

GUIDELINES ON PLANNED RELEASE OF GENETICALLY MANIPULATED ORGANISMS (GMOS) AND POTENTIALLY HARMFUL EXOTIC SPECIES (PHES)

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SECTION 1. Definition Of Terms

For purposes of this monograph, the following terms shall be defined as follows:

1.1 "Animal" means any living stage or form of any member of the animal kingdom. This includes all terrestrial, aquatic and subterranean macroscopic vertebrates and invertebrates, whether parasitic or free-living, and sessile or motile.

1.2 "Biotechnology" means any process that uses living organisms, in their entirety, or parts or subparts thereof, to make or modify products or to improve or develop plants, animals or microorganisms for specific use.

1.3 "Environment" means an ecosystem or habitat that is likely to come into contact with the GMO or PHES to be released.

1.4 "Exotic" means any living organism that is not native to the Philippines or to the region(s) where the planned release shall be made.

1.5 "Fusion" means the joining of the cell membranes of two cells to create a daughter cell that contains genetic material from both parents.

1.6 "GMO" means a genetically-modified organism. These are living organisms whose genetic material has been altered or modified by any of the varieties of techniques of modern molecular biology to make them capable of producing new substances or perform new functions.

1.7 "Host" means an organism whose genetic material has been altered by modification of a part of its own genetic material by the insertion of foreign genetic material or both.

1.8 "Microorganism" means any microscopic or ultramicroscopic organism able to replicate its own genetic material. This includes bacteria, fungi and viruses.

1.9 "New species" means a single distinct kind of animal, plant or microorganism having certain previously underscribed but distinguishing characteristics as determined by taxonomical classification.

1.10 "Organism" means any entity able to replicate its own genetic material.

1.11 "Pathogen" means any organism that can cause disease.

1.12 "Plant" means any living stage or form of any member of the plant kingdom, including aquatic, terrestrial or subterranean eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, lichens which contain algae, and any part (e.g., pollen, seeds, cells, tubers, stems) thereof.

1.13 "Pest" means any living stage, whether in active or dormant form, of insects, mites, nematodes, slugs,

annelids, snails, protozoa, bacteria, fungi and other parasitic plants or reproductive parts thereof; viruses; any plants or animals that can damage aquatic and terrestrial ecosystems; or any infectious agents or substances which can directly or indirectly injure or cause disease or damage in or to humans, plants or animals or any processed, manufactured or other products of plants or animals.

1.14 "Plasmid" means a self-replicating, circular, extra-chromosomal DNA molecule.

1.15 "PHES" means potentially harmful exotic species. This refers to any exotic species which may constitute negative risks to human health and environment.

1.16 "Protoplast" means a plant or bacteris cell that has its outer cell removed.

1.17 "Proponent" means any person or group of persons who submits a project proposal to the Institutional Biosafety Committee, the National Committee on Biosafety of the Philippines, or both, for the purpose of conducting a planned release of a GMO or PHES into the environment.

1.18 "Project Leader" means any person who, under the project proposal, shall be primarily responsible for the implementation of the planned release activities.

1.19 "Region" means a political unit or administrative entity designated to a certain place of the country.

1.20 "Risk" means the combination of the likelihood that the adverse consequence of a biohazardous activity will occur and the magnitude and probabilities of the adverse effects.

1.21 "Risk Assessment" means the process of identifying hazards to human health and the environment that may caused by any planned release activity, including the process of assigning magnitudes and probabilities of the adverse effects.

1.22 "Risk Management" means the measures designed to ensure safety in the handling, use and release of GMOs or PHES.

1.23 "Transgenic" means an organism whose cells, including the germline cells, contain foreign DNA. In the case of animals, it refers to one produced by inserting a foreign DNA into the newly fertilized egg or embryo.

1.24 "Vector" means an organism or molecular vehicle used to transfer genetic material from the donor organism to a recipient organism.

SECTION 2. Scope Of The Guidelines

2.1 Coverage — This Monograph shall apply to the deliberate release of GMOs and PHES into the Philippine environment. Unless otherwise excluded under Section 2.2 hereof, any release of GMOs or PHES into the Philippine environment shall be considered as deliberate.

2.2 Exclusions — The following activities are not covered by this Monograph:

(a)

work performed under contained conditions;

(b)

accidental releases from contained facilities;

(c)

use of pharmaceutical, processed food, animal feed, industrial, and other products that are already being regulated

by other departments, agencies or instrumentalities of the Philippine government;

(d)

working involving organisms which result from natural reproduction or the use of traditional breeding practices;

(e)

such other activities as the CNBP may in the future declare to be excluded.

The activities described in Section 2.2 (a) and (b) above are covered by NCBP Series No. 1 (Biosafety Guidelines for Laboratory Work) and NCBP Series No. 2 (Biosafety Guidelines for Large-Scale Contained Work Including Glasshouse Trials), respectively.

SECTION 3. The Biosafety Organization

3.1 National Biosafety Committee of the Philippines - The highest regulatory body in the Philippines in respect of the introduction, use and transfer of GMOs and PHES is the National Committee on Biosafety of the Philippines (NCBP). It is responsible for ensuring that all institutions, whether public or private, that conduct activities involving GMOs or PHES, including their planned release into the environment, have established their respective Institutional Biosafety Committees (IBCs) to ensure compliance with acceptable measures for the safe handling and use of these organisms.

3.1.1 Composition of the NCBP - The NCBP shall be composed of the following:

Chairperson — Undersecretary for Research & Development of the Department of Science and Technology

Members 1 biological scientist

1 environmental scientist

1 physical scientist

1 social scientist

2 respected members of the community

1 representative each from the Department of Agriculture, Department of Environment and Natural Resources and Department of Health, to be designated by the respective Heads of Offices

3.1.2 Powers and Functions of the NCBP - The powers and functions of the NCBP, as embodied in Executive Order No. 430, Series of 1990, are as follows:

a)

Identify and evaluate potential hazards involved in initiating genetic engineering experiments or the introduction of GMOs and PHES and recommend measures to minimize risks;

b)

Formulate, review or amend national policies and guidelines on biosafety, such as, the safe conduct of work on genetic engineering, pests, and their genetic materials, for the protection of public health, environment and personnel, and supervise the implementation thereof;

c)

Formulate, review or amend national policies and guidelines in risk assessment of work in biotechnology, and supervise the implementation thereof;

d)

Develop working arrangements with the government quarantine services and institutions in the evaluation, monitoring and review of projects vis-a-vis adherence to national policies and guidelines on biosafety;

e)

Assist in the development of technical expertise, facilities, and other resources for quarantine services and risk assessments;

f)

Recommend the development and promotion of research programs to establish risk assessment protocols and assessment of long-term environmental effects of biological research covered by these guidelines;

g)

Publish the results of internal deliberations and agency reviews of the Committee;

h)

Hold public deliberations on proposed national policies, guidelines and other biosafety issues;

i)

Provide assistance in the formulation, amendment of pertinent laws, rules and regulations;

j)

Call upon the assistance in the formulation, amendment of pertinent laws, rules and regulations;

k)

Review the appointment of the members of the IBC upon recommendation by respective heads of institutions; and

l)

Hold discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the purposes or objectives of the proposed genetically modified products, services, or both.

3.2 Institutional Biosafety Committee — Any institution intending to undertake any planned release of GMOs or PHES into the environment must first set up an Institutional Biosafety Committee (IBC). The IBC shall be responsible for evaluating project proposals involving organisms covered by this monograph and for recommending the same for appropriate action by the NCBP. After the project is approved, the IBC shall be responsible for supervising, monitoring and reporting to the NCBP its progress. More importantly, the IBC shall make sure that the environment and human health are safeguarded in the conduct of any potentiality biohazardous activities by the institution or by any of its employees or researchers. Likewise, the IBC shall be responsible for informing the surrounding communities of plans for planned release, including the concomitant risks thereof, if any.

3.2.1

Composition of the IBC — The IBC shall be composed of at least five (5) members, all of whom must first be approved by the NCBP. At least three (3) members shall be designated as the "scientist-members", and they must possess scientific or technological knowledge and expertise sufficient to enable them to evaluate and monitor properly any work involving GMOs or PHES conducted by the institution. The other members, who shall not be less than two and who shall be designated as "community representatives", must not be affiliated with the institution (apart from their affiliation with the IBC) and must be in a position to represent the interests of the communities surrounding the institution or which may be affected by the planned release.

3.2.2

Responsibilities of the IBC Specific to Planned Release — With regard to planned release of GMOs or PHES, the IBC shall have the following responsibilities:

(a)

Undertake the assessment and review of all planned release proposals to identify potential hazards to human health and the environment and to advise the Project Leader on their proper management;

(b)

Review the qualification and experience of personnel involved in potentially biohazardous projects;

(c)

Ensure competence, acceptable professional practices and adequate supervision of project staff;

(d)

Take necessary steps to inform the public of the proposed planned release and provide the public the opportunity to comment, including, but not limited to, the conduct of public hearings, if so warranted;

(e)

Submit to the NCBP all required project documents for review and approval;

(f)

Ensure that all communications from the NCBP are conveyed to and, if applicable, complied with by the Project leader;

(g)

Ensure that all relevant regulatory agencies have been consulted and necessary permits, licenses or approvals have been obtained before any planned release is made;

(h)

Visit the release site periodically to monitor and evaluate the biosafety of on-going projects and recommend additional safety measures, if necessary;

(i)

Notify immediately the NCBP of any accidents or incidents arising from or related to the planned release activity;

(j)

Keep records of all procedures, decisions and directives relative to the planned release;

(k)

Submit a terminal report to NCBP at the end of the planned release project; and

(l)

Submit annual reports to the NCBP, as provided for under Section 3.2.4 hereof.

3.2.3

Authority to Formulate Rules — The IBC shall have the power to draft rules and regulations to supplement this Monograph. These rules and regulations may include, but are not limited to, containment procedures and operations and the handling, transport and storage of GMOs and PHES by and within the institution.

3.2.4

Annual Report — The IBC shall submit a report to the NCBP not later than the 15th day of March of each year. The report shall be for the period January to December of the preceding year, and shall include the following information:

(a)

Composition of the Committee;

(b)

Planned release activities conducted during the year, including any changes of Project Leaders;

(c)

Modifications in the planned release activities vis-a vis the original proposals submitted to the NCBP;

(d)

Description of unexpected results from planned release work and its adverse impact to health or the environment;

(e)

Description of accidents or incidents attributable to the planned release work and the adverse effects thereof; and

(f)

Any other matters which the IBC may wish to bring to the attention of the NCBP.

3.2.5

IBC of Small Institutions — The NCBP recognizes the difficulty that small institutions may have in setting up a comment IBC due to the limited number of scientists who can serve in the IBC. Hence, subject to the prior approval of the NCBP, potentially biohazardous activities of these institutions may be supervised by the IBC from another institutions. However, this arrangement, which shall be in writing, must specify, among others, the following: (i) that the Heads of both institutions shall be jointly responsible in ensuring compliance with these guidelines; and (ii) that a senior member of the supervised institution shall liaise closely with the supervising IBC throughout the conduct of the proposed activity.

3.3 Heads of Institutions — The responsibility for ensuring that potentially biohazardous projects within the institution are in full compliance with relevant NCBP guidelines for the following:

(a) creating an IBC and providing it with resources necessary to enable it to evaluate and monitor properly

projects involving GMOs or PHES; and

(b) making sure that necessary resources are provided to employees or researchers for safe work within and outside the institution.

3.4 Project Leaders — For each planned release proposal, there shall be designated a Project Leader who shall have overall responsibility for all aspects of the planned work. The Project Leader must be thoroughly familiar with the provisions of the Guidelines. He must ensure that the project he leads complies with the Guidelines and, where appropriate, with all the conditions imposed by the NCBP for its approval. In particular, the Project Leader shall:

(a)

Prepare the project proposal in accordance with Annex "B" and submit the same to the IBC for proper action;

(b)

Conduct an initial evaluation of the project proposal to determine if the same falls within the coverage of the Guidelines. In case of doubt, the Project Leader shall consult the IBC;

(c)

Provide any information on the project proposal and its conduct which the IBC may require for its assessment and monitoring activities;

(d)

Comply with NCBP and IBC advice and recommendations on the project proposals;

(e)

Carry out work under conditions approved by the IBC and NCBP;

(f)

Ensure that all members of the project staff are aware of any potential hazards of the work and that they have received appropriate training in safety and emergency procedures;

(g)

Notify the IBC of all changes in the conduct or composition of the project staff involved in the planned release work;

(h)

Report immediately to the IBC all unexpected results or accidents and unexplained illnesses or absences of personnel which may be attributed to the planned release;

(i)

Advise the IBC of any intention to import or transport biological materials covered by the Philippine Biosafety Guidelines;

(j)

Keep such records as are appropriate for each planned release; and

(k)

Submit a terminal report to the IBC at the end of the project.

SECTION 4. Procedures For Planned Release Application And Review

4.1 NCBP Approval — No person or institution shall release into the environment any GMO or PHES without the prior approval of the NCBP. However, approval by the NCBP does not in any way exempt the project proponent from complying with any rules and regulations or requirements of other government regulatory authorities. It is the sole responsibility of the project proponent to determine if the proposed planned release requires any permit, license or approval of such regulatory authorities, and to obtain the same if required.

4.2 Project Proposal —

(a)

The project proposals shall be in writing and in accordance with the format. The proponent must answer all questions including the sub-questions, if relevant to the proposal. The answer must be supported by data and relevant scientific literature, all of which shall be appended to the proposal. The proponent must disclose all data or literature that allude to potential adverse effects on human health or the environment by the GMO or PHES to be used.

(b)

If the project proposal contains any information which the proponent wishes to be kept confidential, the pages containing such information shall be conspicuously marked as "Commercial-in-Confidence". The proponent shall specify in writing why the marked pages should be held in confidence. However, no information pertaining to the potential adverse effects of the organisms on human health or the environment shall be considered confidential.

(c)

The IBC may require the proponent to state in his or her project proposal any information in addition to those

required by the NCBP.

4.3 IBC Assessment —

(a)

The IBC shall evaluate the project proposal using the rational risk benefit analysis outlined in Part III. Specifically, the IBC shall evaluate whether data obtained in the laboratory or under contained conditions provide sufficient basis to authorize a planned release of the GMO or PHES into the environment. In making such an evaluation, the IBC must ensure that the planned release does not pose any unnecessary risks to the environment or human health.

(b)

During the evaluation, the IBC shall consult and discuss with the proponent and, when appropriate, make suggestions for revisions. The IBC may, in its sole discretion, require the proponent to perform additional experiments under contained conditions before acting on the project proposal.

(c)

The IBC may engage the services of consultants who are experts in the scientific disciplines relevant to the proposed planned release or knowledgeable in the policies of the institution, relevant laws, standards of professional conduct or practice, community attitudes and practices, and the potential environmental and human health impact of the proposed activity. All expenses for consultant services shall be for the account of the proponent, unless the IBC agrees to be liable therefor.

(d)

After the evaluation, the IBC shall either recommend approval of the project proposal to the NCBP or reject the proposal for failing the rational risk-benefit analysis.

4.4 Endorsement of Proposal by IBC to NCBP —

(a)

Approval by a majority of the IBC members, which must include at least one community representative, shall be necessary before any project proposal may be endorsed for approval by the IBC to the NCBP. Dissenting members of the IBC must indicate the reasons for disapproving the proposal.

(b) The IBC endorsement shall be submitted to the NCBP in twelve (12) copies, and shall include the following:

(i) Cover sheet, in accordance with the format.

(ii) project proposal and its attachments;

(iii) Information sheet for public notification/comment;

(iv) biodata of all individuals involved in the project.

The NCBP reserves the right not to act on any project proposal or endorsement which does not comply with the prescribed format or fails to include all the required attachments.

(c)

Materials marked as Commercial-in-Confidence proponent shall be treated as such by the NCBP, unless (i) they contain information pertaining to the potential in adverse effects of the organisms on human health or the environment or (ii) the NCBP, in its sole discretion, determines that there is nothing propriety with the information as would require confidentiality. In the event that the NCBP decides that some disclosure is necessary, the NCBP shall notify the proponent in writing for the purpose of negotiating an acceptable resolution. If agreement is not reached, the proponent must withdraw the proposal; in which case, the NCBP shall be duty bound not to disclose the information deemed confidential by the proponent.

4.5 Initial Assessment by NCBP Secretariat — Upon receipt of the documentary submissions from the IBC, the NCBP Secretariat shall check whether or not the required format and attachments have been complied with. If the project proposal complies with the required format and has all the necessary attachments, the NCBP Secretariat shall calendar the proposal for review by the NCBP. On the other hand, if the project proposal is incomplete or the format is not complied with, the NCBP Secretariat shall immediately inform the proponent of the missing requirements. The proponent shall then be given a reasonable period within which to complete these requirements. No proposal shall be submitted to the NCBP for review unless in the proper format and all the required documents are appended.

4.6 Scientific and Technical Review Panel —

(a)

Upon receipt of the proposal from the NCBP Secretariat, the NCBP shall create a Scientific and Technical Review Panel (STRP) to evaluate potential adverse effects of the project to human health and environment. The STRP shall be appointed by the Chairman of the NCBP. It shall be composed of at least three (3) members drawn, if possible, from the pool of experts listed in the sectoral councils of the Department of Science and Technology. As far as practicable, no member of the NCBP shall be part of the STRP.

(b)

The STRP shall be provided copies of the project proposal after they have executed an undertaking to maintain and respect the confidentiality of information declared by the proponent, and approved by the NCBP its recommendations in writing not later than thirty (30) days from receipt of the project proposal from the NCBP Secretariat.

4.7 Public Notification and Comment —

(a)

Concurrent with the review by the STRP, the NCBP, acting through the IBC, shall take steps to notify the public of the planned release and to invite comments thereon. The following shall be the procedure for the public notification and comment:

(i)

The IBC shall post, for three (3) consecutive weeks, the NCBP-approved Project Information Sheet for Purpose of Public Comment/Notification in at least three (3) conspicuous places in the barangay(s) where the test site is located or which may be affected by the proposed release. Proof of posting, which may either be a certification from the duly authorized barangay leader(s) or an affidavit executed by the Project Leader, shall be submitted to the NCBP within ten (10) days from the last day of posting.

(ii)

In addition, the IBC shall publish the Project Information Sheet once a week for at least two (2) consecutive weeks in a newspaper of general circulation in the areas where the test site is located or which may be affected by the planned release. Proof of publication, consisting of the Affidavit of Publication duly executed by the publisher of the newspaper or any of his representatives, shall be submitted to the NCBP within ten (10) days from the last day of publication.

(iii)

If in the judgment of the IBC, the proposed planned release carries potentially significant risks to human health and the environment, the IBC shall conduct a public hearing not later than ten (10) days from the last day of publication of the Project Information Sheet as required under Section 4.7 (a)(ii) above.

(b)

The IBC shall allow at least thirty (30) days from the last posting, the publication or the public hearing, whichever comes later, for the public to comment on the proposed planned release. The public shall be asked to direct all its inquiries to the proponent, whose name and complete address shall be stated in the Project Information Sheet. The proponent shall provide additional information about the project to any requesting party not later than (10) days from receipt of such request.

(c)

All comments on the proposed planned release shall be sent by personal service, courier or registered mail to: The Secretariat, National Committee on Biosafety Committee of the Philippines, Department of Science and Technology, Gen. Santos Avenue, Bicutan, Taguig, Metro Manila.

(d)

The NCBP shall collate and forward all public comments to the IBC for appropriate response. The proponent, through the IBC, shall respond, in writing to all public comments within fifteen (15) days from receipt thereof. The IBC shall furnish the NCBP a copy of all its responses within the same period.

(e)

The proponent, if he so desires, may amend his or her proposal in response to the public comments. The amendments to the project proposal, public comments and the responses thereto shall be immediately transmitted to the NCBP and shall form part of the record to be used by the NCBP in its deliberations.

(f)

All expenses incurred in the public notifications and comment shall be for the account of the proponent.

4.8 NCBP assessment and Decision —

(a)

In the event that no public comment has been received, the NCBP shall act on the proposal for planned release within sixty (60) days from the end of the period for public comment. Otherwise, it shall act on the proposal within sixty (60) days from submission of the documents mentioned in Section 4.7(e) above.

(b) The NCBP shall base its evaluation on the following:

(i) Project proposal, including amendments and attachments;

(ii) IBC Assessment;

(ii) Comments and recommendations of the STRP;

(iv) Public comments;

(v) Such other documents or information, from whichever source, deemed relevantly by the NCBP.

(c)

The NCBP shall notify the proponent in writing of its decision. Approval may be subject to conditions such as, but not limited to, a detailed description of the planned release and mitigating measures, specific time period for release, specific geographical areas for use as test sites, and additional monitoring and reporting requirements. If the proposed activity requires a permit or authority from other government regulatory agencies, and the issuances

of the same is conditioned upon approval of the project proposal by the NCBP, the NCBP shall issue an endorsement to facilitate the issuance of the said permit or authority. In case a project proposal is disapproved, the NCBP shall state the reason or reasons for disapproval.

4.9 Request for Reconsideration — The proponent may request the NCBP for reconsideration within sixty (60) days from receipt of the notice of disapproval. The request shall state all the grounds for reconsideration. The NCBP shall have sixty (60) days to act on the request for reconsideration. Unless otherwise stated in writing, failure on the part of the NCBP to act within the said period shall be considered to be a denial of the request. The decision of the NCBP relative to the request for reconsideration shall be final.

4.10 New Data or Information on Risks — In case new data or information that will reduce significantly biosafety risks that caused the disapproval of the project proposal later becomes available, the proponent may re-submit the project proposal to the IBC together with the new data or information. The re-submitted project proposal shall be evaluated in the same manner as that of a new proposal.

SECTION 5. Monitoring And Reports

5.1

Monitoring — (a) The IBC and appropriate government authorities shall monitor the planned release. The IBC shall submit to the NCBP the results of monitoring activities at intervals specified in the NCBP approval.

(b)

In accordance with agreements with line agencies, (i) the Department of Agriculture shall be responsible for monitoring the movement and effects of GMOs or PHES approved for release; (ii) the Department of Environment and Natural Resources shall be responsible for monitoring the environmental effects of the planned release; and (iii) the Department of Health shall be responsible for monitoring the effects of such release to human health.

(c)

The NCBP may inspect the release site(s) at any time. Site inspections shall be carried out in such a manner as to avoid interfering with the activities of the proponent, unless intervention is necessary to avert any imminent danger to human health or the environment.

5.2

Reports — (a) Within ninety (90) days from completion of the planned release, the proponent shall submit to the IBC, for review, a detailed terminal report on the project. The report shall specify, among others, whether the objectives of the release were achieved the nature and consequences of the adverse effects, if any of the release; and the fate of the GMO or PHES after the release.

(b) The IBC shall review the terminal report of the proponent and endorse the same to the NCBP. It shall also

submit its own report to the NCBP in accordance with the format. Both the proponent's report and that of the IBC shall be submitted by the IBC to the NCBP not later than one hundred twenty (120) days from completion of the planned release.

(c) The NCBP may require the IBC to submit follow-up reports on the long-term effects of the planned release.

(d) In case of any accident or untoward incident that may put human health or the environment at risk, the proponent shall immediately report the same to the IBC and the NCBP. The report shall describe the accident or untoward incident, the actions taken to mitigate it, and the persons and government authorities notified. In no case shall reporting the accident or untoward incident to the NCBP relieve the proponent and the institution of their obligation under the law.

SECTION 6. Withdrawal Of NCBP Approval

6.1

Grounds for Revocation of Approval — The following are the grounds for revocation by the NCBP of any project approval:

(a) Failure of the proponent to comply with the Philippine Biosafety Guidelines or any of the conditions imposed by the NCBP for approval of the project, including, but not limited to failure to adhere to restrictions and schedule of activities and protocols imposed by the NCBP;

(b) Receipt by the NCBP of reliable data or information indicating that the planned release may pose a threat to human health or the environment; and

(c) Such other grounds as the NCBP may deem reasonable to protect human health or the environment.

6.2

Procedure for Revocation — (a) The NCBP shall advise the proponent in writing of the existence of grounds to revoke the project approval. The proponent shall have an inextendible period of ten (10) days within which to explain in writing why the approval should not be revoked. The NCBP shall render its decision within ten (10) days from receipt of the explanation of proponent.

(b) In case of imminent danger to human health or the environment, the NCBP Chair may immediately revoke

any project approval on his or her own accord, without need of consulting the other members. Thereafter, the NCBP, after deliberation, shall either confirm or lift, in writing, the revocation order issued by the Chair. The NCBP shall have sixty (60) days therefrom to furnish the proponent a written explanation of its action.

6.3

Effect of Revocation — In the event of revocation, any permit or authority issued by other government authorities on the strength of the previous NCBP approval may also be revoked immediately. Further the NCBP may order the proponent or any government authority to destroy the GMO or PHES.

SECTION 7. Penalties and Sanctions — In addition to the revocation of the project approval, any violation of the provisions of this monograph or the concealment or withholding by the proponent of any information necessary to evaluate risks to human health or the environment shall be ground for the forfeiture of government research grants. Further, any incentives that may have been granted the proponent or institution for contributing to advanced scientific or technological research and development may be withheld. These penalties are exclusive of any other penalties that may be imposed under existing law, including, but not limited to, civil, criminal and administrative liabilities for gross negligence.

SECTION 8. Amendments — The NCBP may, by a majority vote, amend, modify or repeal any of the provisions of this Monograph.

SECTION 9. Repealing Clause — All provisions of the Philippine Biosafety Guidelines (1991 edition), particularly Part III, paragraph 2.3 (Field Release of Regulated Materials), which are inconsistent with this Monograph are hereby repealed.

SECTION 10. In case any provision of this guidelines is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and in effect.

SECTION 11. Effectivity — These Guidelines shall take effect fifteen (15 days) after its publication in a newspaper of general circulation.

Adopted: 13 May 1998

(SGD.) ESTRELLA F. ALABASTRO
Chair, NCBP

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