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Kingdom of Cambodia
Nation Religion King



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ជីវសុវត្ថិភាព
Law
on
Biosafety**



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Promulgation

The Law on Biosafety , which was passed by the National Assembly on December 28, 2007 during the 7th Session, 3rd term and fully passed by the Senate on January 18, 2008 at the 4th session, 2nd term is promulgated on February 15, 2008 and elaborated as follows:

Kingdom of Cambodia
Nation Religion King

Law on Biosafety

CHAPTER I **General Provisions**

Article 1.

The objectives of this law are to:

- Implement the precautionary approach on biosafety;
- Prevent adverse impact on the conservation of biodiversity and natural resources in the Kingdom of Cambodia caused by the transboundary movement, development, handling, transfer, use, storage, and release of living modified organisms resulting from modern biotechnology;
- Ensure effective conservation of biodiversity and sustainable use of biological resources, taking also into account risks to human health;

- Provide a transparent process for making and reviewing decisions on living modified organisms and related activities and operations;
- Develop biotechnology education while preventing environmental and health hazards associated with the use and release of living modified organisms;

Article 2.

Technical terms used in this law shall have the following meaning:

-**"Applicant"** means a legal or natural person that notifies its intent to use living modified organisms and/or applies for prior approval to import into or export from the Kingdom of Cambodia any living modified organism for any purpose;

-**"Biosafety"** is a word to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products.

-**"Contained use"** means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

-**"Intentional introduction of LMOs into the environment"** means the deliberate use of LMOs subject to this act that is not contained use, including field release and planting, release into water and/or air, placing on the market for sale, free gifts/samples and donations but not including LMOs imported for direct use as food or feed, or for processing;

-**"Living modified organism (LMO)"** means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

-**"Living organism"** means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

-**"Modern biotechnology"** means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Article 3.

This law shall apply to the import and export, contained use, intentional introduction into the environment, and direct use as food or feed or for processing of living modified organisms that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

This law shall not apply to:

- Living modified organisms that are pharmaceuticals for human use that are addressed by relevant international agreements and/or organizations;
- Living modified organisms in transit through but not destined for use in the Kingdom of Cambodia;
- Any other categories of living modified organisms that may be exempted by the National Competent Authority; and
- Any processed products containing dead modified organisms or non-living components of genetically modified organisms.

Article 4.

Any legal or natural person who wants to conduct any activity or operation involving contained use, intentional introduction into the environment, and/or direct use as food or feed or for processing of LMOs in the Kingdom of Cambodia shall be subject to approval by the Ministry of Environment prior to authorization by the concerned competent authority.

Any activity or operation involving LMOs covered by this law shall comply with the standards and measures for managing and controlling

the risks identified in the risk assessment process established under Chapter V.

Article 5.

Any legal or natural person responsible for any activity or operation involving LMOs covered by this law shall ensure that contained use, intentional introduction into the environment, direct use as food, feed or for processing, import, and export of LMOs is carried out in conformity with this law and all Sub-decrees implementing this law by, among other things:

- Developing a risk management strategy;
- Providing an emergency response plan for accidental release;
- Establishing 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.

CHAPTER II **Institutional Arrangements**

Article 6.

In collaboration with other concerned ministries, the Ministry of Environment shall manage and control all activities and operations involving LMOs covered by this law.

The Ministry of Environment shall be the National Focal Point and National Competent Authority for implementing the provisions of this law and those of the Cartagena Protocol.

Article 7.

As the National Focal Point stated in Article 6 above, Ministry of Environment shall be the primary contact between the Royal Government of Cambodia and the Secretariat of the Cartagena Protocol.

As the National Competent Authority, the Ministry of Environment shall be responsible for the administrative functions required to implement this law. These functions shall include timely notification to other States, the Biosafety Clearing-House, and relevant international organizations of any event in the Kingdom of Cambodia that may result in the unintentional trans-boundary movement of an LMO.

An authorized official of the Ministry of Environment, in collaboration with designated officers from Ministry of Agriculture, Forestry and Fisheries, may enter and inspect the premises where any activities or operations involving LMOs covered by this law are being, or have been, carried out, take samples and/or confiscate LMOs to facilitate further investigation.

Article 8.

The Royal Government shall establish, following a proposal by the Ministry of Environment, a Scientific Advisory Team (SAT) to provide scientific and other technical advice to the Ministry of Environment in reviewing the applications, applications, risk assessments and approvals, and in setting standards for facilities, operations and activities involving LMOs subject to this law. Ministry of Agriculture, Forestry and Fisheries shall be the chairperson and Ministry of Environment shall be vice-chairperson for the SAT.

Article 9.

The Royal Government shall establish a National Steering Committee for Biosafety chaired by the Minister for Environment to serve as the leading body in the development of a biosafety policy and strategic planning.

CHAPTER III

Import of LMOs

Article 10.

The first import of an LMO into the Kingdom of Cambodia for contained use shall be subject to risk assessment and approval by the Ministry of Environment prior to application to the concerned competent authority for the import permit.

Article 11.

All imports of LMOs into the Kingdom of Cambodia for intentional introduction into the environment shall be subject to risk assessment and approval by the Ministry of Environment prior to application to the concerned competent authority for the import permit.

The applicant shall notify the Ministry of Environment of the intent to import.

Article 12.

Within ninety (90) days, the Ministry of Environment shall acknowledge the receipt of the application and advise the applicant whether it may proceed to the prior approval process.

Article 13.

Within two hundred and seventy days (270 days) after receiving the application as stipulated in articles 11 and 12, the Ministry of Environment shall notify the applicant in writing and the national Biosafety Clearing-House on its decision.

Article 14.

The first import into the Kingdom of Cambodia of an LMO for direct use as food or feed or for processing shall be subject to risk assessment and prior approval by the Ministry of Environment, in consultation

with the concerned competent authority, prior to application for the import permit.

Any legal or natural person who wants to import an LMO for direct use as food or feed or for processing shall submit to the Ministry of Environment written certification issued by the Competent National Authority of the State of export that attests to the accuracy of the information provided concerning the LMO to be imported.

Article 15.

When the Ministry of Environment approves any 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.

Article 16.

The letter of approval of the Ministry of Environment must be attached to the import permit for any LMO.

CHAPTER IV Export of LMOs

Article 17.

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

Article 18.

The concerned competent authority of the Kingdom of Cambodia may issue a permit to export LMOs only after receipt of authorization in writing from the national competent authority of the proposed importing State. The authorization from the proposed importing party

must be attached to the export permit and/or other documentation accompanying the consignment.

Article 19.

The exporter shall get from the Ministry of Environment written certification of the accuracy of all information provided about the LMO to be exported. Such certification shall be attached to the export permit and/or other documentation accompanying the consignment.

CHAPTER V Risk Assessment

Article 20.

The Ministry of Environment shall ensure that appropriate risk assessments are carried out for all actions related to LMOs that require prior approval under this law.

Article 21.

The exporter/applicant shall carry out the risk assessment and shall bear all related costs. Upon receipt of the results of the risk assessment and other documentation required under this law, the Ministry of Environment may grant approval with or without conditions, request additional information, or deny approval.

CHAPTER VI Documentation for LMOs

Article 22.

Any legal or natural person who imports LMOs into or exports LMOs from the Kingdom of Cambodia for any purpose shall provide accompanying documentation that clearly identifies them as LMOs and specifies any requirements for their safe handling, transport, use, and storage.

Article 23.

Except any law or regulations otherwise specify, LMOs that are imported into or exported from the Kingdom of Cambodia shall be accompanied during transboundary movement and upon delivery to the port of entry by documentations that cover:

- 1- LMOs for direct use as food or feed or for processing, clearly identify that the goods may contain LMOs and are not intended for intentional introduction into the environment;
- 2- LMOs for intentional introduction into the environment, specify their identity and relevant characteristics and any requirements for their safe handling, transport, use, and storage, specifies the contact point for further information, and also states that the transboundary movement is in conformity with the requirements of Cartagena Protocol applicable to the exporter;
- 3- LMOs for contained use, clearly identify them as LMOs, specify any requirements for their safe handling, transport, use and storage, and specify the contact point for further information including the name and address of the individual and the institution to which the LMOs are consigned.

Article 24.

Living modified organisms and items containing living modified organisms shall be clearly labeled.

CHAPTER VII Confidential Information

Article 25.

The Ministry of Environment shall require the applicant/importer to provide some information that applicant regard as confidential information to ensure confidentiality.

In the above mentioned case, the Ministry of Environment may decide whether it accepts as confidential the information designated by the applicant.

Article 26.

The Ministry of Environment shall decide whether it accepts or rejects the claims of confidentiality of information to applicant with appropriate justification.

Article 27.

The Ministry of Environment and other concerned ministries shall protect confidential information under Article 25. The use or permit the use of such confidential information shall have the written consent of the applicant before public dissemination.

Article 28.

Detail procedures on confidential information and public information dissemination shall state in the Sub-Decree.

CHAPTER VIII

Review of Decisions

Article 29.

The Ministry of Environment and concerned ministries may review any decision on activities, operations, import or export at any time on obtaining significant new information indicating that the LMOs or the activities, operations, import or export involved may adversely affect the conservation and sustainable use of biodiversity, taking also into account risks to human health.

When the Ministry of Environment revises any decision on an LMO covered by this law it shall inform the Biosafety Clearing-House.

Article 30.

If the Ministry of Environment changes a decision approving import of any LMO for any purpose, the Ministry of Environment shall, within thirty (30) days, inform the applicant that has previously applied for and/or received approval to import the LMO of the reasons for its revised decision.

Article 31.

Any applicant whose request for prior approval of import of an LMO has been denied may request the Ministry of Environment to review its decision when there is additional technical and scientific information available and/or when the applicant considers there has been a change of circumstances that may influence the outcome of the risk assessment.

After considering the new information and/or changed circumstances, the Ministry of Environment may revise or maintain its original decision and shall respond in writing within ninety (90) days, giving the reason for its decision.

CHAPTER IX

Public Information, Awareness Public and Public Participation

Article 32.

The Ministry of Environment and other concerned ministries shall promote awareness and education for the general public stipulated by this law.

Article 33.

Information related to LMOs shall be regularly disseminated among the Ministry of Environment and other concerned authorities.

Article 34.

The Ministry of Environment and other concerned ministries shall encourage public to participate and provide feedback in planning and decision making process relevant to biosafety issues.

CHAPTER X

Penalties

Article 35.

Penalty of biosafety crime composes of: imprisonment, fine in cash, transitional fine, confiscation, and warning.

Imprisonment, fine, and confiscation are under the court jurisdiction.

Transitional fine and warning are under the competence of Ministry of Environment.

In the case of violator denies the transitional fine, Ministry of Environment shall prepare a complaint case to the competent court.

Article 36.

Fine under any verdict or court decision or transitional fine or money from selling evidences shall return to the national treasury.

Article 37.

Legal or natural person, who is permitted to operate or conduct LMOs related activities, become aware of any significant new scientific information finding out risks from his or her activities may adversely affect the conservation and sustainable use of biodiversity and/or human health but fails to report to Ministry of Environment, shall be subject to a written censure.

Ministry of Environment shall review its decision and/or cancel the permit.

Article 38.

Any operator who obstructs or causes the obstruction of an authorized official of the Ministry of Environment in the process of fulfilling his/her duties under paragraph 3 of article 7 of this law shall be fined by the Ministry of Environment an amount between five hundred thousand (500,000) Riel to one million (1,000,000) Riel.

In the event of repeated offenses, Ministry of Environment shall make a complaint to a competent court.

Article 39.

Any violator of the provisions of article 10, article 11, or article 14 of this law shall be fined by the Ministry of Environment an amount between one million (1,000,000) Riel to five million (5,000,000) Riel.

In the event of repeated offenses, the fine shall be doubled without prejudice to other crimes resulting in adverse effects on the conservation and sustainable use of biodiversity and/or human health.

Article 40.

Anyone who has given, by any mean, intentionally false, misleading or confusing information required by the provisions of Article 22 of this law shall be subject to imprisonment for one (1) year to five (5) years and/or a fine of four million (4,000,000) Riel to twenty million (20,000,000) Riel.

In the event of repeated offenses, the fine and criminal sanction shall be doubled without prejudice to other serious crimes resulting in adverse effects on the conservation and sustainable use of biodiversity and/ or human health.

Article 41.

In the case of having a clear evidence that legal or natural person as stipulated article 37 intentionally conceals information on risks caused by living modified organisms related activities on biodiversity and/or human health, shall be fined from ten million (10,000,000) riel to fifty million (50,000,000) riel or to imprison from one year to five years or both.

Article 42.

All evidences concerning LMO-related activities and equipment which is the subject of offenses committed as stipulated in article 39 and 40 shall be confiscated. The act of confiscation shall be within the jurisdiction of the court.

Article 43.

Any environmental inspection official or agent who is negligent, fails to pay attention to, or fails to comply with rules and regulation of the Ministry of Environment or conspires with a violator or facilitates the commission of violation, shall be subject to administrative sanctions or faces prosecution before the court.

Any environmental inspection official or agent that take part in the misconduct or facilitate in the fraud process shall be applied the same punishment as mentioned in this article.

CHAPTER XI Final Provisions

Article 44.

Ministry of Environment shall consider issuing regulations, rules, orders and guideline to implement this law especially provision stipulated under: article 6, 15, 17, 20, 22, 25 and 31 of this law.

Article 45.

Any previous provisions contrary to this law shall be considered as null and void.

Annex

Terms

- **Contained use:** means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.
- **Intentional introduction of LMOs into the environment:** means the deliberate use of LMOs subject to this act that is not contained use, including field release and planting, release into water and/or air but not including LMOs imported for direct use as food or feed, or for processing.
- **Modern biotechnology:** means the application of:
 - In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
 - Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.
- **DNA:** Abbreviation for deoxyribonucleic acid, former spelling desoxyribonucleic acid. A long chain polymer of **deoxyribonucleotides**. **DNA** constitutes the genetic material of most known organisms and organelles, and usually is in the form of a double helix, although some viral genomes consist of a single strand of **DNA**, and others of a single- or a double-stranded **RNA**.
- **Living organism:** means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

- **Abiotic:** Absence of living organisms. The part of living modified organisms, which incapable of sexual, plants, or feeds to consider as Abiotec component.
- **Risk:** means the risk of living modified organisms on environment, biodiversity, social, culture, and economic.
- **Transboundary movement:** means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.
- **National Focal Point:** means the government agencies, which responsible on its behalf for liaison CBD secretariat and Cartagena Protocol on Biosafety and the member parties.
- **Competent National Authorities:** means the ministries and departments, which designed by the government for research and development on LMOs uses and LMOs risk assessment.
- **Biological Diversity:** means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

