





# Convention on Biological Diversity

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AFRICAN REGIONAL WORKSHOP ON THE NAGOYA
– KUALA LUMPUR SUPPLEMENTARY PROTOCOL
ON LIABILITY AND REDRESS TO THE
CARTAGENA PROTOCOL ON BIOSAFETY
Addis Ababa, Ethiopia, 21-22 July 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 from the African 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 French 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 situation.
- 4. The Secretariat invites Parties to review, confirm or update the completeness, accuracy and timeliness of the information that they have made available to the BCH, including 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

#### **BENIN**

a) **Draft National Biosafety Framework**<a href="http://bch.biodiv.org/database/attachedfile.aspx?id=1262">http://bch.biodiv.org/database/attachedfile.aspx?id=1262</a>

#### VI- THE MONITORING AND THE CAPACITY BUILDING

#### *6.1 –Monitoring and update*

The notification and authorisation mechanism brought out in the national biosafety framework with idea in mind that the Republic of Benin for the safe use agricultural products stemming from genetic engineering, propel a dynamic promoting biosafety which will be enforced with time by an inevitable process of update as the innovations on the matter go by. In fact, the normative framework which is the CP has certainly fixed the guide lines from which many aspects of the biosafety issue must be tackled. However, some questions must be subject to work within the Conference of Parties before precising the normative orientations. We can cite for example, the issues surrounding the questions of labeling, of the liability and redress.

#### **BOTSWANA**

a) Draft National Biosafety Framework, 2006 http://bch.biodiv.org/database/attachedfile.aspx?id=1265

From Section Three: Consultant's Draft Bill

#### PART I – Preliminary

#### 2. Intent of Act (Scope)

An Act to provide for the safe application of modern biotechnology by regulating and managing its products through the implementation of the Cartagena Protocol on Biosafety, the establishment of the Biosafety institutional framework, risk assessment, risk management plan and a licensing system and matters incidental thereto.

#### PART VII - Offences and Penalties

#### 57. Operation without a license

- (a) A person is guilty of an offence if he/she undertakes modern biotechnology activities without a licence.
- (b) An offence under subsection (a) is punishable on conviction of imprisonment for a term not exceeding 5 years or liable to a fine not exceeding P100 000.00.
- (c) A person who is guilty of an offence under subsection (a) or (b) is guilty of a separate offence in respect of each day (including the day of a conviction for the offence or any later day) on which the person is guilty of the offence.

#### 58. Failure to Comply with a Licence

- (a) A person is guilty of an offence if he/she fails to comply with the conditions of the licence.
- (b) Such an offence is punishable on conviction by whichever of imprisonment of a term not exceeding 3 years or a fine not exceeding P60 000.00.

#### 59. Unintentional release

- (a) A licence holder for contained use is guilty of an offence if he/she unintentionally releases LMOs or GMOs into the environment.
- (b) Such an offence is punishable on conviction by whichever of imprisonment for 1 year or a fine of P20 000.00.

#### 60. Failure to provide required information and Miscellaneous Offences

A person commits an offence and is liable on conviction by whichever imprisonment for 3 years or a fine of P60 000.00, if that person

- (a) fails to furnish an information as required by or under this Act, or
- (b) uses confidential information for a purpose not authorised by or under this Act, or
- (c) obstructs or fails to assist the Authority or officers of the Authority in the performance of a function under this Act, or
- (d) contravenes any other provision of this Act
- (e) gives false or misleading information to the Authority

#### PART VIII - Liability and Redress

#### 62. Civil liability and redress

Liability or redress for a damage that occurs as a result of an activity under this Act is subject to the applicable Laws.

#### **BURKINA FASO**

a) Draft National Biosafety Framework, 2005 http://bch.biodiv.org/database/attachedfile.aspx?id=1266

Cette loi devra en avant par rapport certaines mesures de prévention des risques biotechnologiques, conformément au Protocole, comme par exemple:

- la procédure d'accord préalable donnée en connaissance de cause,
- la procédure simplifiée,
- les règles en cas de situation d'urgence,
- l'évaluation et la gestion des risques,
- un régime de responsabilité et de réparation,
- le processus de suivi et de contrôle.

#### **BURUNDI**

a) Draft National Biosafety Framework, 2006 http://bch.biodiv.org/database/attachedfile.aspx?id=1267

## III.2. IMPLEMENTATION OF THE REQUIREMENTS OF THE CARTAGENA PROTOCOL

The stock-taking and analysis of the existing legal texts and their relevant provisions relating to the Biosafety issues have revealed that these texts are not completely adapted to answer to the requirements of the Protocol. That is why Burundi has chosen to set up a new system that allows fulfilling its role towards the requirements relating to the GMO regulation by elaborating a draft law specific to Biosafety issues. This draft law comprises the following main elements:

- General provisions;

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- Institutional framework;
- Notification and authorization;
- The decision procedure and review;
- Risk assessment and management;
- Unintentional release and emergency measures
- Identification and labelling;
- Confidential information of commercial nature;
- Export of genetically modified organisms or products derived of genetically modified organisms;
- Liability;
- Penal provisions;
- Various provisions;
- Final provisions;

In the aim of harmonizing the whole of the Burundian regulations to the new Biosafety policy, Burundi will amend and adapt the existing closely related legislations.

#### **CAMEROON**

a) Law to lay down safety regulations governing modern biotechnology in Cameroon Entry into force 2003

http://bch.biodiv.org/database/attachedfile.aspx?id=508

#### Chapter V - Identification of risks and liability

#### Section 10

Users shall be responsible fore ensuring that appropriate measures have been taken to prevent any negative impact on the environment that may result from the use and handling of genetically modified organisms.

#### Section 11

- (1) Liability for any damage resulting from the release of genetically modified organisms shall be borne by the implicated user.
- (2) When an inspector or controller seizes such an organism as stipulated in section 56 of this law, the user concerned at the time of use or of the release thereof shall not be liable for any damage caused, except where the latter had anticipated or was in a position to foresee and prevent the said damage, and had however failed to take acceptable action to that effect.

#### Section 37

The user of genetically modified organisms shall be liable for any damage caused by the deliberate or accidental release of such organisms.

#### II Penalties

#### Section 60

Whoever is found guilty of violating the safety measures provided for in section 7, 9, 13, 14, 20, 22 and 55 of this law, shall be punished with imprisonment for from 6 (six) months to 2 (two) years or with fine of from 100,000 to 1,000,000 CFA francs or with both such imprisonment and fine.

#### Section 61

Whoever violates the approval, authorisation, notification and urgent intervention measures provided for in section 25, 26, 28, 30 and 36 above shall be punished with imprisonment for from 2 (two) to 5 (five) years or with fine of from 1,000,000 to 5,000,000 CFA francs or with both such imprisonment and fine.

#### Section 62

Whoever is found guilty of putting genetically modified organisms and products thereof into dangerous use shall be punished with imprisonment for from 5 (five) to 7 (seven) years or with fine of from 5,000,000 to 10,000,000 CFA francs or with both such imprisonment and fine.

#### Section 63

Whoever is found guilty of an offence committed in relation to a micro-organism shall be punished with imprisonment for from 7 (seven) to 10 (ten) years or with a fine of from 10,000,000 to 100,000,000 CFA francs or with both such imprisonment and fine.

#### Section 64

Any second offender shall be liable to twice the maximum of the penalties provided for above.

#### Chapter II - Settlement

#### Section 65

- (1) The competent national administration in charge of biosafety shall have full powers to work out a compromise. To this end, the accused must refer the matter to the authority concerned.
- (2) The amount of money paid as settlement shall be determined in consultation with the authority in charge of finance. The said amount shall not be less than the minimum amount of the corresponding penal fine.
- (3) Under pain of nullity, the settlement procedure shall be carried out before any possible court proceeding.
- (4) The method of collecting and allocating the proceeds of the settlement shall be determined by regulation.

#### **CONGO**

#### a) Draft National Biosafety Framework,2004

http://bch.biodiv.org/database/attachedfile.aspx?id=1271

## II.5. Responsabilité et réparation II.5.1.Principe

Un certain nombre de questions se posent en matière de responsabilité et de réparation notamment :

- quel type de réparation devrait s'appliquer aux dommages résultant de mouvement transfrontière d'OGM?
- quel type de perte ou de dommage devrait lieu à réparation ?
- qui devrait payer ces dédommagements ?
- dans quelles circonstances?
- un régime spécifique de responsabilité ?

Ces principales interrogations seront prises en considération conformément aux décisions éventuelles de la Réunion des Parties. Les règles qui s'appliquent concernent :

- le champ d'application des règles et des procédures ;
- l'affectation des responsabilités ;
- l'accès et la qualité à agir;
- les sources complémentaires de réparation ;
- la définition des dommages ;
- les critères de diligences et de prudence etc... conformément à l'article 27 du Protocole de Cartagena.

#### CONGO, Democratic Republic of the

#### a) Draft National Biosafety Framework, 2007

http://bch.cbd.int/database/record-v4.shtml?documentid=43383

#### II. LEGAL AND REGULATORY ENVIRONMENT

#### II.2. Guidelines for the legal framework of biosafety management in the DRC

The development and the implementation of a national legal framework relating to biotechnological research, development, production, release, import, export and transit and use of the genetically modified organisms and derived products constitute one of the requirements of the implementation of the Cartagena Protocol.

To fulfill the requirements of the implementation of this protocol, the national biosafety legislation will have to approach the following important aspects: the scope, deliberate and unintentional movements, institution of advance informed agreement, information-sharing mechanisms, the protection of confidential information, risk assessment and management mechanisms, the plan of sanction prevention and repression, liability and redress regimes as well as the public participation mechanisms in the decision-making process.

#### EGYPT, Arab Republic of

#### a) The Environment Law, 1994 and Executive Regulations

 $\frac{http://www.egbch.com/regulations.html}{Egypt's Biosafety Clearing House website)} (the link provided in the central portal – BCH - is that of Egypt's Biosafety Clearing House website)$ 

# PRELIMINARY PART Chapter One General Provisions

#### <u>Article 1</u>

In the application of the provisions of this Law, the following words and expressions shall have the meanings hereby assigned to them:

#### 28. Compensation

Means compensation for the damage resulting from pollution accidents in accordance with the application of the provisions of the Civil Code and the provisions of the International Convention on Civil Liability to which the Arab Republic of Egypt adheres or to which it will adhere in future, including the International Convention on Civil Liability for Damage Caused by Oil Pollution Accidents signed in Brussels in 1969, or any other pollution accidents mentioned in the executive regulations of this Law.

#### 37. Environmental Disaster:

An accident resulting from natural factors or human action which causes severe damage to the environment and requires resources beyond the local means.

# PART ONE PROTECTION OF LAND ENVIRONMENT FROM POLLUTION CHAPTER ONE DEVELOPMENT AND ENVIRONMENT

#### Article 22

Pursuant to the provisions of this Law, the owner of an establishment shall keep a written register to record the impact of his establishment activities on the environment. The executive regulations will determine the standard form of the required register, the time frame of the establishment obligation to keep it and the data to be entered therein. The EEAA is authorized to follow up entries in the register to ensure that they conform to the facts, to take samples as required and to conduct appropriate tests to determine the impact of the establishment activities on the environment and the extent of its compliance with the criteria laid down for the protection of the environment. In case of any violation, the EEAA shall notify the competent administrative authority to direct the owner of the establishment to rectify such violation forthwith. If the owner fails to comply within 60 days, the EEAA shall be entitled, in agreement with the competent administrative authority, to take such legal and judicial procedures as are necessary to stop the offending activity and claim adequate damages to redress the harm resulting from the violation.

#### **ETHIOPIA**

a) Biosafety Framework, 2007
<a href="http://bch.biodiv.org/database/attachedfile.aspx?id=1278">http://bch.biodiv.org/database/attachedfile.aspx?id=1278</a>
From Annex II containing Draft Biosafety Law

## PART SIX Enforcement and Compliance

#### 29. Liability and Redress

- 1. Approval for any transaction by the Authority does not exonerate the applicant from liability.
- 2. A person who is engaged in any transaction shall be strictly liable for any harm caused by such a genetically modified organism or products thereof. The harm shall be fully compensated.
- 3. Without prejudice to sub-Article 2 of this Article, exemption from liability shall be granted only when it is verified that it is the victim himself or a third person for whom the proponent is not responsible that has caused the damage.
- 4. Liability shall attach to the person responsible for the transaction, which results in the damage, injury or loss as well as to the provider, supplier or developer of the genetically modified organism or product thereof.
- 5. If there is more than one person responsible for the damage, injury or loss, then the liability shall be joint and several.
- 6. In the case of harm to the environment or biological diversity, compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the costs of preventive measures.
- 7. In the case of harm to human health, compensation shall include:
  - a) All costs and expenses incurred in seeking and obtaining the necessary and appropriate medical treatment;
  - b) Compensation for any disability suffered, for diminished quality of life, and for all costs and expenses incurred in reinstating, as far as possible, the quality of life enjoyed by the person before the harm was suffered;
  - c) Compensation for loss of life and all costs and expenses incurred for funeral and other related expenses;
- 8. Liability shall also extend to harm or damage caused directly or indirectly by the genetically modified organism or its product to:
  - a) The livelihood or indigenous knowledge systems of local communities,
  - b) Technologies of a community or communities,
  - c) Damage or destruction arising from incidence of public disorder triggered by the genetically modified organism or product thereof,
  - d) Disruption or damage to production or agricultural systems,
  - e) Reduction in yields,
  - f) Soil contamination,
  - g) Damage to the biological diversity,
  - h) Damage to the economy of an area or community, and
  - i) Any other consequential economic, social or cultural damages
- 9. The right to bring any civil action in respect of harm caused by a genetically modified organism or a product thereof shall, having due regard to the laws on limitations of rights, commence from the date on which the affected person(s) or the community or communities could reasonably be expected to have learned 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 correlate the harm with the genetically modified organism or the product thereof, taking into consideration the situation or circumstance of the person(s) or community or communities affected.
- 10. Any person, group of persons, or any private or state organization is entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision of this law, including any provision relating to damage to human health, biological diversity, the environment, or to socioeconomic or cultural conditions of local communities or to the economy of the country,
  - a) in that person's or group or class of persons' interest;

- b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
- c) in the interest of, or on behalf of, a group or class of persons whose interests are affected;
- d) in the public interest; and
- e) in the interest of protecting the environment or biological diversity.
- 11. 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 human health, biological diversity or the environment.
- 12. The burden of proving that an action was not instituted out of public interest or in the interest of protecting human health, biological diversity or the environment rests on the person claiming thus.

#### 30. Liability of officers of a governmental or a non-governmental entity

Where a private company or a governmental agency commits an offence under this Proclamation, any officer, director, employee or agent of the entity who directed, authorised, assented to, acquiesced in or participated in the commission of the offence is a party to and guilty of the offence, and is liable to the punishment provided for the offence.

#### 31. Offences and Penalties

- 1. Without prejudice to the provisions of the 2005 Criminal Code of Ethiopia, any person who;
  - (a) is involved in any transaction under this Proclamation without the authorization of the Authority;
  - (b) violates any conditions attached to the grant of authorization under this law;
  - (c) fails to furnish any information as required by the provisions of this law;
  - (d) withholds information that has become available to her/him after the authorization of her/his application, and that could change the evaluation of the risk posed by her/his project;
  - (e) provides false, misleading or deceptive information in order to secure an authorization;
  - (f) does not label, package or identify any genetically modified organism or its product in accordance with this law and the directives issued by the Authority;
  - (g) labels, packages or identifies any genetically modified organism or its product in a manner that is false, misleading or deceptive or in contravention of any regulation made under this law;
  - (h) exports a genetically modified organism or its product without the advance informed agreement of the importing country;
  - (i) participates in any proceedings related to decision taking in respect of a subject matter covered by this law in which she/he has any direct or indirect interest of any kind;
  - (j) violates any other provision of this law or any directives issued by the Authority;
  - (k) uses a genetically modified organism or product thereof for hostile purposes;
  - (1) obstructs or fails to assist the Authority or other authorized officers in the performance of their duties under this Proclamation;
  - (m) refuses or fails to furnish information or to give an explanation or to reply to the best of her/his ability to any question lawfully demanded from her/him by any Inspector in the performance of her/his functions as determined by this Proclamation;
  - (n) falsely holds herself or himself out to be an Inspector or any other officer appointed under this Proclamation,
  - (o) fails to inform the Authority of any accident or emergency involving a genetically modified organism or product thereof; Commits an offense and is liable on conviction to imprisonment for a term not less than ----- years or to a fine of ----- or both.
- 2. Any person shall upon conviction of any offense under this Proclamation be prohibited from engaging in any activity in relation to genetically modified organisms or products thereof. Such order of prohibition shall extend to any governmental or non-governmental entity.

3. Where the offense is committed by a governmental or a non-governmental entity, and where the court feels that a custodial sentence ought to be imposed, the executive officer in charge at the time the offense is committed shall be liable to imprisonment.

#### 32. Civil Claims for Environmental Damage

Notwithstanding the results of any criminal proceedings arising under this Proclamation any person, an inspector, including the one who has suffered loss or harm as a result of any release of genetically modified organism or product thereof, may institute a civil claim for damages in court, which may include a claim for:

- (a) economic loss resulting from the release of genetically modified organisms or products thereof or from activities undertaken to prevent, mitigate, manage, clean up or remediate any harm from such release;
- (b) costs incurred in any inspection, audit or investigation undertaken to determine the nature of any release of genetically modified organism or product thereof, or to investigate response and risk management options.

#### b) Biosafety Framework, 2007

http://bch.biodiv.org/database/attachedfile.aspx?id=1278

From Annex III containing Directives

### DIRECTIVE NO.FIVE

#### A DIRECTIVE ISSUED TO DETERMINE THE PROCEDURES FOR THE STORAGE OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS THEREOF

## 3. PROCEDURES FOR THE STORAGE OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS THEREOF

3.3 In under taking the licensing and registration premises under the above provision, the Federal Environmental Protection Authority shall require such premises to carry adequate insurance to cover any foreseeable liability for harm to human health or the environment.

#### DIRECTIVE No.SIX

## A DIRECTIVE ISSUED TO DETERMINE RESPONSES TO ACCIDENTAL RELEASE OF GENETICALLY MODIFIED ORGANISMS OR PRODUCTS THEREOF

#### 3. EMERGENCY MEASURES

- 3.1 The Federal Environmental Protection Authority shall, in order to be ready to give direct response to any accidental release of GMOs or products thereof establish an Accidental Release Response Group.
- 3.2 The Accidental Release Response Group shall comprise representatives from relevant institutions capable of undertaking risk management measures.
- 3.3 The Federal Environmental Protection Authority shall appoint a leader, who shall direct the activities of the Accidental Release Response Group and for this purpose shall have the powers and responsibilities provided under this Directive.
- 3.4 The duties and functions of the Accidental Release Response Group shall be to:
  - a) Develop appropriate systems for the detection and reporting of accidental releases of any GMOs or products thereof or of incidents related to the transport and use of GMOs or products thereof which could result in such accident;
  - b) Ensure that prompt response is made in the event of an accidental release of any GMOs or products thereof to prevent damage to biodiversity, the environment or human health.

- c) Ensure that the correct response techniques and risk management measures are used in the event of an accidental release of any GMO or products thereof and that the disposal of recovered GMOs or products thereof is carried out in an environmentally sound manner;
- d) Ensure that complete and accurate records are maintained regarding all the expenditures incurred in responding to the event of an accidental release of any GMOs or products thereof to facilitate cost recovery and the payment of compensation;
- e) Provide adequate protection for public health and the protection of the environment in the event of an accidental release of any GMOs and products thereof;
- f) Ensure the prompt and efficient mobilization of available manpower, resources, equipment which will be used in the event of an accidental release of any GMOs and products thereof; and
- g) Develop, implement and keep under review a national risk management plan.
- 3.5 The Accidental Release Response group leader shall co-ordinate emergency preparedness and response measures, and for this purpose shall use available resources to develop and implement a National Accidental Release of GMOs Risk Management Plan, establish such communications with stakeholders as are necessary to ensure the efficient administration and control of all emergency preparedness when any accidental release of GMOs and products thereof has occurred.
- 3.6 The Accidental Release Response Group shall be the sole authority responsible for response to any accident, and shall direct the activities of agencies or parties that may offer assistance in the event of an accident.
- 3.7 The Accidental Release Response Group shall meet at such times and with such frequency as may be necessary to fulfill the duties and responsibilities required, which in any event shall not be less than every six months.

#### **GAMBIA**

a) National Biosafety Framework, 2005 http://bch.biodiv.org/database/attachedfile.aspx?id=1280

#### 4. SYSTEM TO HANDLE NOTIFICATIONS/REQUESTS

#### 4.7 Administrative and Legal Recourse

Individuals and organizations that obtain authorization shall legally be held responsible for informing the authority about any new elements likely to change the health and environmental risk evaluation undertaken. Non adherence to the administrative and legal provisions resulting to injury to health and the environment will empower the Authority to (i) request the holder of the approval to deposit sufficient money in a commercial bank commensurate to the corrective measures to be undertaken, (ii) levy a penalty on the individual or organization for the performance of the prescribed corrective measures and or (iii) suspend the authorization until such time that the prescribed corrective measures are performed accordingly.

#### **GHANA**

a) Draft National Biosafety Framework, 2004
<a href="http://bch.biodiv.org/database/attachedfile.aspx?id=1281">http://bch.biodiv.org/database/attachedfile.aspx?id=1281</a>
From Annex 2 containing draft of a bill entitled Biosafety Act, 2004

#### Protection from personal liability

10. A matter or thing done by a member of the Board or by an officer, employee or agent of the Authority, shall not, if the matter or thing is done bona fide in the performance of a function of the Authority, render the member, officer, employee or agent personally liable to an action, a claim or demand.

#### Civil liability and redress

43. Liability or redress for a damage that occurs as result of an activity under this Act is subject to the applicable laws.

#### **GUINEA**

a) Draft National Biosafety Framework, 2005 http://bch.biodiv.org/database/attachedfile.aspx?id=1282

La législation devra comporter également, une procédure particulière pour le cas des organismes vivants modifiés destinés à être utilisés directement dans l'alimentation humaine ou animale, ou à être transformés; les mouvements transfrontières et mesures d'urgence, les mesures pour la manipulation, le transport, l'emballage et l'identification des OGM; la sensibilisation et la participation du public, la gestion des informations confidentielles; les règles de responsabilité et de réparation ainsi que l'échange d'informations avec le centre international d'échange pour la prévention des risques biotechnologiques.

#### **KENYA**

a) The Biosafety Act, 2009 http://www.absfafrica.org/

#### PART II-ESTABLISHMENT, POWERS AND FUNCTIONS OF THE AUTHORITY

#### Protection from personal liability

16. No matter or thing done by a member of the Board or by any officer, member of staff, or agent of the Authority shall, if the matter or thing is done bona fide for executing the functions, powers or duties of the Authority under this Act, render the member, officer, employee or agent or any person acting on their directions personally liable to any action, claim or demand whatsoever.

#### Liability for damages

17. The provisions of section 16 shall not relieve the Authority of the liability to pay compensation or damages to any person for any injury to him, his property or any of his interests caused by the exercise of any power conferred by this Act or any other written law or by the failure, wholly or partially, of any works.

#### PART VI—RESTORATION AND CESSATION ORDERS

#### Environmental restoration order

- **40.** (1) The Authority may issue and serve on any person a restoration order in respect of any matter relating to release of a genetically modified organism into the environment.
- (2) An environmental restoration order issued under subsection (1) shall be issued to—

- (a) require the person on whom it is served to restore the environment as near as it may be to the state in which it was before the release of a genetically modified organism;
- (b) levy a charge on the person on whom it is served which, in the opinion of the Authority, represents a reasonable estimate of the costs of any action taken by an authorized person or organization to restore the environment to the state in which it was before the release of a genetically modified organism.

#### Contents of restoration order

- **41.** An environmental restoration order shall specify clearly and in a manner which may be easily understood—
  - (a) the activity to which it relates;
  - (b) the person to whom it is addressed;
  - (c) the time at which it comes into effect;
  - (d) the action which should be taken to remedy the harm to the environment and the time, being not more that thirty days or such further period as may be prescribed in the order, within which the action should be taken; and
  - (e) the penalty which may be imposed if the action specified is not undertaken.

#### LESOTHO

a) Draft National Biosafety Framework, 2005

http://bch.biodiv.org/database/attachedfile.aspx?id=1283

#### 4 NATIONAL BIOSAFETY LAW

#### c) Environment Act (Act 15 of 2001):

The Act focuses on pollution control and has sections dealing with prohibition of discharge of hazardous substances, chemicals and materials or oil into the environment and the spiller liability; it has a section for conservation of biological safety.

Under section 66 the Act deals with Conservation of biological diversity and stipulates that "the authority shall in consultation with the relevant Line Ministry, issue guidelines and prescribe measures for the conservation of biological diversity". These sections do not cover all the criteria and issues of biosafety as per the requirements of the Cartagena protocol on biosafety.

From the draft National Biosafety Policy a National Biosafety Bill was developed (please check Attachment 2 for the Bill). The Bill would be administered by Ministry responsible for Environment as both the Competent Authority and the Focal Point. The Bill would establish the National Biosafety Council (NBC), whose members shall be appointed by the Minister responsible for Environment. According to the Bill only the Ministry responsible for Environment would be a Competent Authority.

The Bill also establishes a National Biosafety Council Registrar (NBCR) within the Competent Authority. The Registrar is answerable to the Competent Authority for discharge of duties under the Bill.

The Competent Authority, the NBC, the NBCR, the SAC and the Socio-economic Panel shall protect information determined by the Competent Authority as being confidential, after a claim for confidentiality is made by the applicant. Other important sections of this Act are Liability and Redress, Offences and Penalties, and Enforcement which include Inspections.

#### **LIBERIA**

a) National Biosafety Framework, 2004 http://bch.biodiv.org/database/attachedfile.aspx?id=1681

#### 3.5 Draft Liberia Biosafety Act (2004)

The Liberia Biosafety Act is as yet a draft legislation. It shall regulate all activities in biotechnology, which include contained use, environmental releases, placing on the market, transit, import, and export of GMOs -except those GMOs for human use which are regulated by other international agreements.

The draft Liberia Biosafety Act is a component of this NBF developed through consultation with major stakeholders. Key provisions of the Act include procedures for handling requests for deliberate releases into the environment, transit and contained use, releases for experimental purposes as well as notification procedures for placing on the market GMOs as or in products and exportation of GMOs. It contains also risk assessment and risk management measures as well as decision-making procedures that involve public participation.

It also proposes institutional arrangement for implementation of Biosafety regulations. The institutions include: National Focal Point, Competent National Authority, National Biosafety Committee, and Institutional Biosafety committee.

Other provisions of the Act include identification and labeling of GMO products, unintentional release and emergency measures; it deals also with the issues of liability and redress –placing strict liability on offenders.

Additionally, the Act defines what constitutes offenses and stipulates penalties appropriate for such acts or non-actions.

#### 3.6 DRAFT LIBERIA BIOSAFETY REGULATIONS

Pursuant to Section 8.5 of the draft Biosafety Act, Regulations have been drafted for implementation of the provisions of the draft Act subsequent to its enactment into law. The regulations are arranged in eleven (11) parts as follow:

viii) **Part Eight** deals with liability and redress. It imposes strict liability on any person, natural or legal, whose activities in relation to GMOs cause harm, or injury, or loss directly or indirectly to person or the environment.

#### *MADAGASCAR*

a) National Biosafety Framework, 2004 http://bch.biodiv.org/database/attachedfile.aspx?id=1285

From Appendix 5: Draft bill relating to the biosafety system

## CHAPTER IV IDENTIFICATION, CLASSIFICATION OF THE LEVELS OF SECURITY AND RESPONSIBILITY

#### Article 6

The responsibility for any damage caused as a result of the introduction or the activities relating to the GMO and/or derivatives falls to the blamed importer or user.

Any person victim of introduction, use, marketing, research or industrial activities related to

GMO and/or derivatives can claim for damage in reparation of his wrong to the court concerned against his authors.

#### Article 7

The State can have certain responsibilities because of its decision relating to the GMO and/or derivatives or to non adherence to the regulations provided by this law.

At the international level, the Malagasy State can take the various available mechanisms as regards the settlement of trade disputes on issues concerning the agricultural GMO and their derivatives.

#### **MALI**

#### a) National Biosafety Framework, 2005

http://bch.biodiv.org/database/attachedfile.aspx?id=1287

From PART II-DRAFT BILL RELATING TO BIOSAFETY IN THE REPUBLIC OF MALI

#### CHAPTER XV: LIABILITY AND REDRESS

#### Article 57

Any person that imports, uses in confined environment, releases or puts on the market a genetically modified organism or a product of such genetically modified organism is strictly held responsible for damages caused by this genetically modified organism or this product of such genetically modified organism. These damages must be fully redressed.

#### Article 58

The redress of a damage lies with the person responsible for the activity that caused the damage, the nuisance or the loss as well as with the supplier, of the trustee or of the developer of genetically modified organisms or products of such genetically modified organism.

#### Article 59

If there is more than one person responsible for the damage, the nuisance or the loss, each will jointly share the responsibility.

#### Article 60

In case of damage to the environment or to the biological diversity by a genetically modified organism or a product of such genetically modified organism, the compensation amount will include the costs of the extent of restoration, rehabilitation and sanitation that would have really been incurred and in some cases, the costs associated with the preventive measures.

#### Article 61

In case of damage to the human health, the compensation will include:

- the total costs incurred to find and obtain the required and appropriate medical treatment;
- the amount of allowances for disability, for the reduction of the quality of life and the total costs incurred to restore, if possible, the quality of life that the person enjoyed before he suffered the damages;
- the amount of death benefit and the total costs incurred for the funeral;

#### Article 62

The liability and redress will also extend to the socioeconomic considerations:

- the nuisances and the damages directly or indirectly caused by the genetically modified organism or the product of such genetically modified organism to the economy;
- the social and cultural conditions, especially the negative effects on the life styles, the traditional knowledge and technologies of one or more communities;
- the damages and losses caused by public unrests emanating from the genetically modified organism or the product of such genetically modified organism;
- the complete or agricultural partial destruction of industrial or production systems, the loss of harvests, the contamination of soils;
- the damages caused to the biological diversity, the economy of a region and any other direct and indirect damages;

#### Article 63

In case of damage provoked by a genetically modified organism or a product of such genetically modified organism, the right to take legal action can only be null and void after a time limit of 10 days from the damage awareness by the affected person or community, taking into accounts the following elements:

- the time required for the damage manifestation; and
- the time required to make a link between the damage and the genetically modified organism or the product of such genetically modified organism, taking into account the situation of the person(s) or the affected community(ies), or the circumstances in which they are found.

#### Article 64

Any person, group of persons or private or public organisations can sue and request for redress in case of breach or risk of breach to the obligations of this law, especially the provisions linked to the damages caused to the human health, the biological diversity, to the environment or even to socioeconomic conditions:

- in the interest of this person or the group of persons;
- in the interest or in the name of a person who, for practical reasons, is incapable to launch such a procedure;
- In the interest or in the name of a group or class of people whose interests are threatened;
- in the general interest; and
- for the protection of the environment and biological diversity.

#### Article 65

No request for a claim for damages coming from a natural person and moral entity being sued can validly be accepted if the above law suit was intended in a disinterested way or in the general interest or the aim of protecting the environment or the biological diversity.

#### CHAPTER XVIII: SPECIAL PROVISION

#### Article 75

The damages caused by genetic resources to communities following the transfer, the use, the handling of GMO and GMO products and their use in the biotechnology, will be subject to redress and/or sharing to the benefit of the said communities.

#### **MAURITIUS**

#### a) THE GENETICALLY MODIFIED ORGANISMS ACT 2004

http://bch.biodiv.org/database/attachedfile.aspx?id=1130

#### 20. Accidents

- (1) Every person who is informed or becomes aware of an accident shall immediately notify the Permanent Secretary.
- (2) Where a GMO permit holder notifies an accident, he shall supply to the Permanent Secretary –
- (a) all relevant information on the circumstances of the accident, the identity, quantity and quality of genetically modifies organisms released and any other information necessary to assess the impact of the accident on the environment and on human and animal health; and
- (b) the details of any emergency measures taken to avoid or mitigate any adverse impact on the environment and human and animal health.
- (3) The Permanent Secretary shall appoint on an ad hoc basis a Special Committee comprising a Chairperson and 2 members, being persons having wide expertise in the field relating to the accident, to enquire into the circumstances of the accident and make a report with recommendations to the Permanent Secretary.
- (4) The Permanent Secretary may, after taking into consideration the report and recommendations of the Special Committee, and where he considers that the accident has had an adverse impact on the environment or on human or animal health, take a decision under section 9(2).
- (5) The Permanent Secretary shall inform as soon as reasonably practicable any other country of any accident which may have an impact on that country's environment or on human and animal health in that country.

#### 22. Offences

- (1) A person who –
- (a) fails to comply with any condition, permit, or prohibition under this Act;
- (b) obstructs or hinders an authorised officer in the exercise of his functions under this Act;
- (c) provides information under this Act which is false or misleading in any material particular;
- (d) otherwise contravenes this Act, shall commit an offence and shall, on conviction, be liable –
- (i) on a first conviction to a fine not exceeding Rs 50,000 and to imprisonment for a term not exceeding 2 years;
- (ii) on a second or subsequent conviction, to a fine not exceeding Rs 100,000 and to imprisonment for a term not exceeding 4 years.
- (2) In addition to any penalty under subsection (1), the Court may order the forfeiture of any animal, plant, organism or any article used in, or connected in any way with, the commission of an offence.

#### 24. Regulations

(1) The Minister may make such regulations as he thinks fit for the purposes of this Act.

- (2) Any regulations made under subsection (1) may
  - (a) provide for the levying of fees and charges;
  - (b) lay down requirements for laboratory development of genetically modified organisms;
  - (c) set out standards to which facilities for activities involving genetically modified organisms should conform;
  - (d) make provision for quarantine, transit, marketing, sale, transport, handling and packaging of genetically modified organisms;
  - (e) provide for liabilities of GMO permit holders in respect of prejudice caused by their activities to other persons;
  - (f) amend the Schedules.
- (3) Regulations made under this Act may provide that any person who contravenes them shall commit an offence and shall, on conviction, be liable to a fine not exceeding 50,000 rupees and to imprisonment for a term not exceeding 2 years.

#### MOZAMBIQUE, Republic of

a) Draft National Biosafety Framework, 2005

http://bch.biodiv.org/database/attachedfile.aspx?id=1289

From ANNEX A-DRAFT BIOSAFETY REGULATION, 2004

#### CHAPTER VI COMMON PROVISIONS

#### Article 18 Liability and redress

The applicant is legally responsible for the accuracy of the entire information contained in the documents submitted for analysis.

- 1. In cases where an accident involving products containing GMOs occurs, the responsible entity under their guard must ensure that the MINAG is notified on:
  - a) The circumstances under which the accident occurred;
  - b) The identity and quantity of the product released;
  - c) The emergency measures taken to mitigate any adverse effects;
  - d) The possible impact on the human health and the environment;
- 2. The applicant is entirely liable to meet the costs of redressing any damage resulting from its activities on GMOs and their products, as well as for the application process and analyses to be conducted.

#### CHAPTER VIII FEES AND PENALTIES

## Article 24 Breaches and fines

- 1. Under the present Regulation and without prejudice to what is stipulated in specific legislation, the following acts constitute breaches:
  - a) The import and placing on the marketing of GMOs and their products destined for food, feed or processing without an authorization from the MINAG.
  - b) The handling, manipulation, production and possession of GMOs and their products without authorization from the MINAG;
  - c) The execution of field experiments with GMOs and its products without an authorisation from the MINAG;
  - d) To provide false declarations or biased information;

- *e)* The obstruction of the work of the inspectors
- f) The lack of labelling and correct identification of products containing GMOs;
- g) The failure to report to the competent authority about any accident involving GMOs that have occurred;
- h) The utilisation of GMOs for purposes different from what was indicated in the import authorization;
- i) The introduction of GMOs and their products in the country through an entry point different from what was stipulated in the import authorization.
- 2. Any infringement under the paragraph 1 of present Article shall be punished through a fine and it shall imply the refusal of entry and subsequent returning of the imported products to the country of origin, or its seizure and subsequent reversion to the State.
- 3. The violator shall be liable for meeting the financial costs resulting from the measures taken to redress the infringement.
- 3. The fines charged under the present Regulation shall be calculated according to the table contained in the Annex VI.
- 4. The deadline for the payment of a fine is 15 days, starting from the date of notification of the violator

#### **NAMIBIA**

a) Biosafety Act, 2006 http://bch.biodiv.org/database/attachedfile.aspx?id=1705

#### Act binds the State

**4.** This Act binds the State, except a provision imposing criminal liability for an offence.

#### Offences and competent court orders

- 47. (1) A person who -
  - (a) forges or utters, knowing it to be forged, or makes any unauthorised alteration to a permit or registration certificate, or any risk assessment report or risk management plan or any other document issued under or provided for in this Act;
  - (b) provides information under this Act which is false or misleading in any material particular;
  - (c) makes any false entry or declaration in any register or document that the Registrar requires to be kept;
  - (d) hinders, obstructs or assaults an inspector in the course of carrying out his or her duties under this Act commits an offence and is liable on conviction to a fine not exceeding N\$8000.00 or to imprisonment for a period not exceeding 2 year, or to both such fine and such imprisonment.
- (2) In the event of a conviction under this Act the court may order that any damage to the environment resulting from the offence be repaired by the person so convicted to the satisfaction of the Minister.
- (3) If within a period of 30 days after a conviction, or such longer period as the court may determine at the time of the conviction, an order in terms of subsection (2) is not being complied with, the Minister may cause the necessary steps to be taken to repair the damage to the environment and recover the reasonable cost thereof from the person so convicted.
- (4) If a person is convicted of an offence under this Act and it appears that the person has by that offence caused loss or damage to any organ of State or any other person, the court may in the same proceedings

at the written request of the Minister or other person concerned, and in the presence of the convicted person, inquire summarily and without pleadings into the amount of the loss or damage so caused.

- (5) Upon proof of such amount, the court may give judgment therefor in favour of the organ of State or other person concerned against the convicted person, and such judgment has the same force and effect, and be executable in the same manner, as if it had been given in a civil action by a competent court.
- (6) If a person is convicted of an offence under this Act, the court convicting the person may summarily enquire into and assess the monetary value of any advantage gained or likely to be gained by the person in consequence of that offence, and, in addition to any other punishment imposed in respect of the offence or compensation order made under subsection (5), impose on that person a fine equal to the amount so assessed or, in default of payment, imprisonment for a period not exceeding one year.
- (7) If a manager, agent or employee of an employer does or omits to do an act which would constitute an offence under this Act if done or omitted to do by the employer, and the act or omission -
  - (a) is of a nature which is the task of the manager, agent or employee, to do or to refrain from doing within the scope of his or her employment; and
  - (b) occurred because the employer failed to take all reasonable steps to prevent the act or omission in question, then the employer is guilty of that offence, and proof of the act or omission by the manager, agent or employee constitutes prima facie evidence that the employer is guilty under this section.
- (8) An employer convicted under subsection 7 must not be imposed a penalty other than a fine specified in the relevant provision, but the court may, in addition, make an order under subsection (2), (5) or (6) against the employer.
- (9) Whenever a manager, agent or employee of an employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, the manager, agent or employee shall be liable to be convicted and sentenced in respect thereof as if he or she were the employer.
- (10) A person who is or was a director, officer or agent of a corporate body at the time of the commission by that corporate body of an offence under this Act, is personally guilty of that offence and liable on conviction to the penalty specified in this Act if -
  - (a) the director, officer or agent connived in the commission of the offence; or
  - (b) the director, officer or agent failed to take all reasonable steps to prevent the commission of the offence, and the issuing of instructions by the director forbidding any act or omission constituting the offence in question is not, by itself, a sufficient defence, and proof of the said offence by the corporate body shall constitute prima facie evidence that the director, officer or agent is guilty under this sub-section.
- (11) Any such manager, agent, employee or director may be so convicted and sentenced in addition to the employer or corporate body.

#### **Forfeiture**

- **48.** (1) The court convicting a person of an offence under this Act may, when requested thereto by the prosecutor, declare any thing through which the offence was committed or which was used in the commission of the offence, or the rights of the convicted person to such thing, to be forfeited to the State.
- (2) A forfeiture under subsection (1) does not affect the rights which any person other than the convicted person may have to the thing concerned, if it is proved that he or she -

- (a) did not know that the thing was being used or would be used for the purpose of or in connection with the commission of the offence; or
- (b) could not prevent such use, and that he or she may lawfully possess such thing.
- (3) The provisions of the law relating to criminal procedure providing for the forfeiture of articles, the custody and disposal thereof, the determination of any third person's claim to the forfeited article, including any subsequent appeal by such person, apply with the necessary changes to any thing declared forfeited in accordance with this Act.

#### **NIGERIA**

#### a) Nigeria Biosafety Guidelines

http://bch.biodiv.org/database/attachedfile.aspx?id=2216

#### 4. SCOPE AND METHODOLOGY

These guidelines shall cover the following:

(f) Liability and redress in the use, handling, transportation of LMOs/GMOs.

#### 14. LIABILITY AND REDRESS

- (a) Any person who carries out any activity in relation to LMOs/GMO(s) or products thereof shall be strictly liable for any harm, injury or loss caused directly or indirectly by such LMOs/GMO(s) or products thereof or 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.
- (b) 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 LMOs/GMO(s) or products thereof.
- (c) Where liability under this section is incurred by a corporate body, any director, manager, secretary or similar officer of the corporate body shall be similarly liable unless he/she can show that he/she did everything in his/her power to prevent the import, deliberate release, placing on the market or contained use which caused the damage in question.
- (d) If there is more than one person responsible for the damage, injury or loss, the liability shall be joint and several.
- (e) 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.
- (f) 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 authorities.
- (g) Liability shall also extend to harm or damage caused directly or indirectly by the LMOs/GMO(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. (h) An applicant shall indemnify:
  - (i) Any other person who deliberately releases or markets LMOs/GMO(s) or products thereof; and
  - (ii) Any person who manufactures, processes or markets food, food ingredients or animal feed containing or derived from LMOs/GMO(s) against any civil liability where the LMOs/GMO(s) or

products thereof in question was first imported, deliberately released, used in contained conditions, or placed on the market by the applicant.

- (iii) Any person who fails to label seeds, food, a food ingredient or animal feed containing or derived from LMOs/GMO(s), against any civil liability.
- (i) The right to bring any action to redress the harm caused by the LMOs/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 itself; and
  - (b) the time that it may reasonably take to correlate the harm with the GMO(s) or products thereof, having regard to the situation or circumstance of the person or community affected.
- (j) 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 draft Guidelines, including any provision relating to damage to the environment and biological diversity:
  - (i) in that person's or group of persons' 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.
- (k) 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.
- (l) It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the competent authorities.
- b) Draft National Biosafety Framework, 2005

http://bch.biodiv.org/database/attachedfile.aspx?id=1292

Section 11. LIABILITY AND REDRESS of the draft National Biosafety Framework includes the same reference as provided in the above Guideline.

#### **RWANDA**

#### a) National Biosafety Framework, 2005

h http://bch.biodiv.org/database/attachedfile.aspx?id=1293

## CHAPTER FOUR: ADMINISTRATION AND DECISION MAKING 4. Administrative, decision making and appeals

#### 4.7 Liability and Remedies

Any person who imports, transits, makes contained or confined use of, releases or places on the market a GMO, shall be strictly liable for any harm caused by such GMO and shall be bound to fully compensate all persons affected by such release, transit, use or placement on the market of the GMO in question (article 34 of the National Biosafety Bill).

#### **SOUTH AFRICA**

a) GENETICALLY MODIFIED ORGANISMS ACT, 1997

http://www.nda.agric.za/docs/geneticresources/AnnexureGMO.htm

#### Accidents

- 7. In the event of an accident involving genetically modified organisms, it shall be the responsibility of the user concerned to ensure that –
- (a) the registrar is notified immediately both verbally and in writing of such accident and the registrar is at the same time, or as soon as possible thereafter, supplied with information regarding -
- (i) the circumstances of the accident;
- (ii) the identity and quantity of the genetically modified organisms released;
- (iii) any information that is necessary to assess the impact of the accident on the environment and human health; and
- (iv) the emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment and human health; and
- (b) all appropriate short-term, medium-term and long-term measures are taken to avoid or mitigate any adverse impact of such accident on the environment and human health.

#### Offences and penalties

10. Any person who contravenes or fails to comply with any provision or requirement of these regulations shall be guilty of an offence and shall be liable to the penalties as provided for in the Act.

#### **SUDAN**

a) Draft National Biosafety Framework, 2005

http://bch.biodiv.org/database/attachedfile.aspx?id=1297

From Annex II- The Biological Biosafety Bill

#### Offences and Penalties

24. (a) Any person who violates a material provision of this Act or fails to comply with a

Cessation Order or regulation issued pursuant to this Act shall be guilty of an offence and shall be liable, upon a conviction or finding of violation by a competent court of law or a duly appointed administrative body, for such fines as may be set by regulation, consistent with those established for violations of similar legislation or regulations, including additional penalties for each day that the offence is continued after legal service of a Cessation Order upon that person.

(b) Any person who repeatedly and knowingly commits offences and is found to be in violation by a competent court of law or duly appointed administrative body under paragraph (a) for such offences may be prohibited from engaging in any further activities subject to this Act.

#### Liability and Redress

25. Liability and redress for any damage that occurs as a result of activities subject to this Act shall be addressed by applicable laws.

#### **SWAZILAND**

a) Draft National Biosafety Framework, 2006 http://bch.biodiv.org/database/attachedfile.aspx?id=1298

#### 3.3.0 The Biosafety Bill

It is clear from the review of local legislations that the sectoral pieces of legislations are not adequate to address biosafety. The country therefore generally lacks legislation designed to protect its citizens' health and the environment from the potential risks of modern biotechnology, in line with the objectives of the CPB. In particular, there is no legislation regulating genetically modified food and feed in order to ensure consumer protection, or allow consumers and farmers to decide if they want to buy food or feed produced from GMOs or not. An Act had then to be drafted to enable the country to have an adequate level of protection of, the environment, human, and animals and in relation to safe transfer, handling and use of GMOs. In this regards, the NCC appointed a drafting team that has developed a draft Biosafety bill as presented on Annex 2. It is hoped that this bill will soon be enacted into a biosafety Act. The draft biosafety bill has the following components:

#### 3.3.1 Objectives of the new Bill.

The objectives of the Bill are to ensure an adequate level of protection in the field of the safe transfer, handling and use of genetically modified organisms (GMOs); to provide a transparent process for review and decision-making on GMOs and related activities; to implement the Cartagena Protocol on Biosafety to the satisfaction of Convention on Biological Diversity.

#### 3.3.7 Liability and redress for damages attributed to release of GMOs

The new act addresses the damages caused by the release of GMOs to the environment, animal and public health. The law specifies that a person who imports, makes contained use of, releases or places on a market a GMO or a product of a GMO shall be liable for any harm caused by such GMO and to make compensation for any harm occasioned. It also states that where there has been harm to the environment or biological diversity, the party liable to pay compensation, shall also pay costs of reinstatement, rehabilitation or clean-up measures which are actually being incurred and, where applicable, the costs of preventive measures. Where human health is adversely affected by a GMO or a product of a GMO, legal action shall be taken against the responsible party, and the resulting decision shall determine:

- the amount of medical expenses;
- compensation for any disability suffered;
- and compensation for loss of life, as the case may be.

In general, fines for breach of any of the laws for biosafety will be specified in the special regulations of the Bill.

#### TANZANIA, United Republic of

#### a) Draft National Biosafety Framework, 2004

http://bch.biodiv.org/database/attachedfile.aspx?id=1299

#### 1.2 Guiding Principles

The following principles, based on national and international regulatory regime, shall guide the implementation of the NBF:

e) Strict liability: A person who imports, arranges transit, makes contained use of, releases or places on the market a GMO or product of a GMO shall be strictly liable for any harm caused by such a GMO or product of a GMO. The harm shall be fully compensated.

#### 3.3 Regulatory Mechanisms

#### 3.3.1 General Principles

The main principles that are embodied in the regulation of development and use of GMOs are the precautionary principle, prevention principle and principle of strict liability (refer to Section 1.2).

#### 3.3.3 Tools of Management

The draft Biosafety Regulations amply provide for tools to facilitate decision making in terms of risk assessment and risk management. It also provides for liability and redress and places strict liability on the one who carries out activity in relation to GMOs. It gives a wide locus standi which proposes that:

- (1) 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 the proposed Biosafety Regulations, including any provision relating to damage to the environment and biological diversity:
  - (a) in that person's or group of person's interest;
  - (b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
  - (c) in the interest of, or on behalf of, a group or class of persons whose interests are affected;
  - (d) in the public interest; and
  - (e) in the interest of protecting environment or biological diversity.
- (2) 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.

The draft Environmental Management Bill provides for the regulation of development, handling and use of GMOs and products thereof. It proposes to empower the Minister responsible for Environment in consultation with sector Ministries to make regulations, issue guidelines and prescribe measures for the regulation of the development, handling, and use as well as the importation and exportation of GMOs and their products. The regulations and guidelines will among other things specify the following:

- measures to protect environment and human and animal health including socioeconomic, cultural and ethical concern;
- measures necessary to regulate the handling, transport, packaging and identification of GMOs and products thereof;
- measure to regulate, manage and control risks associated with import or export of GMOs and products thereof; and
- measures to promote and facilitate public awareness, education and participation concerning the research, development, handling, transit, contained use, transboundary movement, release or placing on the market of any GMO whether intended for release into the environment, for use as food, feed or processing, or a product of a GMO / product thereof.

The draft Bill has penalties for a number of offences. It states that any person who contravenes any provision commits an offence and is liable on conviction to a fine or compensation. The fine of not less than two million shillings but not exceeding ten million shillings, or to an imprisonment of not less than two years but not exceeding seven years or both.

It is on the basis of the draft Bill, the proposed draft Environmental Management (Biosafety) Regulations will be established by the Minister once the Act has been enacted by the Parliament and made operational by the Minister.

#### 3.3.4 Draft Biosafety Regulations

The draft Environmental Management (Biosafety) Regulations are arranged in ten parts as follows:

- a) Part one deals with interpretation of various terms used in the regulations. Biosafety being a new area necessitates definition of some of the terms.
- b) Part two dwells on general principles which give a general direction in implementation. Such principles include precautionary principle, the principle of prevention and strict liability.
- c) Part three on institutional arrangement provides for the establishment of the National Biosafety Focal Point. It also proposes the establishment of the NBC and IBC.
- d) Part four is on approval of an activity. This part prohibits any dealings in GMOs and their products without the prior written approval of the NBFP. It provides for an elaborate procedure of notification and approval, which includes public participation and a duty to disclose certain information to the public.
- e) Part five is on risk assessment and decision making. It is this part which elaborates on the powers of the national focal point in decision making.

- f) Part six deals with risk management and this includes measures that may be imposed by the NBFP that are necessary to prevent effects of GMOs or their products on human and animal health, biological diversity or the environment.
- g) Part seven covers aspects of liability and redress. This part puts in operation the principle of strict liability. Strict liability is imposed on the person carrying out activity in relation to GMOs or their products when they directly or indirectly cause harm, injury or loss.
- h) Part eight is on offences and penalties. It lists a number of things if committed or omitted constitute offences under the regulations. It also provides for sanctions.
- i) Part nine is on schedules. The schedules and any regulations made under or pursuant to this legislation are proposed to be an integral part of this legislation.
- j) Part ten is on entry into force. The proposed regulations shall enter into force on the date of its publication in the official gazette.

#### TOGO, Republic of

a) Draft National Biosafety Framework, 2004 http://bch.cbd.int/database/record-v4.shtml?documentid=43407

## CHAPTER VI: ORIENTATIONS FOR THE BIOSAFETY LEGAL FRAMEWORK MANAGEMENT IN TOGO

In order to prevent biological risks, it is appropriate among others to develop and implement a legal framework on the regulation of biotechnological research, development, production, dissemination in the environment, import, export, transit, trading and use of GMOs and GMO by-products. The national legal framework on biosafety shall be structured as follows: field of application, intentional movements, unintentional transboundary movements, emergency measures, mechanisms for information sharing, protection of confidential information, mechanisms for risks assessment and management, offence prevention and repression measures, liability and redress regimes and mechanisms for public participation.

#### 6.7 Liability, redress and repression regimes

All those who are responsible of a damage shall be compel to repair the direct or indirect damage caused by the products in question on the biodiversity, on the socio-economic strata and on cultural standards. To that effect the right to sue shall be recognised, except in some conditions, to every person, who has a personal interest in acting or defending the general interest in order to require the reparation of the damage or to stop its threat. This right could also be exercised on behalf of a person, who for some reasons, cannot exercise it himself.

*The following shall then be considered as offences:* 

- any activity of import, dissemination, contained use or placing in the market of an GMO or a GMO by-product without any authorisation and the non respect of one of the authorisation conditions;
- the non respect of the obligation concerning the labelling, packaging and identification of GMOs or GMO by-products;
- the non respect of the provisions on import and export;
- the refusal to assist in conformity with the law.

Besides the public liabilities to which they can be subjected, the authors and accomplices of these offences may be punishable by administrative and/or penal sanctions.

b) Loi sur la prévention des risques biotechnologiques
<a href="http://bch.biodiv.org/database/attachedfile.aspx?id=3309">http://bch.biodiv.org/database/attachedfile.aspx?id=3309</a>
Entered into force 2009

## Titre VI responsabilité, infractions et répression

#### Chapitre 1 : responsabilité

- Article 96 : Sans préjudice des sanctions pénales, toute personne qui importe, transite, utilise en milieu confiné, développe, stocke, dissémine ou met sur le marché un OGM et/ou ses produits dérivés est responsable des dommages causés par ses activités en relation avec ledit OGM et/ou ses produits dérivés.
- Article 97 : En cas de dommage à la diversité biologique, au tissu socio-économique et aux valeurs culturelles, le montant de la réparation tient aussi compte des coûts de restauration, de réhabilitation ou de décontamination réellement supportés et, le cas échéant, des coûts liés aux mesures préventives.
- Article 98: La responsabilité s'étend aussi aux préjudices causés directement ou indirectement par les OGM et/ou leurs produits dérivés au tissu socio-économique et aux valeurs culturelles. Les préjudices visés par la présente loi sont notamment la destruction totale ou partielle de productions industrielles ou agricoles, la perte de récoltes, la contamination des sols, la perturbation des écosystèmes, la perte de la vie et autres atteintes à la santé humaine ou animale, les perturbations à l'économie d'une zone ou aux valeurs culturelles d'une communauté.

Article 99 : Le délai d'action en justice en vue de la réparation du préjudice causé par tout OGM ou ses produits dérivés court à partir du moment où la personne ou la communauté ayant subi le dommage a pu raisonnablement prendre conscience du préjudice.

Dans l'appréciation du délai, les éléments ci-après doivent être pris en compte :

- le temps nécessaire à la manifestation du dommage ;
- le temps nécessaire pour faire le lien entre le dommage et l'OGM et/ou ses produits dérivés ;
- la situation de la personne ou de la communauté affectée ;
- les circonstances dans lesquelles s'est produit le dommage.

#### **ZAMBIA**

a) National Biotechnology and Biosafety Policy, 2003 <a href="http://bch.biodiv.org/database/attachedfile.aspx?id=302">http://bch.biodiv.org/database/attachedfile.aspx?id=302</a>

#### **5 GUIDING PRINCIPLES**

**5.7 Liability and Redress:** The liability for any damage caused by the use or release of GMO(s) and products shall be borne by the user and or importer concerned. Where the GMO(s) or products thereof cause damage to the environment, the user concerned shall take remedial measures towards restoring the environment to its original state or harm shall be fully compensated for.

#### III. CONCLUSION

- 5. Almost 90 percent of laws or regulations of African country Parties to the Biosafety Protocol that are currently available in the BCH are in draft forms. However, it is known that not all the information available represents the current legislative situation in several countries. The draft laws have undergone changes. New laws have been adopted. Some have already entered into force. But information on these new developments has not been made available to the BCH.
- 6. 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, including through the provision of some guiding principles;
  - (b) 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;
  - (c) There are laws that provide for: (i) strict liability as the standard of care required; (ii) detail rules on channelling liability who should be liable in different situations; (iii) the right to bring claims who could bring claims; and (iv) time limits to bring claims;
  - (d) There are laws with provisions that require operators to inform competent authorities of the occurrence of any accident and to take redress damage;
  - (e) In several cases, the details of liability rules are left to civil or criminal liability laws;
  - (f) A number of laws provide for liability for violating the provisions of the law. In such instances, several laws stipulate that any liability for the violation of legal obligations should not exonerate one from liability for damage;
  - (g) There are some laws that also include liability for damage caused by products of genetically modified organisms.

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