

Sub-decree
on
Mechanisms and Procedures for Implementing
the Law on Biosafety

Royal Government of Cambodia

- Seen the Constitution of Cambodia;
- Seen the Royal Decree no. NS/RKT/0908/1055 dated 25 September, 2008 on Designation of the Royal Government of Cambodia;
- Seen Reachkram no. NS/02/94 dated 20 July, 1994 promulgated the Law on the Organization of the Council of Ministers;
- Seen Reachkram no. NS/KRM/0196/21 dated 24 January, 1996 promulgated the Law on the Establishment of the Ministry of Environment;
- Seen Reachkram no. NS/RKM/0802/016 dated 31 August 2002 promulgated Forest Law;
- Seen Reachkram no. NS/RKM/0506/011 dated 21 May 2006 promulgated Fisheries Law;
- Seen Reachkram no. NS/RKM/0208/006 dated 15 February, 2008 promulgated the Law on Biosafety;
- Seen Reachkram no. NS/RKM/0508/015 dated 31 may 2008 promulgated Law on Seed Management and Rights of Breeders;
- Seen a Sub-decree no. 57 dated 25 September, 1997 on the organization of the Ministry of Environment;
- Seen a Sub-decree no. 69 dated 28 October 1998 on Standards and Agricultural Materials Management;
- Seen a Sub-decree no. 53 dated 29 May 2006 on International Trade of Endangered Fauna and Flora;
- Seen a Sub-decree no. 209 dated 31 December 2007 on promulgation of banned goods list and restricted goods;
- Approved by the Council of Ministers in a full plenary session on June 04, 2010.

Decision

Chapter I

General Provisions

Article 1.-

This Sub-decree aims at identifying mechanisms and procedures implementing the Law on Biosafety.

Article 2.-

This Sub-decree has following purposes:

1. Curb adverse effective on the conservation of biodiversity, environment and human health;
2. Ensure effectiveness of the conservation and a sustainable use of biological diversity;
3. Promote awareness on modern biotechnology and prevent risks arising from the use of living modified organisms (LMOs); and
4. Protect environment and human health.

Article 3.-

This Sub-decree covers all activities pertinent to the article 3 of the Law on Biosafety.

Article 4.-

Technical terms used in this Sub-decree have following definitions:

- **Risk Assessment:** refers to identifying potential risk, estimating the likelihood that the risk will occur, and estimating how much damage would be caused if the risk does occur.
- **Risk Management:** refers to methods used to reduce identified potential risk to an acceptable level.
- **Damage to human health:** refers to causes leading to diseases, injuries, impairs, or death.
- **Damage to the environment:** refers to a damage leading to spending on restoration of environment and biodiversity

appropriately including the restoration of origins of the biodiversity.

- **Damage to the conservation of biodiversity:** refers to a damage leading to the change in quantities and qualities of living things in the ecosystem.
- **Damage to the sustainable use of biodiversity:** refers to the depletion in both quantities and qualities of biodiversity components that might have an adverse effect to following uses of such components and lead to the loss of economics, loss of incomes, disturbs to livelihoods of local communities or reducing commonly use rights.
- **Living modified organisms:** refers to any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

Chapter II

National Steering Committee for Biosafety

Article 5.-

A National Steering Committee for Biosafety shall be established and is written in a short name as **NSCB**.

Article 6.-

The NSCB composes of:

- | | |
|---|-------------|
| - Minister for Environment | Chair |
| - Secretary of State of Ministry of Agriculture, Forestry and Fisheries, 1 person | Vice-Chair; |
| - Secretary of State of Council of Ministers 1 person | Member; |
| - Secretary of State of Ministry of Interior 1 person | Member; |
| - Secretary of State of Ministry of National Defense 1 person | Member; |
| - Secretary of State of Ministry of Commerce 1 person | Member; |
| - Secretary of State of Ministry of Health 1 person | Member; |
| - Secretary of State of Ministry of Economy and Finance 1 person | Member; |

- Secretary of State of Ministry of Industry, Mine and Energy 1 person
Member;
- Secretary of State of Ministry of Education, Youth and Sport 1 person
Members;
- Secretary of State of Ministry of Rural Development 1 person Member;
- Secretary of State of Ministry of Planning 1 person Member;
- Secretary of State of Ministry of Water Resources and Meteorology 1
person Member;
- Secretary of State of Ministry of Tourism 1 person Member;
- Secretary of State of Ministry of Public Works and Transport 1 person
Member;
- Deputy-Secretary General of Council for Development of Cambodia 1
person Member;

The actual composition of the NSCB shall be issued by the Prakas of the Royal Government of Cambodia.

The members of the NSCB shall participate in the meeting with an invitation of the Chairman. Rules and procedures of the meeting shall be detailed in the internal rule of the NSCB. The NSCB uses Ministry of Environment's stamp.

Article 7.-

The NSCB has roles and responsibilities as follows:

- Develop the policies, biosafety and biotechnology action plan to the Royal Government of Cambodia monitoring and making decision;
- Establish the relation between Royal Government of Cambodia and the secretariat of Convention of Biodiversity for strengthening the implementation on Cartagena Protocol on Biosafety;
- Advise to the RGC on the protocol and draft agreements that related to CPB's implementation
- Develop, control and monitor the enforcement on biosafety and biotechnology action plan;
- Encourage the mainstreaming policy on biosafety and biotechnology in the related sectors;

- Control and monitor the obligation on Cartagena Protocol on Biosafety's implementation
- Encourage for public awareness on developing national biosafety framework needed;
- Control and encourage the international cooperation and institution cooperation on biosafety issues;
- Ensure the national biosafety framework is mainstreamed in the government's environment policy;
- Modify, approve and assess on national biosafety framework developing and ensure the effectiveness enforcement
- Monitor the action plan implementation and review the needs priority of biosafety and biotechnology action plan in every two years by input the related activities
- Advise and assess the general policy for project implementing and project output
- Report its activities to the Royal Government of Cambodia; and
- Implement the other duties as required by the government.

Article 8.-

The NSCB composes of Emergency Response Team with following compositions:

- Representative from Ministry of Environment one person Chair
- Representative from Ministry of Agriculture, Forestry and Fisheries one person Vice chair
- Representative from the National Committee for Natural Disaster one person Member
- Representative from Ministry of Interior one person Member
- Representative from Ministry of Defense one person Member
- Representative from Ministry of Economy and Finance one person Member
- Representative from Ministry of Commerce one person Member
- Representative from Ministry of Health one person Member

- Representative from Ministry of Industry, Mine and Energy one person
Member
- Representative from Ministry of Water Resources and Meteorology one
person Member.

Actual composition and procedures of the Emergency Response Team's meeting shall be addressed by the decision of NSCB Chairman.

NSCB Chairman might invite representatives of other concerned ministries and departments to be members, if necessary.

Article 9.-

The main functions and responsibilities of the Emergency Response Team include:

- (i) Detecting for living modified organisms that exposed into the environment or leaked from use, transport and reporting the risks or this incidence and damages;
- (ii) Obtaining information and take urgent measures whenever there accidentally leakage or exposure of living modified organisms to curb or minimize the magnitude of damages on biological diversity and human health;
- (iii) Training for relevant technical officials on measures and the management of living modified organisms;
- (iv) Fulfill other duties that the NSCB assigned.

Article 10:-

The NSCB Chairman shall have the right to directly order the Emergency Response Team to take measures at appropriately urgent time.

Article 11:-

The NSCB has a secretariat, which bases at the Ministry of Environment.

The secretariat of NSCB shall be chaired by one secretary as a director of department with certain deputy secretaries, if necessary.

Article 12:-

The operation of NSCB's secretariat shall be assigned by a sub-degree.

Chapter III

Scientific Advisory Team

Article 13:-

A Scientific Advisory Team (SAT) shall be established, which is written in short **S.A.T** and bases at the Ministry of Agriculture, Forestry and Fisheries.

Article 14:-

The SAT composes of following scientific specialists:

- (i) One representative from the Ministry of Environment, Chair
- (ii) One representative from the Ministry of Agriculture, Forestry and Fishery, Vice-Chair
- (iii) One representative from the Ministry of Commerce, Member;
- (iv) One representative from the Ministry of Industry, Mine and Energy Member;
- (v) One representative from the Ministry of Health, Member;
- (vi) One representative from Ministry of Education, Youth and Sport, Member;
- (vii) One representative from the Royal Academy, Member;
- (viii) One representative from the university, Member;
- (ix) One representative from relevant laboratories.

Actual composition of the SAT shall be determined by the Government.

The S.A.T may request to the Ministry of Environment additional national or international scientists to assist their works with relevant fields in which additional expertise may be required, including, but is not limited to: ecology, seed science, environmental toxicology, animal breeding and genetics, virology, microbiology, molecular biology, biotechnology, physiology, and plant breeding.

Article 15:-

The S.A.T has duties and responsibilities as follows:

- (i) Reviewing risk assessments that accompany requests for prior approval to apply for an import/export permit and recommending to the Ministry of Environment whether additional risk assessment is required;
- (ii) Reviewing additional risk assessments that the Ministry of Environment may direct to be prepared by independent experts;
- (iii) Keeping any confidential information identified and presenting recommendations to the Ministry of Environment to take strict measures, monitoring procedures as appropriate and providing scientifically sound evidences;
- (iv) Proposing risk management measures;
- (v) Assisting the production of scientific information for improving public awareness activities;
- (vi) Fulfilling the other duties assigned by RGC or Ministry of Environment.

Article 16:-

The secretariat of NSCB serves for S.A.T to undertake their duties and responsibilities.

Chapter IV**Procedures for Import of Living Modified Organisms****Section I****Import of Living Modified Organisms for Contained Used****Article 17:-**

For all imports and utilization of LMOs, as specified in this Chapter IV and Chapter V, an applicant shall submit a request to the Ministry of Environment for prior approval and shall submit all relevant documents of LMOs to the Ministry of Environment.

All requests for prior approval shall include a sworn declaration that the information contained in the requests is correct.

An applicant may withdraw the request for prior approval prior to the issuance of a decision by the Ministry of Environment.

Article 18.

An applicant shall pay administrative fees for his/her request to the Ministry of Environment. State research institutions, universities, public laboratories shall be exempted from payment of administrative fees.

The amount of administrative fees mentioned in above paragraph shall be issued in a joint Prakas between the Ministry of Economy and Finance and the Ministry of Environment.

Article 19:-

The first import of any LMO into the Kingdom of Cambodia for contained use shall be undertaken the risk assessment and subject to prior approval from the Ministry of Environment before applying to the concerned competent authorities.

The application of the LMO contained use shall follow the standard and technical principle that have to be defined by the Prakas of the Ministry of Environment, after discussing with the relevant ministries.

Article 20:-

An applicant shall submit the request as clarify in article 19 for prior approval together with the risk assessment for the LMO to be imported no less than ninety (90) days before the intended date of import.

The request for prior approval shall include, at a minimum, the following information:

- (i) Name and contact information of the Applicant;
- (ii) The location where contained use activities will be undertaken;
- (iii) The nature and identity of the LMO to be imported;
- (iv) The nature and purpose of the activities, including such activities as storing, transporting, producing, culturing, processing, destroying, disposing or using the LMO in any other way;
- (v) Any potential risks associated with the LMO and the activities to be undertaken;

- (vi) A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment caused by the activities to be undertaken.

Article 21:-

The Ministry of Environment may, in consulting with the SAT, notify the applicant in written languages that additional information is required including additional risk assessment.

The Ministry of Environment may require the additional risk assessment be carried out by the applicant or by a designated independent expert(s). The costs of additional risk assessment shall be born by the applicant.

The applicant must respond to a request for additional information within thirty (30) days of the date of the request, either by submitting the additional information required to the Ministry of Environment. If the applicant does not respond within the specified period, the Applicant may ask for delay (days) that defined by Ministry of Environment.

If the applicant does not respond within the specified period, the Ministry of Environment will notify the applicant that its request for prior approval is denied.

If the applicant submits the additional accurate information requested within the prescribed period, the Ministry of Environment shall transmit the information to the SAT. The SAT shall submit the report and advice to the Ministry of Environment for responding to the request.

After review and comment on the report from the SAT, the Ministry of Environment shall inform in writing on it's decision within 30 days to the applicant and to the national Biosafety Clearing House (nBCH) indicating the follow key points:

- (i) The approval to apply for the permit, with or without conditions, and indicate the approval for subsequent imports of the same living modified organism; or
- (ii) Denying to the proposal for import.

Article 22.

In approving a request, the Ministry of Environment shall impose specific risk management measures and other necessary conditions on the proposed contained use activities of LMOs. Risk management measures,

labeling, and other requirements shall be issued by the Prakas of the Minister for Environment. Once the request is approved, the applicant shall include the original approval with the application for the import permit to competent agencies.

Article 23.-

If the request is denied, the Ministry of Environment shall state reasons for denying the approval.

Section II

The intentional introduction into the environment

Article 24:-

Any legal or natural person who imports LMOs into the Kingdom of Cambodia for intentional introduction into the environment shall be subject to risk assessment and prior approval by the Ministry of Environment before applying to the concerned competent ministries for the import permit.

Article 25:-

The applicant shall include in the request for prior approval:

- (i) the information specified in Annex I;
- (ii) the comprehensive report of a risk assessment carried out in conformity with Annex III of this Sub-decree; and
- (iii) any additional information which the Applicant deems relevant to an assessment of the potential risk and/or benefit of his or her request.

Article 26:-

The Ministry of Environment shall, within ninety (90) days of receipt of a request for prior approval, respond in writing to the Applicant indicating:

- (i) the date of receipt of the request for prior approval; and
- (ii) any additional information required to process the request in which the Ministry of Environment may require additional risk assessment and such risk assessment may be required to be carried

out by the Applicant or by an independent designated expert. The costs of additional risk assessment shall be borne by the Applicant.

Article 27.-

The applicant must respond to the above mentioned request as stated in the second dash (-), article 26, for additional information within thirty (30) days from the date of the request, by submitting the additional information required to the Ministry of Environment.

If the applicant make a justification of the request he or she shall, within ninety (90), submit it to the Ministry of Environment.

If the applicant does not respond within the specified period, the Ministry of Environment shall notify the applicant that its request for prior approval is denied.

If the applicant submits the additional information requested within the prescribed period, the Ministry of Environment shall acknowledge receipt and transmit the additional information to the SAT.

Within one hundred eighty (180) days of receipt of a request for prior approval, or with ninety (90) days of receipt of additional information, the SAT shall submit to the Ministry of Environment its report and recommendation for action on the request. After receipt of the SAT report, the Ministry of Environment shall transmit the report to the applicant. The applicant may, within thirty (30) days of receipt of the SAT report, submit comments on it to the Ministry of Environment. The Ministry of Environment shall take the Applicant's comments into account in making its decision on prior approval.

Within two hundred and seventy (270) days of the date of receipt of a request for prior approval, or of receipt of additional information if required, and/or comments on the SAT report, the Ministry of Environment shall communicate in writing to the applicant and to the national Biosafety Clearing-House (nBCH) its decision, indicating either:

- (i) its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or
- (ii) denial and approval of the proposed import.

Article 28.-

In approving a request on the import of LMOs into the Kingdom of Cambodia, the Ministry of Environment may impose specific risk management measures, labeling or marking requirements, and/or other conditions on the proposed intentional introduction. The risk management measures, labeling and/or other conditions shall declare by the minister of environment.

If the request is approved, the applicant shall include the original approval with the application for the import permit.

If the request is denied, the Ministry of Environment shall state reasons for denying the approval.

Within thirty (30) days of receipt of a denial of approval, the applicant may request the Ministry of Environment to review its decision on the basis of new and/or additional information not brought out during the decision-making process. The Ministry of Environment shall respond in writing to the applicant within ninety (90) days of receipt, giving its reasons for either maintaining its original decision to deny approval or for revising its decision and approving the request.

Section III**Import for direct use as food, feed or for processing****Article 29:-**

The first import into the Kingdom of Cambodia, any LMO for direct use as food, feed or for processing shall be subject to risk assessment and approval by the Ministry of Environment prior to application to the concerned competent ministries for the import permit.

Article 30:-

The applicant shall include following information in its request for prior approval:

- (i) the information specified in Annex II;
- (ii) the comprehensive report of a risk assessment carried out in conformity with Annex III of this Sub-decree; and

- (iii) any additional information which the applicant deems relevant to an assessment of the potential risk and/or benefit of the intended direct use for food of feed or for processing.

Article 31:-

The Ministry of Environment shall, within ninety (90) days of acknowledging receipt of a request for prior approval, respond in writing to the applicant. The response shall:

- (i) include the date of receipt of the request for prior approval; and
- (ii) if necessary, specify any additional information required, in which, as required by the Ministry of Environment, include additional risk assessment. The Ministry of Environment may require such additional risk assessment be carried out by the applicant or by a designated independent expert. The costs of additional risk assessment shall be born by the applicant.

Article 32.-

The applicant must respond to a request for additional information, as stated in article 31 above, within thirty (30) days from the date of the requirement to submit the additional information to the Ministry of Environment.

If the applicant makes a correction of the document or any information in the application, the applicant shall submit such document or information to the Ministry of Environment within ninety (90).

If the applicant does not respond within thirty (30) days, the Ministry of Environment may deny the application for import and shall notify the applicant such denial.

If the applicant completely submits the additional information requested within the prescribed period, the Ministry of Environment shall, acknowledge receipt and transmit the additional information to the SAT.

The SAT shall submit to the Ministry of Environment its report and recommendation for consideration on the application.

After reviewing comments and SAT report, the Ministry of Environment shall communicate in writing to the applicant and to the Biosafety Clearing-House its decision, indicating either:

- (i) its approval and authorization to apply for an import permit, with or without conditions, including how the approval will apply to subsequent imports of the same living modified organism; or
- (ii) denial or approval of the proposed import.

Article 33.-

In approving a request for the import of LMOs, into the Kingdom of Cambodia for direct use as food or feed or for processing, the Ministry of Environment may impose specific risk management measures, labeling or marking requirements, and/or other conditions on the proposed intentional introduction. If the request is approved, the Applicant must include the original approval with the application for the import permit.

If the request is denied, the Ministry of Environment must state the reasons for denying approval.

Article 34.-

When the Ministry of Environment approves a LMO for direct use as food or feed or for processing, it shall inform other parties to the Cartagena Protocol through the Biosafety Clearing-House within fifteen (15) days. This information shall contain at a minimum the information specified in Annex II of this Sub-decree.

Article 35.-

Any planting LMOs regardless, experiment, trial, the use for any purposes and use as modified seeds, shall follow to the standard and technical guidelines based on a case-by-case, which shall be issued by Prakas of Minister of Environment, by consultation with the line relevant ministries.

Any raising LMOs regardless, experiment, trial, the use for any purposes and use as animal breeds, shall follow to the standard and technical guidelines based on a case-by-case, which shall be issued by the Prakas of the Minister of Environment, by consultation with the line relevant ministries.

Article 36.-

Every application for import that was denied by Ministry of Environment as stated in Chapter IV of this Sub-Decree, the applicant has right to legally make a complaint according to the law entered into force.

Chapter V

Risk Assessment

Article 37.-

Risk assessment shall be carried out in a scientifically sound manner, in accordance with Annex III, using recognized risk assessment procedures.

Risk assessment shall be based on the information provided in the request for prior approval and any other available scientific evidence.

The Ministry of Environment, by consultation with relevant ministries, shall issues the detail declaration on the parameter for risk assessment and risk management.

Article 38.-

The Ministry of Environment shall audit risk assessments submitted by the Applicant and shall conduct or cause to be conducted any additional risk assessments as required on a case-by-case basis.

The SAT shall take into account any risk management measures proposed by the applicant and any additional risk management measures that may be necessary to minimize any identified risks.

Article 39.-

The applicant shall take the risk management measures mentioned in the following:

- Development of risk management strategy
- Providing an emergency response plan for accidental release
- Establishment mechanisms for internal monitoring of safety;
- Reporting immediately to the Ministry of Environment when the operator becomes aware of new scientific information indicating that these activities or operations and/or the LMOs involved may adversely affect the conservation and sustainable use of biodiversity, taking into account risks to human health;
- Taking measures to prevent an unintentional introduction of LMOs into the environment and to respond to and mitigate any

harm to biodiversity and human health when unintentional introduction into the environment occurs.

Article 40.-

Upon conclusion of reviewing risk assessment results and/or reviewing additional risk assessment results, the SAT shall provide to the Ministry of Environment a report with its recommendations for action on each request for prior approval, including any specific risk management measures, labeling or any requirements, and/or other conditions to be taken to ensure the safe use of the LMO.

The substance report stated in the above paragraph shall be summarized the risk assessment results of each application with feedbacks require to have a risk management strategy but shall not include any confidential information subject to protection under Chapter VII of the Law on Biosafety and Chapter VII of this Sub-decree.

Chapter VI

Exports of LMOs

Article 41.-

All exports of LMOs from the Kingdom of Cambodia shall be undertaken in according with Chapter IV of the Law on Biosafety.

Article 42.-

Any legal or natural person who intends to export LMOs covered by the Law on Biosafety from the Kingdom of Cambodia shall notify in writing to the competent national authority of the proposed importing country in writing, prior to applying to the concerned competent authority of the Kingdom of Cambodia for an export permit.

Article 43.-

A written notification to the competent national authority of the proposed country of import shall include information specified in Annex I of this sub decree.

The information described in the notification as mentioned in the above paragraph shall be certified as correctness by the Ministry of Environment.

Article 44.-

The detail procedure for export of LMOs shall be issued by the Prakas of Minister of Environment.

Chapter VII**Confidential Information****Article 45.-**

The Ministry of Environment shall request to the applicant to provide further information, in which the Applicant considered that it is the confidential information such as the information on announcement letter or on the documentary of the permitted request for import of LMO for keeping confidentiality.

In the case of stated above, the Ministry of Environment has right to make decision for approval or not approval to consider as the confidential information which was indicated by the applicant, providing the suitable reason to the applicant.

The confidential information is information which could not be flowed without permission.

The information was considered as confidential information unless the information consists of the follow key points:

- The information was kept as confidentiality from any one, even, the person works with the source of information;
- The information is valuable for commerce; and
- The information which the applicant shall has appropriate measure for keeping it.

Article 46.-

The applicant shall separate all confidential information and mark any page of the document application by writing as "confidential".

This confidential information shall then be sealed in a separate package to be opened only by the Secretary of secretariat of the National Steering Committee for Biosafety (NSCB), who shall be responsible for maintaining its confidentiality.

Article 47.-

Even the information that the Ministry of Environment has denied as confidential information, the Ministry of Environment shall provide the suitable reason and a chance to the Applicant for consultation before the information was appealed by Ministry of Environment.

Article 48-

All confidential information shall be made available to the Scientific Advisory Team (SAT) for the review on risk assessment and risk management.

Article 49-

In the case, the applicant proposes to withdraw or has withdrawn the approved request for import of LMO, the Ministry of Environment shall continue to keep the confidentiality of information which was proposed as confidential information, even the information, the Ministry of Environment was accepted as confidential information or not accepted.

Article 50-

The Ministry of Environment and other concerned competent authorities must not apply or permit the confidential information for any trade without the agreement in writing by the applicant.

Article 51-

Without referring to the article 50 above, certain information sated below, shall not be considered as confidential information:

- Name and address of the Applicant,
- General description of LMO,
- Summary report on risk assessment and negative impact on conservation and sustainable use of biodiversity to environment and human health, and
- Description of methodology and promptly response plan for emergency case or appeal by chance of LMO,

Article 52-

Relevant ministries, institutions and the public shall have the right to be aware of the risks of LMOs.

Chapter VIII

Risk Assessment Management

Article 53-

Whenever there accidentally leakage or exposure of living modified organisms, the Applicant or person who in charge on transportation or the happened place shall reporting to Ministry of Environment in emergency.

Article 54-

If the case of receiving information on the event resulting from the LMO application, the Chair of the NSCB shall take urgent measures to prevent the risk or harm or damage of biodiversity and/or human health.

Article 55-

While taking such urgent measures to response to the event occurred, the NSCB shall directly carry all activities in cooperation with signatory countries or international agencies as development donors to make an appropriate emergency response measures.

Article 56-

The Chair of the NSCB shall inform to its member for the emergency meeting to take urgent measures, if received the comment on whenever there accidentally as specified in article 55 above.

Chapter IX

Public Information, Awareness-raising and Participation

Article 57.-

The Ministry of Environment and other concerned competent ministries shall promote awareness of and education to the general public, with special attention to those conducting activities and operations concerning biosafety through dissemination of law on biosafety and regulation to implement the law on biosafety.

Article 58.-

The Ministry of Environment shall disseminate information regarding requests for prior approval to import into the Kingdom of

Cambodia LMOs for contained use, intentional introduction into the environment and/or for direct use as food or feed or for processing.

Article 59.-

The Ministry of Environment shall make available to the public any information that does not qualify as confidential under Article 25 of the Law on Biosafety.

Article 60.-

Any person may submit written comments on a request for prior approval within sixty (60) days from the date the notice is published. Such comments shall be considered as part of the decision making process. Any comments received by the Ministry of Environment and response thereto shall also be made available to the public upon request.

Chapter X

Resources

Article 61.-

The NSCB shall have a separate budget as a part of the Ministry of Environment's annual budget, which is disbursed by the national budget.

The NSCB shall have the right to receive funds and grant from development partners and from other resources to fulfill its work effectively.

Chapter X

Penalties

Article 62.-

Any contrary activities to any provisions of this sub-decree shall be subject to the penalties of law on biosafety and other relevant laws and regulation entered into force in the Kingdom of Cambodia.

Article 63.-

The administrative penalties, which shall be used for any activities contrary to this sub-decree, covers as follows:

- Warning in writing;

- Postpone or temporarily withdraw the prior approval letter issued by The Ministry of Environment; and
- Ultimately withdraw the prior approval letter issued by the Ministry of Environment.

The procedures of the administrative penalties shall be issued by the Prakas of the Minister of Environment.

Chapter XII

Transitory Provisions

Article 64.-

In six months (6) after this sub-decree enter into force, any legal or natural person, who have been undertaking or operating the producing, planting, and raising LMOs shall report to and provide relevant documents to NSCB to conduct risk assessment and set up risk management measures.

Chapter XIII

Final Provisions

Article 65.-

Any previous provisions concerning LMOs covered by the law on Biosafety contrary to this sub decree shall be considered null and void.

Article 66.-

The Minister in charge of the office of the Council of Ministers, the Minister of Environment, the Minister of Agriculture, Fisheries and Forestry, the Minister of Health, the Minister of Industry, Mine, and Energy, the Minister of Commerce, and secretaries of states of all other concerned ministries shall implement this Sub-decree from the date of its signature.

Phnom Penh, June 24, 2010

Prime Minister

**SAMDECH AKAK MOHASENA
BHDEY DECHO HUN SEN**

Annex I

Information Required in Requests for Prior Approval for Intentional Introduction in the Environment

- 1 Name, address and contact details of the exporter
- 2 Name, address and contact details of the importer,
- 3 Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export
- 4 Intended date or dates of the transboundary movement, if known
- 5 Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety
- 6 Centers of origin and centers of genetic diversity, if known., of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate
- 7 Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety
- 8 Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism
- 9 Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combination of replicable genetic material obtained through the use of modern technology
- 10 Quantity or volume of the living modified organism to be transferred
- 11 A previous and existing risk assessment report consistent with Annex II

- 12 Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate
- 13 Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban
- 14 Result and purpose of any request for prior approval by the exporter to other States regarding the living modified organism to be transferred
- 15 A declaration that the above mentioned information is factually correct.

Annex II

Information Required in Requests for Prior Approval for Import of Living Modified Organisms Intended for Direct Use as Food of Feed, or for Processing

1. The name and contact details of the applicant for a decision for domestic use.
2. The name and contact details of the authority responsible for the decision.
3. Name and identity of the living modified organism.
4. Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
5. Any unique identification of the living modified organism.
6. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
7. Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
8. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
9. Approved uses of the living modified organism.
10. A risk assessment report consistent with Annex III.
11. Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.

Annex III

Risk Assessment

Objective

1. The objective of risk assessment, under the Law on Biosafety, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, among other things, used by the Ministry of Environment to make decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk.

5. Risk associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by- case basis. The required information may vary in nature and level of detail from case to case depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about scientific subjects, which may be identified and requested during the assessment process, while on the

other hand information on other subjects may not be relevant in some instances.

8. To fulfill its objective, risk assessment entails, as appropriate, the following steps:

- (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risk to human health;
- (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
- (c) An evaluation of the consequences should these adverse effects be realized
- (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
- (e) A recommendation as to whether or not the risk are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
- (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristic of the following subjects:

- (a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centers of origin and centers of genetic diversity, if known, and a

description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organism;

(c) Vector. Characteristic of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristic of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centers of origin of the likely potential receiving environment.