organism whose cells, including the germline cells, contain foreign DNA; transgenic animals are produced by the insertion of the foreign DNA into the newly fertilized egg or embryo.
Vector	A self-replicating agent (for example, a plasmid or virus) used to transfer foreign DNA into a host cell.
Viroid	A disease-causing agent of plants that is smaller than a virus and consists of a naked RNA molecule.
Virulence	Ability of an organism to cause disease.

Virus	A submicroscopic infectious particle, containing genetic material (DNA or RNA) and protein, which can replicate only within the cell of an organism (plant, animal, or bacteria).
Xenotropic retrovirus	A retrovirus that is endogenous to a species but cannot replicate well in that species, generally because of a receptor back. Xenotropic retroviruses tend to have a wide range for replication in cell of heterologous species.
Zygote	The cell produced by the union of the male and female gametes.

ISBN 974-7575-94-9

National Center for Genetic Engineering and Biotechnology
National Science and Technology Development Agency
539/2 Gypsum Metropolitan Tower, 15 th Floor
Sri-Ayudhya Road, Bangkok 10400 THAILAND
Phone (66 2) 642 5322 TO 31 Fax (66 2) 248 8303