



Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/L&R/RW-APAC/1/2
8 November 2011

ORIGINAL: ENGLISH

ASIA-PACIFIC REGIONAL WORKSHOP ON THE
NAGOYA – KUALA LUMPUR SUPPLEMENTARY
PROTOCOL ON LIABILITY AND REDRESS TO THE
CARTAGENA PROTOCOL ON BIOSAFETY
New Delhi, India, 17-18 November 2011

DOMESTIC BIOSAFETY OR ENVIRONMENTAL LAWS AND REGULATIONS WHICH INCLUDE PROVISIONS ON LIABILITY AND REDRESS

I. INTRODUCTION

1. This document presents an overview of liability and redress provisions included in domestic laws and regulations that are in force or in draft form, of some Parties to the Biosafety Protocol in the Asia and Pacific region. The overview includes only domestic laws and regulations or the summary of such laws that have been made available to the Biosafety Clearing-House (BCH) by the Parties themselves.
2. The relevant provisions highlighted in the present document may be official versions in English or unofficial English translations depending on whether a copy of the original or equivalent translation was made available by each Party for the purpose of fulfilling the obligations under the Biosafety Protocol. Article 20 of the Cartagena Protocol requires each Party to make available to the BCH any relevant national laws and regulations regarding living modified organisms.
3. While each Party is expected to maintain complete, accurate and up-to-date information in the BCH, some of the laws and regulations referred to in the present overview might have already undergone changes and therefore may not reflect the latest status.
4. The Secretariat invites Parties to review, confirm or update the timeliness, completeness, and accuracy of all the information that they have made available to the BCH, in particular information on their domestic laws, regulations and guidelines adopted for the implementation of the Biosafety Protocol.

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II. DOMESTIC LAWS AND REGULATIONS WHICH INCLUDE PROVISIONS ON LIABILITY AND REDRESS FOR DAMAGE RESULTING FROM LIVING MODIFIED ORGANISMS

BANGLADESH

- a) **Biosafety Guidelines of Bangladesh, 2005**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1495>

**CHAPTER III
GENERAL PROVISIONS ON BIOSAFETY**

3.1. RISK ASSESSMENT

3.1.6. Criteria for Risk Assessment

v. *The primary responsibility for the safe use or transfer of organisms GMOs/LMOs or their products lies with the user. Consequently users should be well informed, competent and well aware of their responsibility.*

3.3. Sanctions against violation of Biosafety guidelines

In addition to the revocation of the project approval, any violation of the provisions of this guideline or the concealment or withholding by the proponent of any information necessary to evaluate risks to human health or the environment shall be penalized by the concerned ministry by stopping the work immediately and forfeiting the government grants/funds.

Further, any incentives that may have been granted the proponent or institution for contributing to advanced scientific or technological research and development will be withheld. These penalties are exclusive of any other penalties tenable by existing law. It means that until and unless, specific acts and rules pertaining to Biosafety of GMO/LMO is in place, any activity undertaken in violation of Biosafety guidelines shall also be treated under the penal provisions of existing law, including, but not limited to, civil, criminal and administrative liabilities for gross negligence.

The NCB will inform the government (MOEF) on all issues pertaining to violations of these guidelines by any organization. The Ministry will, if necessary issue public statement on any such violation to caution other organizations.

- b) **National Biosafety Framework, 2006**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1338>

**CHAPTER 3
3. REGULATORY REGIME ON BIOSAFETY**

3.5.7. Offences and penalties

Violation of any of the rules, or conditions attached in the license, etc should constitute an offence. If rules are made under the ECA 1995, the offences should be punishable under the Act itself.

3.5.8. Jurisdiction of environmental courts

In the case of establishing regulations under the ECA, 1995; the Environmental Courts should have jurisdiction to try the offences or to award damages or to provide civil remedies arising from the illegal dealings with GMOs under the Rules/Acts to be framed.

CHAPTER 5
5. MONITORING AND ENFORCEMENT

5.11. Liability and redress

Although no specific provisions are mentioned for liability and redress it is anticipated that existing provisions would be applicable in any unlikely event raising the liability and redress issues.

c) Annex 2: Statutes with potential relevance to biosafety

9. Environmental laws
9. C. The Environment Court Act

(i) Title: The Environment Court Act (Act No. 11 of 2000)

(ii) Status: adopted, year of adoption: 2000

(iii) What does it regulate? It provides for the establishment of environmental courts in Bangladesh.

(iv) Brief summary of the procedures and content: Section 4 of the Act empowers the Government to establish one or more environmental court (s) in each division in order to fulfil the purposes of this Act. Section 5 deals with the jurisdiction of environmental courts. Under section 8(1), environmental courts will be treated as criminal courts while trying offences committed under the 1995 Act and in such cases courts will follow the procedures prescribed for session courts in the Criminal Procedure Code, 1898. Under section 8(6), environmental courts will be treated as civil courts while trying suits for damages and in such cases the Code of Civil Procedure, 1908 will apply. Under section 11, an aggrieved person may prefer an appeal to a higher court within 30 days from the date of decrees or orders passed by environmental courts.

(v) Responsible institutions for implementing the law: Department of Environment; High Court Division of the Supreme Court; Ministry of Law, Justice and Parliamentary Affairs.

(vi) Gaps in the law: There is no clear provision in the Act to deal with GMOs related disputes or disputes that might arise from the adverse impacts of GMOs on the environment, biodiversity or human health. Rules may be made under section 20 of the 1995 Act to empower the environment courts to try matters relating to GMOs.

Bibliographic reference: BG dated 10 April 2000; 52 DLR 2000, pp. 45-48.

BHUTAN

- a) Draft Biosafety Rules and Regulations of Bhutan
Annex 1 to the Draft National Biosafety Framework (2006)**
<http://bch.biodiv.org/database/attachedfile.aspx?id=3326>

DEFINITION OF TERMS

f. “Emergency” means any significant unintended release into the environment of genetically modified organisms or products of genetically modified organisms which could present an immediate or delayed hazard to human health or the environment.

n. “Operator” means a legal or natural person, national or non-national, whether authorized or unauthorized, that undertakes any activity or operation including but not limited to import, development, fermentation, export, contained use, intentional release into the environment, and field testing of any GMO for any purpose in the Kingdom.

MANAGEMENT

9. *The Bhutan Agriculture and Food Regulatory Authority (BAFRA) is designated as the National Competent Authority for the purpose of administering this Rules and Regulations. BAFRA has the sole authority to grant or deny permission for import, export and use of GMOs and GMO products in the Kingdom. In implementing this Rules and Regulations, BAFRA shall perform the following functions:*

g. Ensure that mechanisms are in place to communicate information and receive comments concerning applications, decisions, emergencies, and other matters related to GMOs and GMO products, including but not limited to through the BBCH;

l. In coordination with other relevant national authorities, develop special safety and emergency measures to respond to and contain the effects of any risks and damages that might result from an unintentional transboundary movement or any activity that relates to GMOs;

p. Enforce this Rules and Regulations and monitor compliance with it;

PROCEDURES

29. *All in-country operations involving GMOs and GMO products are subject to payment of a security bond which amounts to 25% of the total value of the activity or operation must be deposited with BAFRA at the time of prior approval. The amount of the bond shall be returned to the Operator, without interest, on completion of the activity or operation for which prior approval or permission is granted. The security bond shall be used, if needed, to recover any unforeseen costs associated with issues of non-compliance and/or for risk management actions.*

Emergency response

63. *BAFRA shall, in coordination with the relevant agencies, form an emergency response team to deal with emergencies involving GMOs or for the use of GMOs in an emergency within the Kingdom. BAFRA shall issue guidelines for these purposes.*

64. *In the event of an emergency involving a GMO or GMO product, any person with knowledge of the emergency must immediately inform BAFRA or Geog and/or Dzongkhag authorities who must immediately notify BAFRA.*

65. *In the event that an emergency may lead to an unintentional transboundary movement of a LMO that is likely to have significant adverse effects on the environment, on the conservation and sustainable use of biological resources or on human health, BAFRA shall immediately notify the NEC, which shall immediately notify the BCH, the potentially affected States, and any relevant international organizations.*

Inspection

72. *Where there is a clear and present danger for human health or the environment, an authorized inspector may immediately destroy or order the destruction of GMOs and/or GMO products at the owner's cost.*

75. *Where BAFRA has reasonable grounds to believe that any condition of a permit issued under this Rules and Regulations has been breached, BAFRA may serve an order on the holder of the permit in question:*

a. requiring that person to remedy the breach within a specified period at his/her own cost; or

b. suspending the permit with immediate effect if this is considered necessary to prevent or mitigate an immediate risk of significant adverse effects to the environment or to human health.

Liability

78. *No authorized official of the Royal Government shall be jointly or severally liable in respect of anything done in good faith in the exercise of a power or duty under this Rules and Regulations unless the act or omission contravenes any of the provisions of this Rules and Regulations or any direction or order made pursuant to it. The relevant agency shall be liable for paying the appropriate compensation.*

79. *Any person who intentionally or negligently commits any act or is responsible for an omission involving GMOs and/or GMO products which causes damage or threatens potential harm to human health and the environment shall be liable for the costs of restoration and remediation.*

Legal action

80. *Legal action may be initiated by any person affected by damage or threatened by potential harm to human health or the environment caused by violations of this Rules and Regulations, on that person's own behalf or on behalf of that person and other affected persons having similar or common interests in the proceedings.*

Offences and penalties

81. *Offences under this Rules and Regulations which are listed in the Penal Code shall be penalized as provided in the Penal Code.*

82. *The following offences not listed in the Penal Code shall be penalized as follows:*

a. *The penalty for any transboundary movement of GMOs and/or GMO products that is not accompanied by the permits specified in this Rules and Regulations shall be a cash fine not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, or imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate. The person responsible for the unauthorized transboundary movement of any GMO shall, at the discretion of BAFRA, repatriate or destroy the GMO at his/her own expense;*

b. *The penalty for breaching the conditions of a permit or order issued under this Rules and Regulations shall be payment of a cash fine not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, or imprisonment for not less than one (1) month and not longer than one (1) year, or both, as appropriate;*

c. *The penalty for failure to comply with an order issued under this Rules and Regulations shall be payment of a cash fine equivalent to the value of the damage caused, imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate;*

d. *The penalty for making a statement that is false or misleading for the purposes of obtaining an authorisation under this Rules and Regulations shall be payment of a cash fine of not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate;*

e. *The penalty for making a statement that is false or misleading for the purposes of obstructing an inspector in the exercise or performance of powers or duties under this Rules and Regulations shall be payment of a cash fine not less than the equivalent of ten (10) man/months at the National Wage Rate applicable at the time of the imposition of the fine and not greater than one hundred (100) man/months at the National Wage Rate applicable at the time of the imposition of the fine, or imprisonment for not less than one (1) month and not longer than one (1) year, or both, as appropriate.*

83. *If any of the offences set out in Sections 81 are committed by a corporation, the corporation and every director or officer of the corporation shall be jointly and severally liable. The penalty shall be payment of*

a cash fine of not less than one (1) per cent of the total value of the operation and not greater than ten (10) per cent of the total value of the operation, or imprisonment for not less than one (1) year and not longer than three (3) years, or both, as appropriate.

CAMBODIA

- a) **Second Draft Law on Biosafety
Annex 3 of the National Biosafety Framework (2004)**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1340>

CHAPTER I General Provisions 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 X Penalties Article 36

Any violator of the provisions of Articles 4, 11, or 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 37

Anyone who has given, by any mean, deliberately false, misleading or confusing written or verbal information required by the provisions of Articles 22 or 23 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 39

Any operator that becomes aware of any significant new scientific information indicating that his or her

authorized activities involving LMOs may adversely affect the conservation and sustainable use of biodiversity and/or human health but fails to report to the Ministry of Environment or intentionally conceals this information shall be subject to a fine of ten million (10,000,000) Riel to fifty million (50,000,000) Riel or to imprisonment for one (1) year to five (5) years or both.

Article 40

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, shall be fined from one million (1,000,000) Riel to five million (5,000,000) Riel or imprisoned from one (1) month to three months or both.

- b) Draft Sub decree on the Management and Control of Living Modified Organism
Annex 7 of the National Biosafety Framework (2004)
<http://bch.biodiv.org/database/attachedfile.aspx?id=1340>**

Chapter IX Penalty Article 38

Any person who violates any provision of this sub decree shall be subject to punishment according to chapter 10 of the Law on Biosafety.

In the event of an accidental release or unintentional release, the operator or user shall mitigate the damage immediately and pay for its full cost.

CHINA

- a) Regulations on Safety of Agricultural Genetically Modified Organisms
<http://bch.biodiv.org/database/attachedfile.aspx?id=557>**

Chapter III Production and Processing

Article 24 *When any accident happens during the process of production and processing of agricultural GMOs, the organization or person engaged in such production and processing shall immediately take remedial measures and report to the local agricultural administrative department of the people's government at the county level.*

Chapter VI Supervision and Inspection

Article 42 *When discovering that agricultural GMOs endanger human beings, animals, plants or the environment, the competent agricultural administrative department of the State Council has the power to prohibit the production, processing, GMOs, or to destroy the agricultural GMOs in question.*

Chapter VII Penalty Provisions

Article 44 *Those who, in violation of these Regulation, arbitrarily conduct enlarged field testing or productive testing without approval, or with approval but fail to take safety management measures in accordance with the relevant provisions, or conduct testing beyond the approved scope, shall be ordered to stop testing and to pay a fine of not less than 10,000 yuan but not more than 50,000 yuan by the*

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competent agricultural administrative department of the State Council or the agricultural administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government in accordance with their respective functions and powers.

Article 54 *Those who, in violation of these Regulations, cause an accident in research, testing, production, processing, storage, transportation, marketing, import or export of agricultural GMOs, thus resulting in any damage, shall bear the liability for compensation in accordance with law.*

DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA

- a) **Regulations on the Safe Management of GMOs (interim)**
Appendix II of the National Biosafety Framework, July, 2004
<http://bch.biodiv.org/database/attachedfile.aspx?id=1345>

Chapter 1. General Provisions

Article 3 *These regulations shall apply to the institutions, enterprises and associations (hereinafter called institutions and enterprises), DPRK citizens, DPRK compatriots residing outside the territory of DPRK, foreign-invested enterprises and foreign individuals related to management of safety of GMOs.*

Article 23 *The institutions, enterprises and individuals shall disinfect thoroughly the GMOs whose approval has been cancelled and treat the affected soil in physical and chemical manner.*

Article 25 *When any escape of GMOs occurs, the institutions, enterprises and individuals shall evaluate the detailed contents and adverse effects of GMOs in time and take the emergency measures and then inform SAGOST accordingly.*

Article 26 *The institutions and enterprises desiring to transport the GMOs shall ensure the containment, package and proper labeling to prevent the escape of GMOs, and take appropriate measures so as not to affect the human health and the environment in case of embarkation and disembarkation.*

Chapter 4. Supervision and Control

Article 30 *In case of breach of these regulations, those who are convicted of offence on these regulations shall be liable to the administrative punishment such as the cessation of R&D, introduction, moving of GMOs, compensation for damages and fines according to the severity of the cases and even to the criminal penalties.*

INDIA

- a) **Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/Genetically engineered organisms or cells**
<http://bch.biodiv.org/database/attachedfile.aspx?id=540>

4. COMPETENT AUTHORITIES

(3) Institutional Biosafety Committee (IBSC)

The committee or any person/s authorised by it shall have powers to take punitive action under the Environment (Protection) Act.

15. PENALTIES

- (1) *If an order is not complied with, the District Level Committee or State Biotechnology Co-ordination Committee may take measures at the expenses of the person who is responsible.*
- (2) *In cases where immediate interventions is required in order to prevent any damage to the environment, nature or health, the District level Committee or State Biotechnology Co-ordination Committee may take the necessary steps without issuing any orders or notice. The expenses incurred for this purpose will be repayable by the person responsible for such damage.*

16. RESPONSIBILITY TO NOTIFY INTERRUPTIONS OR ACCIDENTS

- (1) *Any person who under rule 7-11 is responsible for conditions or arrangements shall immediately notify the District Level Committee \State Biotechnology Co-ordination Committee and the state medical officer of any interruption of operations or accidents that may lead to discharges of genetically engineered organisms or cells which may be harmful to the environment, nature or health or involve any danger thereto.*
- (2) *Any notice given under sub-rule (1) above shall not lessen the duty of the person who is responsible to try effectively to minimise or prevent the effects of interruptions of operations of accidents.*

INDONESIA

- a) **Joint Decree of the Minister of Agriculture, the Minister of Forestry and Estate Crops, the Minister of Health, and the State Minister of Food and Horticulture Concerning Biosafety and Food Safety of Genetically Engineered Agricultural Products, 1999**
<http://indonesiabch.org/docs/dec1999.pdf>

CHAPTER V RIGHTS AND OBLIGATIONS Article 43

When the GEAP (Genetically engineered agricultural products) causes biosafety and food safety harm, then in that case the person or legal entity who or which has obtained approval for the utilization of the GEAP is obligated to participate in the control and overcoming.

- b) **Regulation of the Government of the Republic of Indonesia number 21, year 2005, on Biosafety of Genetically Engineered Product (GEP)**
<http://bch.cbd.int/database/record.shtml?documentid=11576>

CHAPTER VI SUPERVISION AND CONTROL OF GEP Article 27

(1) Any person who produces, imports from abroad and or distribute GEP which appears to create negative impact on the environment, human health and or animal health, shall report the accident to the Minister, competent Minister and or Head of competent LPND.

(2) Any consumer or community knowing the release, distribution and or use of GEP, which appears to create negative impact on environment, human health and or animal health may report the case to the Minister, competent Minister and or Head of competent LPND.

(3) *The Minister, competent Minister and or Head of competent LPND, after receiving the report as referred to in the paragraph (10) and paragraph (2) shall assign BC to conduct inspection and prove the correctness of the report.*

(4) *If the inspection result shows that the GEP so reported has caused negative impact on environment, human health and or animal health then:*

a. The Minister shall suggest the competent Minister or Head of competent LPND to revoke the decision of release or distribution of the GEP.

b. The competent Minister or the Head of competent LPND shall then revoke the decision of release and distribution of GEP.

(5) *If the released GEP is found to create negative impact on environment, human health and or animal health then the responsible person shall conduct control as well as prevention and withdrawal of the related GEP from distribution.*

(6) *Further regulation on GEP withdrawal shall be provided by the competent Minister or Head of competent LPND, based on input from BC;*

ISLAMIC REPUBLIC OF IRAN

a) National Biosafety Act, 2009

<http://bch.cbd.int/database/attachment/?id=10351>

Article 6:

In case that each one of the competent administrative bodies observe any violation of any provision of this act by the actions of real and legal entities are obliged to temporarily suspend the permit and forward the issue to the competent judicial authorities for judicial investigation. The judicial authority should investigate the documents out of queue. In case of confirmation of violation by the judicial authority if the violation has caused damage to the rights of other peoples or has caused harm or damage to other people or environment, the guilty person is sentenced to compensate up to 3 times the introduced damage, in case of repeating for a second time, apart from the above method all of the previous permits are cancelled and all of his/her activities are prevented.

Article 9:

At the same time that a real or legal entity submits his/her request to the administrative body to receive a permit, he/she should prepare an emergency plan for conservation of the environment, biodiversity, human health, livestock and plants. This emergency plan should consist of emergency measures and other services to confront with conditions arising from unintended release and submit it to the administrative body.

Amendment: In case of any emergency condition arising from accidents or unintentional release of LMOs, the competent administrative body has the authority to officially notify the certificate holder and withdraw some of the confidential information from the classification status and submit them to other administrative bodies to carry out other necessary actions. In this case, the certificate holder has no right to claim.

b) Draft National Biosafety Framework, 2004

<http://bch.cbd.int/database/record.shtml?documentid=43440>

PART THREE: REGULATORY REGIME ON BIOSAFETY

3. Laws and Enforcement systems

3.2. Existing Laws and Regulations in the Islamic Republic of Iran related to Biosafety

With regard to liability, Article 14 of the Environmental Protection and Enhancement Act enables the Department of Environment, as a representative of the government, to claim compensation before Iranian courts for any recorded damage caused to the environment and/or ecological balance in the country.

More generally, in accordance with Iran's Civil Code and Civil Liability Act, each individual has a right to claim compensation before Iranian courts for any prejudice caused to his/her person and/or health. The courts are bound to file their suit and to deliver a verdict compensating the plaintiff.

Gaps and conclusions

In case of damage caused to the environment by any activity in relation to LMO or products thereof, liability and redress still need to be specifically defined in the national legislation.

3.3. Suggested biosafety related laws

3.3.1. Liability and redress

- *Applicants who carry out any activity in relation to LMO(s) or products thereof shall be strictly liable for any harm injury or loss caused directly or indirectly by such LMO (s) or products thereof any activity in relation to them. The harm injury or loss includes personal injury damage to property financial loss and damage to the environment or to biological diversity.*
- *Liability shall attach to the applicant, the person responsible for the activity which results in the damage injury or loss as well as to the provider, supplier or developer of the LMO(s) or products thereof.*
- *If there is more than one person responsible for the damage, injury or loss then the liability shall be joint and several.*
- *In the case of harm to the environment or to biological diversity, redress shall include the costs of reinstatement, rehabilitation or clean – up measures actually incurred or to be incurred and, where applicable, the costs of preventive measures and any loss or damage caused by the taking of the preventive measures; provided that the person responsible may be required to carry out the reinstatement or rehabilitation at its own cost and to the satisfaction of the National Biosafety Committee.*

More details on this section are in appendix 9.

3.3.2. A Draft of the National Biosafety Law

Pivotal and general issues which have to be included and considered in the draft of the National Biosafety Law (at present, necessary measures are being taken for the ratification of this draft in a governmental commission) are:

- *Any event resulting from carelessness or lack of caution or from ignoring governmental rules and regulations can potentially be considered an offence; in addition, in certain cases, such events can damage the environment and human health. That is why a particular chapter or article should be included in the law dealing with compensation of possible damages.*

Appendix 9, Transfer and transboundary movements of LMOs (export, import and labeling)

9.5. Liability and Redress

- *Where liability under this section is incurred by a body corporate any director manager secretary or similar officer of the body corporate shall be similarly liable unless he/she can show that he/she did*

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everything in his/her power to prevent the import, deliberate release, placing on the market or contained use which caused the damage in question.

- *Where proceedings are brought against more than one person it shall not be a requirement for the person bringing the proceedings to identify the person who caused the damage in question provided that he/she can prove that one or more of the persons so proceeded against could have caused the damage.*
- *Liability shall also extend to harm or damage caused directly or indirectly by the LMO(s) or products thereof to the economy social or cultural practices livelihoods indigenous knowledge systems, or indigenous technologies. Such harm includes the following: disruption or damage to production systems, agricultural systems, reduction in yields, and damage to the economy of an area or community.*
- *An applicant shall indemnify:*
 - *any other person who deliberately releases or markets LMO(s) or products thereof; and*
 - *any person who manufactures, processes or markets food, food ingredients or animal feed containing or derived from LMO(s) against any civil liability where the LMO(s) or products thereof in question was first imported, deliberately released, used in contained conditions, or placed on the market by the applicant.*
- *An applicant shall indemnify against any civil liability any person who fails to label seeds, food, a food ingredient or animal feed containing or derived from GMO(s), but where the applicant can show that he took all reasonable steps to prevent such failure the indemnity shall not apply.*
- *The right to bring any action to redress the harm caused by the GMO(s) or products thereof shall lapse only after a reasonable period from the date on which the affected person or community could reasonably be expected to have learned of the harm, taking due account of:*
 - (a) the time the harm may take to manifest; and*
 - (b) the time that it may reasonably take to co-relate the harm with the GMO(s) or products thereof, having regard to the situation or circumstance of the person or community affected.*
- *Any person or group of persons may be entitled to bring a claim and seek relief in respect of the breach or threatened breach of any provision of this Act, including any provision relating to damage to the environment and biological diversity:*
 - (i) in that person's or group of person's interest;*
 - (ii) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;*
 - (iii) in the interest of, or on behalf of, a group or class of persons whose interests are affected;*
 - (iv) in the public interest; and*
 - (v) in the interest of protecting the environment or biological diversity.*

No costs shall be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting the environment or biological diversity.

- *It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the competent authority.*

JORDAN

- a) **Proposed By-Law for Biosafety of Genetically Modified Organisms Issued in Accordance with Article No (23) of the Law of Environment Annex 1 of the National Biosafety Framework, 2004**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1343>

Article 7: Powers and tasks of the National Biosafety Committee

In order to realize the objectives of this By-law, the Committee shall, in coordination and with the co-operation of the related authorities, have the following powers and perform the following tasks.

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A. *The powers of the Committee are to:*

4. *Co-ordinate the efforts of national authorities in the event of an emergency created by the release, whether intentional or unintentional, of a LMO into the environment, and/or of an unintentional transboundary movement of a LMO;*

B. *The tasks of the Committee are to:*

4. *Monitor domestic handling and use of LMOs and their products and assure appropriate application of all procedures;*

Article 10: Risk management

F. *Risk management measures which domestic facilities and activities may be required to put in place include, but are not limited to, establishing:*

5. *Procedures for immediate notification and emergency response in the event of an unintentional release;*

6. *Mitigation plans in the event of an unintentional release or unforeseen consequence of an intentional release;*

Article 14: Emergency response

A. *In the event of an unintentional release or transboundary movement of a LMO or in the event of an unforeseen consequence of intentional use of a LMO, any person with knowledge of the emergency shall immediately inform the local authorities who shall immediately notify the Committee.*

B. *On receiving notification of an emergency involving LMOs, the Committee shall:*

1. *Take immediate steps to inform the appropriate national and local authorities;*

2. *Co-ordinate the actions of all relevant national and local authorities, according to an emergency response plan issued by the Ministry as a regulation;*

3. *Inform the national focal point for the Biosafety Clearing-house and the competent national authorities in potentially affected States.*

Article 17: Violations

A. *Any violator of the provisions of this By-law shall be sanctioned according to the penalties provided in the Law for Environment No. (1), Year 2003.*

B. *In the event of illegal transboundary movement of a LMO into Jordan, in addition to any sanctions that may be applied under paragraph A above, the Committee may request the competent authority in the country of export, at its own expense, to dispose of or destroy the illegally transported LMO, or send it back to the country of origin under controlled and safe conditions.*

KAZAKHSTAN

a) **Draft law on Safety in gene-engineering activity**

Appendix I of the National Biosafety Framework, 2004

<http://bch.biodiv.org/database/attachedfile.aspx?id=1344>

Chapter 1. GENERAL PROVISIONS

Article 1. The basic notions used in the present Law

In the present Law the following basic notions are used:

1) *emergency . an incident attracting inadvertent release of genetically modified organisms into the environment during their use in closed systems, able to have the immediate or subsequent consequences for human health and the environment;*

15) *the user . a physical or legal person who carries out and has responsibility for the activity connected to reception, testing, production and realization of genetically modified organisms in the closed or open*

/...

systems, and also with reception, testing, production and realization of the products made of these organisms;

Chapter 2. GOVERNMENT MANAGEMENT IN THE FIELD OF BIOSAFETY

Article 7. The competence of the Authorized Body on Biosafety

The authorized body in the field of biosafety organizes works on realization of the legislation of the Republic of Kazakhstan in the field of biosafety.

The competence of the Authorized body in the field of biosafety includes:

7) delivery of sanctions for the kinds of activity regulated by the present Law, on the basis of the decision of the National Commission on Biosafety;

Chapter 3. USE OF GENETICALLY MODIFIED ORGANISMS IN THE CLOSED SYSTEMS

Article 10. Emergencies

1. In case of emergency the user should inform immediately the Authorized Body on Biosafety about it and present the corresponding information;

2. In case of emergency the Authorized Body on Biosafety informs the public on it, having estimated and having specified a degree of danger for human health and the environment;

3. The Authorized Body on Biosafety makes more detailed assessment of the emergency and in case of need gives recommendation on prevention of similar emergencies in the future to the user, and also on possible consequences of such an emergency.

Chapter 6. RESPONSIBILITY IN THE AREA OF GENIC-ENGINEERING ACTIVITY

Article 20. Actions in case of illegal genetic-engineering activity

1. Illegal activity on reception, testing, production, use, realizations, import / export of genetically modified organisms implies responsibility according to the legislation of the Republic of Kazakhstan;

2. If owing to the activity on reception, testing, production, use, realizations and import of genetically modified organisms there is a risk or damage to human health and the environment, the user and/or the importer, according to the circumstances, has the responsibility according to the legislation of the Republic of Kazakhstan;

3. The degree of risk, character and the size of the damage caused by the activity, stipulated regarding part (2), and is defined by a commission of experts appointed by the National Commission on Biosafety from representatives of the central bodies of environmental protection, agriculture and public health services;

4. Measures on compensation of the damage, suggested by a commission of experts, are established by judicial instance;

5. If the damage is caused by means of import and use on the territory of the country of genetically modified organism, the provisions of the international legal acts are applied.

KIRIBATI

a) Draft Biosafety (Living Modified Organisms) Regulations, 2005

<http://bch.biodiv.org/database/attachedfile.aspx?id=1757>

PART II REGULATORY FRAMEWORK FOR LIVING MODIFIED ORGANISMS

Role of the Division

9.

(1) For matters relating to the Cartagena Protocol the Division shall be responsible for –

(e) liaising with other Ministries, Departments, Divisions and agencies, and working collaboratively with them to -

(ii) implement measures to control and prevent unintentional and illegal transboundary movements of living modified organisms, and to respond to such movements, including the taking of necessary emergency responses;

**PART III
PROCEDURES RELATING TO THE IMPORTATION OF
LIVING MODIFIED ORGANISMS**

Withdrawal of approvals

17.

(2) Upon the withdrawal of any approval in accordance with sub-regulation (1) the National Competent Authority may –

(c) direct that any further action be taken to –

(i) contain, prevent or minimise any risks to human health or to the environment from the living modified organism;

(ii) isolate any area where the living modified organism has been released, used or moved to; or

(iii) remedy or reinstate any aspect of the damage that has or may have been caused to the environment.

(3) To implement sub-regulation (2) directions may be given to the importer of the living modified organism or to any person making use of a living modified organism in accordance with any approval to take any necessary action, and the cost of all such actions shall be the responsibility of the importer or that person.

PART VI MISCELLANEOUS PROVISIONS

Liability and redress

28. Issues of liability and redress arising under the Cartagena Protocol shall be applied as directed by Cabinet, taking account of the rules and procedures agreed to by the Parties.

KYRGYZSTAN

- a) **LAW OF THE KYRGYZ REPUBLIC On Biological Safety (Draft)
Annex II of the National Biosafety Framework, 2005**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1347>

CHAPTER 1. General provisions

Article 1. Basic notions used in the present law

Accident – biological and social accident that lead to considerable incidental release to the environment of living modified micro organisms/organisms during their usage in closed systems or transboundary movement, and having serious threat for human health and environment;

Incidental introduction into environment – any cases of release into environment of living modified organisms or their combinations that happened incidentally.

user – legal or physical person that carries out and liable to activities related to creation, testing, production, cultivation and realization of transgenetic organisms in a closed and non-closed systems, and also with receiving, testing production and marketing of derivative products of these organisms;

Article 8. Special competent administrative bodies.

8.2. Council on National Security:

- carries out control over the emergency measures in case of large emergency conditions having potential transboundary danger of living modified organisms impact on ecological conditions of the region.

CHAPTER 9. Special requirements to the usage (turnover) of living modified organisms.

Article 26. Measures on risks regulation during the use of living modified organisms

26.2

In case of an accident and/or incidental release of living modified organism regardless of risk level, User has to take immediate measures on elimination of emergency situation consequences and inform Intersectoral Coordination Council (Commission) and submit the following information:

- circumstances that lead to an accident;*
- any other information necessary for the assessment of accident's consequences;*
- information on measures taken.*

26.7. In case of an accident User has to take measures taking into account Precautionary Principle – absence of valid scientific information on accident consequences with considerable damage is not the basis to avoid actions aimed at prevention of environmental deterioration.

26.8. Intersectoral Coordination Council (Commission) in case of an accident has to take the following actions:

- immediately inform general public, stating the risk level for human health and environment;*
- execute full assessment of an accident and, if necessary, make recommendations on prevention of such kind of accidents in future and exclusion of possible consequences;*
- provide taking necessary measures and, depending on circumstances, immediately inform competent bodies of neighboring countries that can be touched upon by the same accidents.*

CHAPTER 10. Control over the turnover of living modified organisms and liability.

Article 30. Liability for the infringements of the present law

30.1. Natural and legal entities in case of infringements of the present law, liable in accordance with legislation of the Kyrgyz Republic. Illegal activity on creation, testing, production, use, realization, import/export of living modified organisms and/or derivative products thereof, implies liability in accordance with present law.

30.2. Natural and legal entities, including decision makers, guilty in committing a crime in accordance with the Administrative Code, are bringing to administrative account which is not release from caused damages.

30.3. In case of activity on creation, testing, production, use, realization and import of living modified organisms and/or derivative products that lead to damage to human health and environment, User and/or Importer, depending on circumstances, are liable in accordance with the legislation of the Kyrgyz Republic.

Natural and legal entities determined as guilty are responsible for damage reimbursement and expenses on liquidation of emergency situations (accidents) and consequences of incidental release to the environment of living modified in accordance with legislation of the Kyrgyz Republic.

LAO PEOPLE'S DEMOCRATIC REPUBLIC

- a) **National Biosafety Frameworks, December 2004**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1348>

**Chapter II:
The Regulatory regime for Biosafety**

2.2. The draft of Biosafety Law

The draft of Biosafety Law will be approved by Lao Government Meeting in the beginning of year 2005 and considered by Lao National Assembly in the end of year 2005. The several changes of technical items might happen as necessary that will be developed and detailed by the framework of regulations to implement Biosafety Law.

2.2.8. Inspection and Redress

- **Liability and Redress:** *to establish regulation on the liability and redress for damage resulting from the research, development, service, management and using of biotechnology and living modified organism.*

MALAYSIA

- a) **BIOSAFETY ACT 2007**
Entered into force in December, 2009
<http://bch.cbd.int/database/attachment/?id=10801>

**PART V - RISK ASSESSMENT AND RISK MANAGEMENT REPORTS AND EMERGENCY
RESPONSE PLAN**

Section 37. Emergency response plan

(1) An emergency response plan shall provide-

(a) safety measures and procedures for the protection of human, plant and animal health, the environment and biological diversity against harm or damage caused directly or indirectly by living modified organisms or products of such organisms; and

(b) all necessary measures to be taken in the event of an emergency.

(2) Any approved person who fails to take the necessary measures in an emergency according to the emergency response plan commits an offence and shall, on conviction, be liable-

(a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;

(b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

PART VII – MISCELLANEOUS

Section 62. Assistance from multi-agencies in emergency

(1) The Director General shall forward the emergency response plan submitted under paragraphs 13(1)(b) and 24(a) to all relevant agencies for their necessary action.

(2) *In the event of any emergency involving any living modified organism or product of such organism, the Director General may seek the assistance and co-operation of the relevant agencies in implementing any emergency measure including those measures provided in the emergency response plan.*

(3) *Any costs incurred by any agency in implementing any emergency measure shall be borne by the approved person.*

(4) *Nothing in this section shall absolve or be deemed to absolve the approved person from any of his or its obligation to take all necessary measures in the event of any emergency.*

Section 64. Offence by body corporate

Where a body corporate commits an offence under this Act or any regulations made under this Act, any person who at the time of the commission of the offence was a director, manager, secretary or other similar officer of the body corporate or was purporting to act in any such capacity or was in any manner or to any extent responsible for the management of any of the affairs of the body corporate or was assisting in such management-

(a) may be charged severally or jointly in the same proceedings with the body corporate; and

(b) where the body corporate is found guilty of the offence, shall be deemed to be guilty of that offence unless, having regard to the nature of his functions in that capacity and to all circumstances, he proves-

(i) that the offence was committed without his knowledge, consent or connivance; and

(ii) that he took all reasonable precautions and had exercised due diligence to prevent the commission of the offence; and

(c) shall, on conviction, be liable to the penalty applicable to an individual.

Section 65. Offence by partner, agent or servant

Any person who would have been liable to any penalty under this Act or any regulations made under this Act for any act, omission, neglect or default if the act, omission, neglect or default is committed by him personally shall be liable to the same penalty if the act, omission, neglect or default is committed by his partner, agent or servant unless he proves-

(a) that the act, omission, neglect or default was committed without his knowledge, consent or connivance; and

(b) that he took all reasonable precautions and had exercised due diligence to prevent the act, omission, neglect or default.

MALDIVES

a) National Biosafety Framework 2006

<http://bch.biodiv.org/database/attachedfile.aspx?id=1350>

**CHAPTER III
Regulatory Regime**

3.3 Proposed National Biosafety Regulations

Emergency response	37.	<i>In the event of an emergency involving a GMO or GMO product, any person with knowledge of the emergency must immediately inform the NBC or local authorities who must immediately notify the NBC.</i>
Penalty	38.	<i>3. Any Operator that becomes aware of any significant new scientific information indicating that authorized activities involving GMOs and/or GMO products may adversely affect biodiversity and/or human health and fails to report to the NBC or intentionally hides this</i>

		<i>information shall be fined no less than Rufiyaa and no more than Rufiyaa, addition to revocation of its operating license and registration with the NBC, and may, at the discretion of the NBC, be prosecuted according to the relevant laws.</i>
		<i>5. In the event of repeated violations, fines shall be progressively increased.</i>
Interpretation	40.	<i>4. “Emergency” means any significant unintended release into the environment of genetically modified organisms or products of genetically modified organisms which could present an immediate or delayed hazard to human health or the environment.</i>
		<i>8. “Operator” means a legal or natural person, national or non-national, whether authorized or unauthorized, that undertakes any activity or operation including but not limited to import, export, contained use, and deliberate release of any genetically modified organism for any purpose in the Republic of Maldives</i>

3.4.8(g). Emergency response

In the event of an unintentional release or transboundary movement of a GMO or in the event of an unforeseen consequence of deliberate release of a GMO, any person with knowledge of the emergency must immediately inform local authorities who must immediately notify the NBC.

On receiving notification of an emergency involving GMOs, the NBC must:

- (a) Take immediate steps to inform the appropriate national and local authorities;*
- (b) Co-ordinate the actions of all relevant national and local authorities, according to an emergency response plan to be prepared;*
- (c) Inform the Minister of Environment, Energy and Water Resources as the national Focal Point for the Cartagena Protocol in order that s/he may inform the Biosafety Clearing-House and the competent national authorities in potentially affected States.*

MONGOLIA

- a) DRAFT LAW ON BIOSAFETY**
Annex IV of the National Biosafety Framework 2005
<http://bch.biodiv.org/database/attachedfile.aspx?id=1351>

PART ONE GENERAL PROVISIONS

Article 3. Use of Terms

3.1. For the purpose of this Law;

3.1.6 “Danger” means any unintentional occurrence that may have adverse effect to human health and external environment in using of genetically modified organisms or raw materials and products originated thereof during contained system use

PART FIVE.

PREVENTATION FROM AND LIQUIDATION OF DAMAGES CAUSED DUE TO GENETICALLY MODIFIED ORGANISM OR RAW MATERIALS AND PRODUCTS ORGINATED THEREOF

Article 17. Prevention from and Liquidation of damages caused due to genetically modified organism or raw materials and products originated thereof.

17.1. Any Entity, Institutions or individuals that carrying out activities related to the genetically modified organism or raw materials and products originated thereof are obliged to implement appropriate measures to prevent from and liquidate the consequences of damages caused due to genetically modified organism or raw materials and products originated thereof, at their own expenses, in accordance with an especially developed program.

17.2. National Committee on Biosafety shall determine the causes and level of damage and organizes appropriate measures to liquidate the consequences of damage caused due to genetically modified organism or raw materials and products originated thereof;

17.3. Under the authority of State Emergency Commission, the National Biosafety Committee, the Disaster Prevention Authority and all other relevant Institutions are to be involved and participated depending on the level of damage, in liquidation of the consequences of damage caused due to genetically modified organism or raw materials and products originated thereof;

17.4. The Government shall bear all expenses in case of widespread serious damage caused due to genetically modified organism or raw materials and products originated thereof and a compensation to be paid back by the faulty Party afterwards;

MYANMAR

- a) **National Biosafety Framework, November 2006**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1352>

3.2. Proposed regulatory regime for Biosafety

The scope of the proposed regulation is as follows:

(b) The Regulation provides a comprehensive and consistent approach to the management of all activities involving GMOs and covers the following activities.

Measures to deal with non-compliance, including monitoring, enforcement, liability, and penalties
□ Procedures to deal with emergencies. These can be of two types. One resulting as a result of the GMO itself and the other involving the use of a GMO to remedy a disaster such as an undesirable spill.

NIUE

- a) **Draft Biosafety (Genetically Modified Organisms) Regulations
Annex 2 of the Draft National Biosafety Framework (July 2006)**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1354>

PART IV

EXEMPTIONS, ENFORCEMENT AND OFFENCES

14. Unintentional releases and transboundary movements

(1) Any person who causes or becomes aware of the unintentional release or transboundary movement of a genetically modified organism shall immediately notify the Department and provide such information as the Director may require.

(2) *An unintentional release or transboundary movement for the purposes of this regulation, is one which*
 (a) *has not been approved under these Regulations; or*
 (b) *arises from the breach of a condition of any approval given under these Regulations.*

(3) *Upon notification under paragraph (1), the Department shall –*

(a) *give notice of the unintentional release or transboundary movement to –*

(i) *the members of the Council;*

(ii) *the Biosafety Clearing-House;*

(iii) *any affected or potentially affected person; and*

(iv) *such international organisations which the Director sees fit; and*

(b) *consult with any affected or potentially affected country to enable them to determine appropriate responses, including the taking of emergency measures.*

15. Illegal releases and transboundary movements

(1) *No person may permit, arrange, assist with, counsel, procure, aid or abet a release or escape, or transboundary movement of a genetically modified organism unless in accordance with these Regulations.*

(2) *In addition to any other penalty imposed for a breach of this regulation, the person responsible for the breach may be ordered to pay the costs associated with the disposal of the genetically modified organism, including all costs associated with its repatriation from or destruction in any country to which it has been permitted to move.*

16. Offences

(4) *In addition to any penalty imposed under this Regulation, an offender may be ordered to pay to or reimburse the Government the costs of any remedial action taken or needed to rectify the consequences of any breach.*

17. Dealing with genetically modified organisms contravening these Regulations

(3) *The cost of destroying any seized genetically modified organism, and of rectifying any adverse effects from a genetically modified organism as a result of breach of these Regulations may be recovered as civil debt from any person making use of the organism in contravention of these Regulations.*

PART IV ADMINISTRATIVE FRAMEWORK

19. The role of the Council

(6) *The Council may develop policies, standards and procedures in relation to these Regulations including –*

(v) *responding to unintentional and unlawful transboundary movements;*

20. The Department

(2) *For the purposes of these Regulations the Department may –*

(e) *liaise with other Departments and agencies, and work collaboratively with them to –*

(ii) *implement measures to control and prevent unintentional and illegal transboundary movements of genetically modified organisms, and to respond to such movements, including the taking of necessary emergency responses;*

b) NATIONAL BIOSAFETY POLICY, 2004

Annex 1 of the Draft National Biosafety Framework(July 2006)

<http://bch.biodiv.org/database/attachedfile.aspx?id=1354>

11. Enforcement

RESPONSIBILITY FOR ADVERSE EFFECTS

Responsibility for any adverse effects associated with LMO activity lies with the persons or companies who have caused the adverse effect. Those persons or companies will be responsible for making good any damage, including compensating those adversely affected.

OFFENCES AND PENALTIES FOR NON-COMPLIANCE

Implementing legislation will contain a range of offences for unlawful LMO activity and related acts and omissions including:

- *unintentional or negligent release of an LMO, LMO product or LMO derivative;*

Penalties for these offences should be substantial to provide a deterrent effect and to reflect the levels of risk to the environment and human health posed by LMO activity.

They should also take into account any irrevocable or substantial damage to biodiversity, human health and livelihoods.

12. Emergency Measures

UNINTENTIONAL AND UNAUTHORIZED TRANSBOUNDARY MOVEMENTS

The External Affairs Office of the Premier's Department is the contact and the focal point for biosafety matters. It will act as the contact point for notifications of any unintentional transboundary movements, which is LMO activities originating from outside Niue that could impact adversely on Niue's biodiversity and human health. The External Affairs Office will refer any such communications to relevant agencies, as a matter of urgency.

This may include notifying the Biosafety Clearing House.

Similarly, the External Affairs Office will notify other countries of any unintentional transboundary movements of LMOs originating from Niue.

Matters concerning unintentional release of LMOs, high risk LMO activities or emergency measures may be referred to the National Disaster Committee.

PAKISTAN

a) PAKISTAN BIOSAFETY RULES, 2005

<http://bch.biodiv.org/database/attachedfile.aspx?id=979>

9. Functions of Institutional Biosafety Committee .

(1) The Committee shall perform the following functions, namely:-

j) to withhold funds and or use administrative authority to immediately refrain programmes if biosafety guidelines are violated;

k) to prepare and implement the institutional emergency and response plan according to the details provided in the manuals and guidelines prepared by National Biosafety Committee;

23. Responsibility to notify interruptions or accidents.

(1) Any person, institution or organization whether obtained licence under rule 11 or not shall immediately notify the Technical Advisory Committee of any interruption of operations or accidents that may lead to discharges of genetically engineered organisms or cells which may be harmful to the environment, nature or health or involve any danger thereto.

(2) Any notice given under sub-rule (1) above shall not lessen the duty of the person who is responsible to try effectively to minimize or prevent the effects of interruptions of operations of accidents.

PAPUA NEW GUINEA

- a) **Draft Biosafety and Biotechnology Bill**
Annex of National Biosafety Framework 2005
<http://bch.biodiv.org/database/attachedfile.aspx?id=1355>

PART 8.- ENFORCEMENT.

Division 1. – Directions and Injunctions.

66. COMPETENT NATIONAL AUTHORITY TO GIVE DIRECTIONS.

(1) *The Competent National Authority may-*

- (a) *give written directions to the licence holder, or to the person covered by the licence, requiring the licence holder or the person to take such steps in relation to the activity as the Competent National Authority considers necessary for the person to comply with the Act or Regulation; or*
- (b) *if the Competent National Authority considers it necessary in order to avoid an imminent risk of death, serious illness, serious injury or to protect the environment from serious damage—take such steps in relation to the activity as the Competent National Authority considers appropriate.*

(2) *A person commits an offence if he does not take the steps specified in a notice under Subsection (1)(a) within the time specified in the notice.*

Penalty: Where the person convicted of an offence is-

- (a) *a corporation – a fine not exceeding K125,000.00; and*
- (b) *other than a corporation – a fine not exceeding K50,000.00 or imprisonment for a term not exceeding five years, or both.*

(3) *If the licence holder or the person does not take the steps specified in the notice within the time specified in the notice, the Competent National Authority may arrange for those steps to be taken.*

(4) *If the Competent National Authority incurs costs because of-*

- (a) *steps taken under Subsection (2)(b); or*
- (b) *arrangements made by the Competent National Authority under Subsection (3), the licence holder or the person is liable to pay to the Competent National Authority an amount equal to the cost, and the amount may be recovered by the Competent National Authority as a debt due to the Competent National Authority in a court of competent jurisdiction.*

Division 2. – Inspections and Monitoring.

73. EMERGENCY POWERS.

(1) *Subject to Subsection (3) where-*

(a) *an inspector has reasonable grounds for suspecting that there may be on any premises an activity in respect of which this Act or Regulation have not been complied with; or*

(b) *the inspector considers that it is necessary in the interests of public health to exercise powers under this section in order to avoid an imminent risk of death, serious illness, serious injury, or to protect the environment, the inspector shall immediately inform the Competent National Authority and may do any of the following-*

- (c) *enter the premises; and*
- (d) *search the premises for the thing; and*
- (e) *secure the thing, if the inspector finds it on the premises, until a warrant is obtained to seize the thing; and*

(f) if the inspector has reasonable grounds for suspecting that a person has not complied with this Act or Regulation in respect of the thing—require the person to take such steps that the inspector considers necessary for the person to comply with this Act or Regulation.

(2) The inspector may exercise the powers in Subsection (1) only to the extent that it is necessary for the purpose of avoiding an imminent risk of death, serious illness, serious injury or serious damage to the environment.

(3) Where, in the opinion of the Competent National Authority, an emergency has arisen that requires action to be taken not otherwise authorized by this Act, the Competent National Authority shall immediately inform the relevant government agencies and cooperate with the government agencies to prevent, contain or remedy the situation.

Division 3. – Offences.

77. LIABILITY OF LICENCE HOLDERS.

A licence holder or a person covered by the licence who takes an action or omits to take an action and the action or omission contravenes the licence is guilty of an offence.

Penalty: Where the person convicted of an offence is-

(a) corporation – a fine not exceeding K125,000.00; and

(b) other than a corporation – a fine not exceeding K50,000.00 or imprisonment for a term not exceeding five years, or both.

78. CIVIL LIABILITY.

(1) A person who carries out any activity in relation to genetically modified organisms shall be strictly liable for any harm, injury or loss caused directly or indirectly by such genetically modified organism or any activity in relation to them.

(2) The harm, injury or loss referred to in Subsection (1) includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity.

(3) Civil liability shall attach to the licence holder, the person responsible for the activity which results in the damage, injury or loss, as well as to the provider, supplier or developer of the genetically modified organism.

(4) Where liability under this section is incurred by a body corporate, any director, manager, secretary or similar officer of the body corporate shall be similarly liable unless he can show that he did everything in his power to prevent the import, deliberate release, commercialization or contained use which caused the damage in question.

(5) If there is more than one person responsible for the damage, injury or loss, then the liability shall be joint and several.

(6) Where proceedings are brought against more than one person it shall not be a requirement for the person bringing the proceedings to identify the person who caused the damage in question, provided that he can prove that one or more of the persons so proceeded against could have caused the damage.

(7) In the case of harm to the environment or to biological diversity, redress shall include the costs of reinstatement, rehabilitation or clean-up measures actually incurred or to be incurred and, where applicable, the costs of preventive measures and any loss or damage caused by the taking of the preventive measures, provided that the person responsible may be required to carry out the reinstatement or rehabilitation at its own cost and to the satisfaction of the Competent National Authority.

(8) Liability shall also extend to harm or damage caused directly or indirectly by the genetically modified organism to the economy, social or cultural practices, livelihoods, traditional knowledge systems, or traditional technologies and such harm includes the following-

(a) disruption or damage to production systems; and

(b) damage to agricultural systems; and

(c) reduction in yields; and

(d) damage to the economy of an area or local community.

(9) A licence holder shall indemnify-

(a) any other person who deliberately releases or commercializes genetically modified organism; and

(b) any person who manufactures or processes genetically modified organisms, against any civil liability where the genetically modified organism in question was first imported, deliberately released, used in contained conditions, or commercialized by the applicant.

(10) A licence holder shall indemnify against any civil liability any person who fails to label genetically modified organisms, but where the licence holder can show that he took all reasonable steps under the Act to prevent such failure the indemnity shall not apply.

(11) The right to bring any action to redress the harm caused by the genetically modified organism shall lapse only after a reasonable period from the date on which the affected person or local community could reasonably be expected to have learnt of the harm, taking due account of-

(a) the time the harm may take to manifest itself; and

(b) the time that it may reasonably take to co-relate the harm with the genetically modified organism, having regard to the situation or circumstance of the person or local community affected.

(12) It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the Council or the Competent National Authority.

80. GENERAL PENALTY.

A person who fails to comply with a requirement under this Act applicable to him in respect of which a specific penalty is not provided, is guilty of an offence.

Penalty: A fine not exceeding K50,000.00.

Division 4. – Proceedings.

81. MEDIATION.

Before hearing an action under this Act, a court shall endeavor to have the matter settled by mediation.

82. INSTITUTION OF PROCEEDINGS.

(1) Subject to Section 81, an offence against this Act shall be prosecuted-

(a) before a District Court where the offence provides for a maximum monetary penalty of K50,000.00 or less in the case of a person other than a corporation; or

(b) in the National Court in any other case.

(2) The Competent National Authority may, after consultation with the Public Prosecutor, lay information and institute prosecution for offences under the Act.

(3) Subject to Subsection (4), a person may, on his own behalf or on behalf of a group or class of persons representing that group or class or the public as a whole, take proceedings—

(a) where an alleged offence against this Act or Regulation has occurred or is likely to occur; or

(b) where there is an alleged failure to perform an act or duty under this Act or Regulation that is not discretionary, in a court against—

(c) the State; or

(d) a government body; or

(e) a holder of a licence issued under the Act; or

(f) another person, or all or any of them jointly.

(4) Proceedings under Subsection (3) shall not be commenced—

(a) where the State or a government body is proceeding in an action in a court for the same offence or failure to perform an act or duty; or

(b) in any other case, before the expiry of 60 days, from the service of written notice of the alleged offence or failure to perform an act or duty to—

(i) the Council; and

(ii) the Competent National Authority; and

(iii) the party responsible for the alleged offence or failure to perform an act or duty.

(5) Where an action is commenced under Subsection (4)(a), any person may intervene as a matter of right.

(6) In an action under this section, the court may, in making any order—

(a) award such costs; and

(b) make an order as to the lodging of a bond or equivalent security, as it thinks fit.

(7) This section does not restrict any right that a person or class of persons may have under any other law.

(8) No costs shall be awarded against a person under Subsection (3) who fails in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting the environment or biological diversity.

83. FORFEITURE.

(1) Where a court convicts a person of an offence against this Act or a Regulation, the court may order forfeiture to the State of any substance or thing used or otherwise involved in the commission of the offence.

(2) A substance or thing ordered by a court to be forfeited under this section becomes the property of the State and may be sold or otherwise dealt with in accordance with the directions of the Council.

PART 10. - MISCELLANEOUS.

91. PROTECTION OF WHISTLEBLOWER.

(1) An employee or an agent of a licence holder who discloses information or material leading to the prosecution of the licence holder under this Act shall not be liable for any act or default of himself done or omitted to be done in good faith.

(2) An employee or an agent of a licence holder who discloses information or material leading to the prosecution of the licence holder under this Act shall not be terminated, suspended or discriminated in any manner by the licence holder or his agent for the reason that he provided information or material leading to the prosecution of the licence holder.

PHILIPPINES

- a) **National Biosafety Framework**
Annex A to Executive Order No. 514, March 2006
<http://bch.cbd.int/database/attachment/?id=11733>

SECTION 2. PRINCIPLES

2.10 Availability of Remedies. Effective access to judicial and administrative proceedings, including redress and remedy, shall be available in accordance with Philippine law;

SECTION 3. SCOPE, OBJECTIVES AND DEFINITIONS

3.3.7. "Hazard" refers to traits inherent to or activities of a regulated article that may cause harm to human or animal health or to the environment;

3.3.13. "Risk" refers to the combination of the likelihood that an adverse consequence of a biohazardous activity or trait will occur and the magnitude of such a consequence;

SECTION 9. REMEDIES

In cases of violations of laws, rules, and regulations related to biosafety, the following remedies shall apply.

9.1 Administrative Remedies. *The concerned departments and agencies shall ensure, in accordance with law, that the right of appeal and other administrative remedies are available to applicants and relevant stakeholders in biosafety decisions.*

9.2 Criminal Liability. *Natural or juridical persons committing offenses in violation of existing laws shall be prosecuted and penalized in accordance with such laws.*

9.3. Civil Liability. *Philippines laws on liability and compensation for damages resulting injuries committed on persons shall apply in accordance with such laws.*

9.4. International Law. *International legal norms on liability and compensation, including those developed and adopted under the Cartagena Protocol on Biosafety, shall likewise apply.*

REPUBLIC OF KOREA

- a) **Transboundary Movements of Living Modified Organisms Act (2001) Entered into force in 2008 when the Republic of Korea became a Party to the Cartagena Protocol on Biosafety.**
<http://bch.biodiv.org/database/attachedfile.aspx?id=296>

Chapter 1 General Provisions

Article 5 Country responsibilities

The central government and provincial government shall take necessary measures to prevent any adverse effects that living modified organisms may have on public health and on the conservation and sustainable use of biological diversity.

Article 6 Competent national authority

1. In accordance with Article 19 of the Protocol, the Ministry of Foreign Affairs and Trade shall be the National focal point and the Ministry of Commerce, Industry, and Energy shall comprise the competent national authority.

2. In accordance with the Presidential Decree, the head of the competent national authority shall take necessary and timely measures to implement the Protocol.

Chapter 2 Activities Including Import or Export, and Safe Administration of Living Modified Organisms

Article 27 Emergency measures to prevent potential risks

1. The head of the competent national authority shall take immediate and necessary measures, as prescribed by the Presidential Decree, where living modified organisms are deemed to have had, or possibly have had, significant adverse effects on public health, and the conservation and sustainable use of biological diversity.

2. When an individual, who undertakes activities, including import or export of living modified organisms, comes to know of any adverse effects thereof, the individual shall immediately report the fact to the head of the related central government authority, or the head of the competent national authority.

Chapter 5 Supplementary Provisions

Article 34 Acquisition of a fund

The head of the competent national authority shall take due measures to create a contingency fund, where activities, including import or export of living modified organisms, have adverse effects on public health, and the conservation and sustainable use of biological diversity.

Chapter 6 Penal Provisions

Article 39 Penal provisions

One who falls into any of the following subparagraphs shall be sentenced to imprisonment for no more than five years, or fined, not exceeding seventy million won:

1. *One who has imported, or produced, living modified organisms (including organisms specified in subparagraph 2 below) whose import or production is prohibited, or restricted, pursuant to Article 14,*
2. *One who has imported, or produced, living modified organisms for which approval is revoked, pursuant to Article 17, paragraph 1, subparagraph 1, and*
3. *One who has distributed living modified organisms within the country, violating the order to take action, including the destruction or return of the living modified organisms under Article 19, paragraph 1.*

b) **National Biosafety Framework, March 2004**

<http://bch.biodiv.org/database/attachedfile.aspx?id=1346>

Chapter III Development of National Biosafety Frameworks**3.1 Development of a legal system on Biosafety****3.1.3 Development, Production, Import, Export and Safe Management of LMOs****11) Emergency measures**

According to Article 27 of the Act, there is a provision on emergency measures to prevent potential risks. The objective of this provision is to take necessary measures in cases where LMOs are deemed to have had or possibly have had significant adverse effects on the public health and the conservation and sustainable use of biological diversity. However there is no provision on this in the Protocol. The reason being that it is a matter relating to risks resulting from LMOs originating at home, and not in transboundary movements.

3.1.5 Special Institutions**4) Security of Financial Resource**

There are a lot of problems in compensating for the damage resulting from LMOs from the general budget. The mechanism that he who imports or exports LMOs takes out an insurance and settles the matter does not fit the basic principle of compensation for the damage resulting from them, since he who takes out an insurance can compensate whilst he who does not cannot compensate enough for the damage, and after all government should compensate for the damage. Nevertheless, a security system for financial resources to ensure safety was introduced in Article 34 of the Act. This means that financial resources to ensure biosafety will get from government budget. This provision is considered not to fully reflect 'causer-pays-principle' and should be discussed in the next amendment of the Act.

SAMOAa) **Draft BIOLOGICAL DIVERSITY PROTECTION BILL 2004****Annex 5 of the National Biosafety Framework**

<http://bch.biodiv.org/database/attachedfile.aspx?id=1357>

PART II**REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS**

8. Role of the Ministry – *For matters relating to the Cartagena Protocol the Ministry shall be the designated national focal point, and shall also be responsible for –*

- (g) *liaising with other Ministries and agencies, and working collaboratively with them to –*

(ii) implement measures to control and prevent unintentional and illegal transboundary movements of genetically modified organisms, and to respond to such movements, including the taking of necessary emergency responses;

**PART III
PROCEDURES RELATING TO THE IMPORTATION OF GENETICALLY MODIFIED
ORGANISMS**

14. Confidential information –

(1) When giving notification under section 12 or providing any additional information that is required, the notifier may indicate that certain information is of a confidential nature, if it is information other than –

(d) any proposed methods and plans for emergency response.

**PART IV
OTHER REGULATORY REQUIREMENTS RELATING TO
GENETICALLY MODIFIED ORGANISMS**

21. Unintentional releases and transboundary movements – (1) Any person who permits or becomes aware of an unintentional release of a genetically modified organism into the environment within Samoa, or an unintentional transboundary movement of a genetically modified organism from Samoa, shall immediately notify the Ministry and provide such information as the Chief Executive Officer may require.

(2) An unintentional release or transboundary movement of a genetically modified organism for the purposes of this section, is one which –

(a) has no required approval under this Act; or

(b) arises from the breach of a condition of any approval given under this Act – but which has not been intentionally released or moved by any person having control of it.

(3) Upon receiving a notification under sub-section (1), the Ministry shall immediately give notice of the unintentional release or transboundary movement to –

(a) the members of the National Competent Authority;

(b) the Biosafety Clearing-House;

(c) any affected or potentially affected Party or non-Party; and

(d) any other international organisation which the Chief Executive Officer determines – and shall consult with any affected or potentially affected country to enable them to determine appropriate responses, including the taking of emergency measures.

(4) A notification given under sub-section (3) shall comply with Article 17(3) of the Cartagena Protocol.

22. Illegal releases and transboundary movements

(3) In addition to any other penalty imposed for a breach of this section, the person responsible for the breach may be ordered to pay the costs associated with the disposal of the genetically modified organism, including all costs associated with its repatriation from or destruction in any country to which it has been permitted to move.

**PART V
OTHER PROVISIONS CONCERNING
GENETICALLY MODIFIED ORGANISMS**

23. Offences – (1) Any person who –

(j) breaches section 22(1) in relation to an unintentional release or transboundary movement of a genetically modified organism;

24. Dealing with organisms contravening this Act – (1) For the purposes of enforcing the provisions of this Act, all Environment Officers may exercise the powers relating to investigating, monitoring, prosecuting and preventing the continuation of any breach that are vested in them in any other Act.

(2) In relation to any genetically modified organism which has been imported into Samoa in contravention of this Act, or which is or remains in Samoa in breach of this Act or any condition imposed under it, an Environment Officer may –

(a) seize the genetically modified organism;

(b) destroy the genetically modified organism as determined by the National Competent Authority or the Chief Executive Officer; or

(c) deliver up the genetically modified organism to an officer of another Ministry to be dealt with in accordance with law.

(3) Nothing in this Act shall affect the powers to search, seize and deal with items under laws relating to plant and animal quarantine, customs and excise and any other law that has application to the development, use, handling, storage or movement of genetically modified organisms.

25. Regulations concerning genetically modified organisms – (1) The Head of State, acting on the advice of Cabinet, may make Regulations for the purposes of implementing the provisions of this Act and the Cartagena Protocol.

(2) Without limiting the generality of sub-section (1), the Regulations may make provision in relation to -

(a) any forms or fees relating to any notification, approval or other procedure under this Act;

(b) the keeping of information confidential as provided by this Act;

(c) any requirements, consistent with laws regulating the carriage of goods by land, air or sea, relating to the transportation of genetically modified organisms; to cover effective containment within Samoa.]

(d) requirements applying to planned releases of genetically modified organisms;

(e) requirements applying to field tests of genetically modified organisms and other aspects of research into them;

(f) the grounds and procedures for the withdrawal of any approval given under this Act, and the implications of a withdrawal of approval;

(g) emergency responses to any unintentional or unlawful release of a genetically modified organism, or any other which release which has, or may have, an adverse impact on biological diversity or which poses a risk to human health and the environment; and to use GMOs as an emergency response for bioremediation or treatment of outbreaks and it would be advisable to cover that aspect in the legislation.]

(h) the application of agreed rules and procedures relating to liability and redress for damage resulting from transboundary movements of genetically modified organisms.

(2) Regulations made under sub-section (1) may prescribe offences and impose penalties of fines not exceeding 50 penalty units.

26. Indemnities – The Government, the Minister, the Chief Executive Officer, Environment Officers and members of the National Competent Authority and Technical Advisory Groups established under this Act shall not be liable for any loss or damage, or subject to any criminal prosecution, in relation to any exercise of any power in relation to a genetically modified organism taken in accordance the provisions of this Act.

SRI LANKA

- a) **NATIONAL BIOSAFETY FRAMEWORK, April 2005**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1358>

PART I

1.0 INTRODUCTION

1.2 Objective

It is strongly suggested that the National Biosafety Framework is an initial step towards a more permanent legislative framework for biosafety in Sri Lanka. As such, it will continue to have many gaps and inadequacies of the existing system. In particular, critical issues related to creation of new agencies, funding and legal remedies for liability and compensation are not addressed adequately in this draft as new legislation is required to deal with these issues. In the meantime, however, having an initial biosafety framework brings many advantages, particularly its flexibility. The framework should be revisited, reviewed and revised periodically to ensure that it is effective in meeting its stated objectives.

PART III

3.0 LAW AND ENFORCEMENT SYSTEM

3.3 Proposed Biosafety Law for GMOs

This new enactment will details (i) The approving authority (its composition, powers and duties), (ii) The procedures for granting approval, (iii) Monitoring mechanisms and powers vested in it, (iv) Enforcement powers, (v) Emergency powers, (vi) Offences and related aspects, and (vii) Powers to make relevant regulations to enforce the provisions of the act.

The issues of liability and redress for damages resulting from the release of GMOs to the environment have to be carefully considered and a suitable legal regime should be brought in to address the potential problems and implications. This law should not confine itself to LMOs but should include all types of GMOs and products.

This new law could even address the damages caused by the release of all other types of animals and plants such as alien invasive species, in addition to addressing the issue of GMOs, so that it covers damages caused by any introduced species.

SYRIAN ARAB REPUBLIC

- a) **National Biosafety Framework, October 2006**
<http://bch.biodiv.org/database/attachedfile.aspx?id=1359>

TWO Current status of policies, national Strategies and Regulatory regimes related to Biotechnology and Biosafety in Syria

2.8. Regulatory System

2.8.2. BIOSAFETY GUIDELINES IN SYRIA

2-8-4-2. Risk management

Accidents and Emergency Planning:

An accident is an incident involving a significant and unintended release of the GMO in the course of an activity involving the authorized use of the GM that represents an immediate or delayed hazard to human health or environment.

It would very useful for Syria to have a special bureau with representative from all concerning parties (ministries of health, agriculture, environment, atomic energy commission, etc) for an effective and quick response to contain a hazard should it happen.

Steps to follow in emergency plan

- *Appointment of an Accident Services Officer (Health & Safety Officer).*
- *Notification of an accident immediately*

- *Draw up emergency plan to be followed in the event of any accident with reference to the health and safety of persons immediately exposed to the hazard*
- *Draw up emergency plans separately for each category of risk since dimension of damage will be greatest with the GM categorized as most risky (Level III and above)*

The plan must specify

- *Methods specific to the GMO for procedures to control the GMO in case of unexpected spread*
- *Method to decontaminate or eliminate the effects of an accident*
- *Method for disposal of sanitation of plants, animals, soils etc. that were exposed during the accident or spread*

3-2. Proposed by-law “Biosafety Bill 2007 for the Syrian Arab Republic”

Ministry of Agriculture and Agrarian Reform and Ministry of Local Administration and Environment (MLAE), General Commission for Environmental Affaires are working on jointly in cooperation with the NBC for preparing a draft by-law on Biosafety which will be entitled “ Biosafety Bill 2007 for the Syrian Arab Republic” for regulating all biosafety related issues including the introduction / importation, exportation and handling of LMOs/GMOs.

It will include the following items:

- Handling requests for approval: Application for contained use, Application for introduction into the environment, Application to import or place on the market, Application to export, Genetically modified organisms in transit, Confidential information, Acknowledgement of application, Risk assessment and risk management, Exemption, Determination of the application, Communication of decision, Review of approval, Withholding information, Appeals board, Technical advisory committee, Functions of the committee, Remuneration, Conflict of interest, Duties of regulatory agencies, Unintentional release into the environment, Appointment of inspectors, Functions of inspectors, Funds of the Authority, Investment of funds, Annual estimates, Accounts and audit, Regulations, Offence and penalties, Public awareness and participation, Civil liability and redress, Interpretation;

- The SNBC must be notified in the following cases:

In the event of accidental release of the transgenic product (notification within 24 hours).

If the manipulated product or the associated host organism differs substantially from the characteristics set out in the application, if it shows signs of disease or if there are indications of mortality or any unforeseen effect in organisms for which it is not intended; written notification must be made within five days.

- At any time, the personnel authorized by the SNBC may inspect the place where the manipulated products are to be released into the environment, the closed areas before and after movement and the records relating to the product in question. The costs incurred in the checking procedure, by one or more members of the SNBC, shall be borne by the applicant.

PENALTIES

Any private institution or individual involved, in any way, in the process of importation, movement and release into the environment, or in the evaluation of manipulated products, who fails to comply with the provisions set out in this document shall be punished in accordance with the provisions of the Syrian Agriculture Quarantine Law 237 dated 1960 and the decree 91 of the Syrian Ministry of Agriculture dated 1991 and the Syrian Law 158 (prevention of fraud and cheating) dated 1960 and their future modifications, and by laws upcoming on the basis of the inspection reports and the findings of the monitoring units and certification bodies which shall be submitted, as applicable, to the office responsible for supervising compliance with the regulations.

The New by-law will determine strong punishment procedures for the illegal activities

According to this by-law, any introduction of LMOs will follow the following procedures shown below in the diagrammatic representation:

TAJIKISTAN

a) LAW on Biological Safety

Entered into force in 2005

<http://bch.biodiv.org/database/attachedfile.aspx?id=802>

Chapter III. Contained use of genetically modified microorganisms/organisms

Article 13. User's responsibilities in case of accident

In case of accident the user has to inform immediately the National Commission and submit:

- *information on the terms of the accident;*
- *information on the type and number of used genetically modified microorganisms/organisms;*
- *any information required for the assessment of the accident's impact on human health and the environment;*
- *information on the measures taken.*

In case of accident the National Commission:

- *informs immediately the public, having assessed the degree of risk for human health and the environment;*
- *makes full assessment of the accident and if required provides recommendations on further prevention of such accidents and elimination of the accidents possible impacts;*
- *takes required measures, informs competent authorities which may be impacted by such accidents.*

Chapter VI. Import and export of genetically modified organisms or their products

Article 25. Actions in case of illegal transportation of the genetically modified organisms

In case of illegal transportation of the genetically modified organisms a special authorized state institution on biological safety has to request from the country-exporter their repatriation or elimination on its own account according to the regulations of international legislation, admitted by the Republic of Tajikistan.

Competent international institutions are informed of the illegal transportation of genetically modified organisms according to the procedures stipulated by international legislation in this area.

In case of non-deliberate transboundary movement of genetically modified organisms and/or their products a special authorized state institution on biological safety provides notification stipulated in the international legislation as well measures to exclude any risks for human health and the environment.

The National Commission informs the public on preventing situations while carrying non-deliberate transboundary movement of genetically modified organisms and/or their products.

Chapter VII. Final provisions

Article 27. Order of settlement the disputes on biological safety issues

Disputes on biological safety issues and the related property debates are settled by legal proceedings.

Article 28. Liability for the present Law violation

Physical and juridical persons are liable for violation of the present Law regulations according to the legislation of the Republic of Tajikistan.

TONGA

- a) **BIOSAFETY ACT 2009**
<http://bch.cbd.int/database/attachment/?id=11329>

PART II - ADMINISTRATIVE RESPONSIBILITIES

6. Functions of the National Biosafety Advisory Committee

(1) The Committee shall be the Competent National Authority in the Kingdom for all matters arising from the Cartagena Protocol.

(2) The functions of the Committee as a competent authority shall be to:

(e) monitor the development, use, handling and transboundary movement of living modified organisms within the Kingdom, and all matters related to the application of modern biotechnology, and coordinate responses to unintentional and unlawful transboundary movements;

8. Role of the Ministry

For matters relating to the Cartagena Protocol, the Ministry shall be the designated focal point and shall be responsible for:

(f) implementing measures to control and prevent unintentional and illegal transboundary movements of living modified organisms, and to respond to such movements, including the taking of necessary emergency responses;

PART IV - OTHER REGULATORY REQUIREMENTS

21. Unintentional release and transboundary movements

(1) Any person who permits or becomes aware of an unintentional release of a living modified organism into the environment within the Kingdom, or an unintentional transboundary movement of a living modified organism from the Kingdom, shall immediately notify the Ministry and provide such information as the Secretary may require.

(2) An unintentional release or transboundary movement of a living modified organism for the purposes of this section, is one which –

(a) does not require approval under this Act; or

(b) arises from the breach of a condition of any approval given under this Act, but which has not been intentionally released or moved by any person having control of it.

(3) Upon receiving a notice under sub-section (1), the Ministry shall immediately give notice of the unintentional release or transboundary movement to:

(a) the members of the Committee;

(b) the Biosafety Clearing-House;

(c) any affected or potentially affected State Party or non-State Party; and

(d) any other international organisation which the Secretary determines, and shall consult with any affected or potentially affected country to enable them to determine appropriate responses, including the taking of emergency measures.

(4) A notice given under sub-section (3) shall comply with Article 17(3) of the Cartagena Protocol.

22. Illegal releases and transboundary movements

(3) In addition to any other penalty imposed for a breach of this section, the person responsible for the breach may be ordered to pay the costs associated with the disposal of the living modified organism, including all costs associated with its repatriation from or destruction in any country to which it has been permitted to move.

PART V – MISCELLANEOUS

25. Regulations

(1) *The Minister may, with the consent of Cabinet, make Regulations for the purposes of implementing the provisions of this Act and the Cartagena Protocol, which are not inconsistent with this Act.*

(2) *Without limiting the generality of sub-section (1), the Regulations may make provision in relation to:*

- (a) any forms or fees relating to any notice, approval or other procedure under this Act;*
- (b) the keeping of information confidential as provided by this Act;*
- (c) any requirements, consistent with laws regulating the carriage of goods by air or sea, relating to the transportation of living modified organisms;*
- (d) emergency responses to any unintentional or unlawful release of a living modified organism, or any other release which has, or may have, an adverse impact on biological diversity or which poses a risk to human health; and*
- (e) the application of agreed rules and procedures relating to liability and redress for damage resulting from transboundary movements of living modified organisms.*

(3) *Regulations made under sub-section (1) may prescribe offences and impose penalties of fines not exceeding \$10,000.*

VIET NAM

- a) **DECREE 69/2010/ND-CP OF GOVERNMENT on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms**
<http://bch.cbd.int/database/attachment/?id=11119>

CHAPTER II

RISK ASSESSMENT AND MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS

ARTICLE 8. RESPONSIBILITIES FOR RISK MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS TO THE ENVIRONMENT, BIODIVERSITY AND HUMAN, ANIMAL HEALTH

1. *Organization, individual who engages in scientific research, technological development; trial; production; import; export; storage; transportation of genetically modified organisms must apply measures of risk management to ensure biosafety as stipulated by law.*

2. *In case of risk occurrence, an organization/individual shall have to promptly carry out measures to reduce risks, and timely report to the Peoples' Committee of the province where the risk occurs.*

3. *Any organisation, individual who does comply with the risk management measures shall be subject to administrative sanctions, criminal liabilities, or damage compensation according to the law.*

4. *Ministries in charge of related sectors, provincial Peoples' Committees have responsibilities to direct and organize the implementation of the risk management, and to report to the Ministry of National Resources and Environment when a risk occurs.*

CHAPTER IV

TRIALS OF GENETICALLY MODIFIED ORGANISMS

Article 14. Requirements for trials of genetically modified organisms

3. *When uncontrollable risks to the environment, biodiversity and human, animal health that causes by the regulated genetically modified organism, is confirmed; the trial conductor must terminate the trial of genetically modified organism, apply emergency measures to treat the risk, and dispose the genetically modified organism.*

Article 20. Responsibilities to conduct trials and reporting results of trials of genetically modified organism

2. An organization, individual that has obtained a permit for a genetically modified organism trial shall have to implement measures to ensure biosafety after trial completion or termination.

**CHAPTER VII
PRODUCTION, TRADING, IMPORT, EXPORT, TRANSPORT AND STORAGE OF
GENETICALLY MODIFIED ORGANISMS, PRODUCTS OF GENETICALLY MODIFIED
ORGANISMS**

Article 42. Storage, packaging, and transportation of genetically modified organisms that haven't been granted a Safety Certificate

2. Storage, packaging, and transportation of GMO which doesn't meet conditions as in Item 1 of this Article shall have to apply measures to ensure environmental safety and no incident release during transportation and must provide information requested in Appendix 1 of this Decree.

In case incident occurrence, organization, individual who is in charge of storage, packaging, and transportation shall be responsible for gathering and destroying by appropriated measures; mark the location where incident occurred and inform the Ministry of Natural Resource and Environment, Peoples' Committee of the province where the incident occurred, and the relevant ministries to ding out remedies.

**b) Draft Biosafety Management regulation for GMOs and their products
Annex III of the National Action Plan to 2010 for implementation of the Cartagena Protocol on Biosafety 2004.**

<http://bch.biodiv.org/database/attachedfile.aspx?id=1364>

Chapter V Risk assessment and management

Article 15. Risk management

3. Organization /individuals importing and using and releasing GMOs and their products are responsible for the application of appropriate management measures to prevent, reveal timely happened risks to handle and overcome its consequences and notify timely to concerning institution on the risk which have occurred during their activity.

Chapter VII Handling of violations

Article 23. Handle violations

1. Organizations/individuals that commit acts of violating the Decree provisions will, depending on the nature and seriousness of their violations, be sanctioned or examined for penal liability before law; if causing serious damage, they will have to pay compensation according to provisions stipulated by law.

3. Those who abuse their positions and powers to commit acts of violating the stipulations of this Decree and commit other acts contrary to the stipulations of law, depending on the nature and seriousness of their violations, be disciplined or examined for penal liability according to law provisions.

Article 24. For export activity

1. In the import contract for GMOs and their products to Vietnam, the importer should require the exporter to undertake compensation when causing damage by the imported goods, undertake technical and financial contribution to handle and overcome the bad consequences on human health and the environment in happened place.

2. In the case of disagreement between the importer and the exporter on the measures of safety that are stipulated and on undertaking compensation when the breakdown takes place, but the importer still deliberately imports the GMOs and their products, if any hazard or risk happens by the use of imported product and causes damage to human health, the environment, economy and society, the importer should be responsible for compensation and acceptance of any cost for handling and overcoming the consequences. If causing severely damage, organizations/individuals will be examined for penal liability according to law provisions.

YEMEN

- a) **Proposed Regulatory Regime**
Annex 3 of the National Biosafety Framework (2005)
<http://bch.biodiv.org/database/attachedfile.aspx?id=1365>

Chapter three

Objectives

Article 5: Objectives

This Regulation aims to achieve the following:

2. Taking measures to ensure that the risks that may be caused by modern biotechnology and its products are minimized and managed.

Chapter Eight

Facing Emergency Conditions

Article 24:

2. It is a must, in the case of unintentional release, trans-boundary movement or unexpected effect of the direct use of a GMO, for a person who comes to know about an emergency condition to inform the local authorities immediately, which in turn have, immediately and directly to notify the NBC.

3. As soon as NBC receives the notification regarding the emergency condition related to GMOs, it has to:

- a) Take urgent steps to inform the concerned local and national authorities.
- b) Coordinate the works of the related local and national bodies, in accordance with an emergency facing plan to be issued by a resolution from the Minister.
- c) Inform the National Focal Point which shall contact the Bio-safety Clearing House, and the competent national authorities in damaged countries.

Article 25: NBC shall, in close coordination and cooperation with concerned bodies, prepare, develop and set up an appropriate emergency strategy and implementing plans.

Chapter Ten

Violations, Penalties and Compensation

Article 29:

1. Without prejudice to the Law on Environment Protection and provisions of other laws and regulations in force any person violates the provisions of this Regulation shall be strictly subjected to criminal and civil liability as well as bearing the responsibility to compensate for any damages that occur as a result of activities regulated by this Regulation, in accordance with the Environment Protection Law, its executive regulation and other related legislation in force.

2. Without prejudice to any other penalties under paragraph (1), in case of transboundary movement of GMOs or their products into the Republic of Yemen in a way violating the provisions of the effective laws, the NBC may request the competent authority in the country of export, at its own expenses, to dispose of

or destroy the illegally transported GMOs or its product/s, or send it back to the country of origin under controlled and safe conditions.

III. CONCLUSION

5. There are 41 Parties to the Biosafety Protocol in the Asia and the Pacific region. This compilation includes provisions of national laws or regulations from 29 Parties. The laws and regulations of 19 Parties are available only in draft form.

6. It should be noted that some of the texts included in the compilation may not necessarily reflect the current situation. Experience shows that Parties' fulfillment of their obligation to make available to the BCH their existing national laws, regulations and guidelines, does not keep pace with developments at the national level. The draft laws might have already been adopted and come into force. They might have undergone changes before their adoption. New laws might have been added and some might have been repealed. But information on these new developments might not have been made available yet in the BCH.

7. The following conclusions may, however, be made from the review of the domestic laws and regulations highlighted in the preceding section as it relates to liability and redress:

- (a) Liability and redress issues are addressed in some form or another;
- (b) A number of laws address accidental release of genetically modified organisms or emergency situations and associated responsibilities;
- (c) There are laws that address liability and redress for damage to the environment, biodiversity, human health, and socio-economic damage. The scope of damage includes both traditional and non-traditional types of damage – loss of life, personal injury, damage to property, damage to social and economic interests, damage to the environment and/or biodiversity;
- (d) There are laws that provide for strict liability as the standard of care required;
- (e) There are laws with provisions that require operators to inform competent authorities of the occurrence of any accident and to take measures to redress damage;
- (f) In some cases, the details of liability rules are left to civil or criminal liability laws;
- (g) A number of laws provide for liability for violating the provisions of the law.
