#### Study Paper 3b - ANNEX III

Access to Genetic Resources, Gene-based Inventions and Agriculture

## AFRICAN MODEL LEGISLATION FOR THE PROTECTION OF THE RIGHTS OF LOCAL COMMUNITIES, FARMERS AND BREEDERS, AND FOR THE REGULATION OF ACCESS TO BIOLOGICAL RESOURCES

Whereas, the State and its people exercise sovereign and inalienable rights over their biological resources;

Whereas, the rights of local communities over their biological resources, knowledge and technologies that represent the very nature of their livelihood systems and that have evolved over generations of human history, are of a collective nature and, therefore, are *a priori* rights which take precedence over rights based on private interests;

Whereas, the vital role that women play in the generation, conservation, and sustainable use of biological diversity and associated knowledge and technologies is self evident, and it thus becomes essential to make it possible for their full participation at all levels of policy-making and implementation in relation to biological diversity, and associated knowledge and technologies;

Whereas, it is necessary to protect and encourage cultural diversity, giving due value to the knowledge, technologies, innovations and practices of local communities with respect to the conservation, management and use of biological resources;

Whereas, it is the duty of the State and its people to regulate access to biological resources and to community knowledge and technologies;

Whereas, the State recognizes the necessity of providing adequate mechanisms for guaranteeing the just, equitable and effective participation of its citizens in the protection of their collective and individual rights and in making decisions which affect its biological and intellectual resources as well as the activities and benefits derived from their utilization;

Whereas, there is the need to promote and support traditional and indigenous technologies for in the conservation and sustainable use of biological resources and to complement them by appropriately developed modern technologies;

Whereas, there is the need to implement the relevant provisions of the Convention on Biological Diversity, in particular Article 15 on access to genetic resources, and Article 8(j) on the preservation and maintenance of knowledge, innovations and practices of indigenous and local communities;

Whereas, all forms of life are the basis for human survival, and, therefore, the patenting of life, or the exclusive appropriation of any life form or part or derivative thereof violates the fundamental human right to life;

*Now, therefore,* it is hereby legislated as follows:

#### PART I – OBJECTIVES

The main aim of this legislation shall be to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, and knowledge and technologies in order to maintain and improve their diversity as a means of sustaining all life support systems.

The specific objectives of this legislation shall be to:

- a) recognize, protect and support the inalienable rights of local communities including farming communities over their biological resources, knowledge and technologies;
  - b) recognize and protect the rights of breeders;
- c) provide an appropriate system of access to biological resources, community knowledge and technologies subject to the prior informed consent of the State and the concerned local communities;
- d) promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, knowledge and technologies;
- e) ensure the effective participation of concerned communities, with a particular focus on women, in making decisions as regards the distribution of benefits which may derive from the use of their biological resources, knowledge and technologies;
- f) promote and encourage the building of national and grassroots scientific and technological capacity relevant to the conservation and sustainable use of biological resources;
- g) provide appropriate institutional mechanisms for the effective implementation and enforcement of the rights of local communities, including farming communities and breeders, and the conditions of access to biological resources, community knowledge and technologies;
- h) promote the conservation, evaluation and sustainable utilisation of biological resources with a particular focus on the major role women play;
- i) promote improvements in the productivity, profitability, stability and sustainability of major production systems through yield enhancement and maintenance of biological diversity;
  - j) promote the supply of good quality seed/planting material to farmers; and
- k) ensure that biological resources are utilised in an effective and equitable manner in order to strengthen the food security of the nation.

#### PART II - DEFINITIONS AND SCOPE

#### **Definitions**

1.

The use of the following terms shall take the meanings in this legislation, as defined below:

**Access** is the acquisition of biological resources, their derivatives, community knowledge, innovations, technologies or practices as authorised by the National Competent Authority.

**Benefit Sharing** is the sharing of whatever accrues from the utilisation of biological resources, community knowledge, technologies, innovations or practices.

Biological resource includes genetic resources, organisms or parts thereof, populations, or any other component of ecosystems, including ecosystems themselves, with actual or potential use or value for humanity.

**Collector** is any natural or legal person, entity or agent obtaining access to biological resources, local practices, innovations, knowledge or technologies under authority given by the National Competent Authority.

Community Rights are those rights held by local communities over their biological resources or parts or derivatives thereof, and over their practices, innovations, knowledge and technologies.

Community Knowledge or indigenous knowledge is the accumulated knowledge that is vital for conservation and sustainable use of biological resources and/or which is of socio-economic value, and which has been developed over the years in indigenous/local communities.

**Derivative** is a product developed or extracted from a biological resource; a derivative may include such products as plant varieties, oils, resins, gums, proteins etc.

Ex Situ Condition is the condition in which a biological resource is found outside its natural habitat. Under the present law, any lineage that is cultivated within its country of origin is not considered to be in an ex situ condition.

**Innovation** is any generation of a new, or an improvement of an existing, collective and/or cumulative knowledge or technology through alteration or modification, or the use of the properties, values or processes of any biological material or any part thereof, whether documented, recorded, oral, written or in whatever manner otherwise existing.

*In Situ* Condition is the condition in which a biological resource is found in its ecosystem or natural habitat. In the case of a domesticated or cultivated variety, its condition is in situ when that variety is found in the cultural context in which its specific properties have been developed.

**Local Community** is a human population in a distinct geographical area, with ownership over its biological resources, innovations, practices, knowledge, and technologies governed partially or completely by its own customs, traditions or laws.

**National Competent Authority** is the entity authorised by the State to supervise and watch over the implementation of one or more of the components of the present law.

**Prior Informed Consent** (PIC) is the giving by a collector of complete and accurate information, and, based on that information, the prior acceptance of that collector by the government and the concerned local community or communities to collect biological resources, or indigenous knowledge, or technologies.

#### Scope 2.

- 1) This legislation applies to:
  - i) Biological resources in both *in situ* and *ex situ* conditions;
  - ii) The derivatives of the biological resources;
  - iii) Community knowledge and technologies;
  - iv) Local and indigenous communities; and
  - v) Plant breeders
- 2) This legislation shall not affect the following:
- i) The traditional systems of access, use or exchange of biological resources;
- ii) Access, use and exchange of knowledge and technologies by and between local communities:
- 3) The sharing of benefits based upon the customary practices of the concerned local communities, provided that the provisions of paragraph 2 shall not be taken to apply to any person or persons not living in the traditional and customary way of life relevant to the conservation and sustainable use of biological resources.

#### PART III - ACCESS TO BIOLOGICAL RESOURCES

Application for 3.

access to biological resources and knowledge and written permit.

1) Any access to any biological resources and knowledge or technologies of local communities in any part of the country shall be subject to an application for the necessary prior informed consent and

local communities

- technologies of 2) Any access to any biological resource in a protected area shall be subject to an application for the necessary prior informed consent and written permit.
  - 3) All applications for the necessary consent and written permit to access any biological resource, community knowledge or technology, shall be directed to the National Competent Authority unless otherwise explicitly provided for by law.

4.

- 1) In making an application for access as provided in article 3 above, the following information shall be provided by the applicant:
- the identity of the applicant and the documents that testify to her/his legal capacity to contract, including, where appropriate, the identity of all partners with the contracting party;
- ii) the resources to which access is sought, including the sites from which it will be collected, its present and potential uses, its sustainability and the risks which may arise from access to it;
- iii) whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access;
- iv) the purpose for which access to the resource is requested including the type and extent of research, teaching or commercial use expected to be derived from it:
- v) description of the manner and extent of local and national collaboration in the research and development of the biological resource concerned:
- vi) the identification of the national institution or institutions which will participate in the research and be in charge of the monitoring process;
- vii) the identity of the location where the research and development will be carried out;
- viii) the primary destination of the resource and its probable subsequent destination(s);
- ix) the economic, social, technical, biotechnological, scientific, environmental or any other benefits that are intended, or may be likely to, accrue to the country and local communities providing the biological resource as well as the collector and the country or countries

where he/she operates;

- x) the proposed mechanisms and arrangements for benefit sharing;
- xi) description of the innovation, practice, knowledge or technology associated with the biological resource; and
- xii) an environmental and socio-economic impact assessment covering at least the coming three generations, in cases where the collection is in large quantities.
- 2) Nothing in paragraph (1) shall prevent the National Competent Authority requesting for any other information which it may deem necessary for the effective implementation of this legislation.

## Requirement of Consultation and Prior Informed Consent (PIC)

#### 5.

- 1) Any access to biological resources, knowledge and or technologies of local communities shall be subject to the written prior informed consent of:
  - i) the National Competent Authority; as well as that of
- ii) the concerned local communities, ensuring that women are also involved in decision making.
- 2) Any access carried out without the prior informed consent of the State and the concerned local community or communities shall be deemed to be invalid and shall be subject to the penalties provided in this legislation or any other legislation that deals with access to biological resources.
- 3) The National Competent Authority shall consult with the local community or communities in order to ascertain that its/their consent is sought and granted. Any access granted without consultation with the concerned community or communities shall be deemed to be invalid and in violation of the principle and requirement for prior informed consent as required under this Article.

#### Placement of Completed Application Form in Public Registry

#### 6.

- 1) Upon completion of the application, the National Competent Authority shall place or cause to be placed, the said application in a public registry or gazette, or cause it to be published in a newspaper that is reasonably accessible to the public for a period of x days.
- 2) Any person may consult the public registry and comment on the application.
- 3) The National Competent Authority shall cause the wide and effective dissemination of the relevant information to the communities concerned and to other interested parties.

## Granting of Access

#### 7.

1) The granting of an access permit shall be carried out by the National Competent Authority or any person duly authorised to do so under the provisions of this legislation within a specified time limit.

- 2) Any access permit shall be granted through a signed written agreement, between the National Competent Authority and/or the concerned local community or communities on the one hand where applicable, and, the applicant or collector on the other hand.
- 3) The access permit shall only be valid if there is a written prior informed consent.

## Contents of the Agreement

- 1) The agreement referred to in article 7 shall contain commitments undertaken or to be undertaken by the collector, as follows.
- i) to adhere to a limit set by the National Competent Authority on the quantity and specification of the quality of the biological resource that the collector may obtain and/or export;
- ii) to guarantee to deposit duplicates of, with complete field information on, each specimen of the biological resource or the records of community innovation, practice, knowledge or technology collected with the duly designated governmental agencies and, if so required, with local community organizations;
- iii) to inform immediately the National Competent Authority and the concerned local community or communities of all findings from research and development on the resource;
- iv) not to transfer the biological resource or any of its derivatives or the community innovation, practice, knowledge or technology to any third party without the authorization of the National Competent Authority and the concerned local community or communities;
- v) not to apply for any form of intellectual property protection over the biological resource or parts or derivatives thereof and not to apply for intellectual property rights protection over a community innovation, practice, knowledge or technology without the prior informed consent of the original providers;
- vi) to provide for the sharing of benefits;
- vii) access shall be conditioned upon a commitment to contribute economically to the efforts of the State and concerned local community or communities in the regeneration and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought;
- viii) submit to the National Competent Authority a regular status report of research and development on the resource concerned and where the biological resource is to be collected in large quantities on the ecological state of the area; and
- ix) abide by the relevant laws of the country particularly those regarding sanitary control, biosafety and the protection of the environment as well as by the the cultural practices, traditional values and customs of the local communities.
- 2) All efforts should be made for the research to be done in the country and in a manner that facilitates the participation of actors in

the country of the provider of the biological resource.

Patents over Life Forms and Biological Processes

#### 9.

- 1) Patents over life forms and biological processes are not recognized and cannot be applied for.
- 2) The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein.

## Approval of Granting of Access

#### **10**.

The National Competent Authority shall approve the granting of access to the biological resource or the community innovation, practice, knowledge or technology in question with any conditions it may deem necessary. In granting access the National Competent Authority shall ensure that all the requirements under this legislation have been fulfilled.

# Conditions Pertaining to Academic and Research Institutions, Public Agencies and Inter-governmental Institutions

#### 11.

- 1) The National Competent Authority shall subject all applications for access to a biological resource, a community innovation, practice, knowledge or technology to the prior informed consent of the concerned community or communities.
- 2) The National Competent Authority shall determine the appropriate conditions to be met under the written agreement referred to in Article 8, by academic and research institutions, public agencies and intergovernmental institutions.
- 3) The application for access for research purposes shall clearly state the objective of the research and the relation of the applicant to industry. Neither the sample nor the associated information shall be transferred without a material transfer agreement reserving the prior rights of the State and/or community or communities.
- 4) Where the institutions referred to in this Article change their activities to be predominantly the commercialisation of a biological resource, the National Competent Authority shall cause the conditions and terms to be varied accordingly.

#### Benefit Sharing

#### 12

- 1. The access permit should be subject to the payment, made before commencement of collection, of a fee the sum of which will depend on whether or not the collection is to be used for commercial purposes, and the number of samples, the area of collecting, the duration of collection and whether or not the collector is granted exclusive rights.
- 2. The State and the community or communities shall be entitled to a share of the earning derived from when any biological resource and/or knowledge collected generates, directly or indirectly, a product used in a production process.

#### Types of Permit to be Granted for Access

#### 13.

- 1) Having ascertained that the conditions set by the prior informed consent procedure have been fulfilled, the National Competent Authority shall grant the applicant/collector the appropriate permit for access. This may be an academic research permit, a commercial research permit, or a commecial exploitation permit.
- 2) No person shall be in possession of and use two types of permit at the same time for the same resource unless granted written permission to do so
- 3) Nothing in this Article shall be deemed to limit the National Competent Authority's power to issue any other type of access permit.

#### Revocation of 14. Access Permit

- 1) The National Competent Authority may unilaterally withdraw consent and repossess the written permit under the following conditions:
- i) when there is evidence that the collector has violated any of the provisions of this legislation;
- ii) when there is evidence that the collector has failed to comply with the agreed terms; and
  - iii) when there is failure to meet any of the conditions of access;
  - iv) for reasons of overriding public interest; or
  - v) for the protection of the environment and biological diversity.
- 2) Any termination or withdrawal of consent shall be done in consultation with the concerned local community or communities.

#### Restrictions on 15.

Activities Related to Access or Introduction of Biological Resources

The National Competent Authority should establish restrictions to or prohibitions on those activities which are directly or indirectly related to access to or introduction of a biological resource, particularly in cases of:

- i) endangered taxa;
- ii) endemism or rarity;
- iii) adverse effects upon human health or upon the quality of life or the cultural values of local communities;
- iv) environmental impacts which are undesirable or difficult to control:
- v) danger of genetic erosion or loss of ecosystems, their resources or their components, which arise from undue or uncontrolled collection of biological resources;
  - vi) non-compliance with rules on biosafety or food security; and
- vii) use of resources for purposes contrary to national interest and to relevant international agreements entered into by the country.

#### **PART IV - COMMUNITY RIGHTS**

Recognition of 16.

the Rights of Local and Indigenous **Communities** 

The State recognizes the rights of communities over the following:

- their biological resources;
- ii) the right to collectively benefit from the use of their biological resources;
- iii) their innovations, practices, knowledge and technologies acquired through generations;
- iv) the right to collectively benefit from the utilisation of their innovations, practices, knowledge and technologies;
- v) their rights to use their innovations, practices, knowledge and technologies in the conservation and sustainable use of biological diversity:
- vi) the exercise of collective rights as legitimate custodians and users of their biological resources;

#### Application of 17.

the Law on **Community** Rights

The State recognizes and protects the community rights that are specified in Article 16 as they are enshrined and protected under the norms, practices and customary law found in, and recognized by, the concerned local and indigenous communities, whether such law is written or not

#### Prior 18.

Informed Consent (PIC) of Local **Communities** 

Any access to a biological resource, innovation, practice, knowledge or technology, shall be subject to the prior informed consent (pic) of the concerned community or communities ensuring that women fully and equally participate in decision making.

#### Right to

**19**.

Refuse Consent and Access

Local communities have the right to refuse access to their biological resources, innovations, practices, knowledge and technologies where such access will be detrimental to the integrity of their natural or cultural heritage.

#### Right to

**20**. Withdraw or

Place Consent and

Local communities shall have the right to withdraw consent or place restrictions on the activities relating to access where such activities are Restrictions on likely to be detrimental to their socio-economic life, or their natural or cultural heritage.

#### Right to

21.

**Traditional** Access, Use

Access

Local communities shall exercise their inalienable right to access, use, exchange or share their biological resources in sustaining their

and Exchange livelihood systems as regulated by their customary practices and laws.

2) No legal barriers shall be placed on the traditional exchange system of the local communities in the exercise of their rights as provided for in paragraph (1) above and in other rights that may be provided by the customary practices and laws of the concerned local communities.

#### Right to Benefit

#### **22**.

- 1) The State shall ensure that at least fifty per cent of benefits provided for in Article 12.2 shall be channeled to the concerned local community or communities in a manner which treats men and women equitably.
- 2) The sharing the benefits in paragraph 1) above shall involve the full participation and approval of the concerned local community or communities.

#### Recognition of 23.

#### Community Intellectual Rights

- 1) The Community Intellectual Rights of the local communities, including traditional professional groups, particularly traditional practioners, shall at all times remain inalienable, and shall be further protected under the mechanism established by this legislation.
- 2) An item of community innovation, practice, knowledge or technology, or a particular use of a biological or any other natural resource shall be identified, interpreted and ascertained by the local communities concerned themselves under their customary practice and law, whether such law is written or not.
- 3) Non-registration of any community innovations, practices, knowledge or technologies, is not to mean that these are not protected by Community Intellectual Rights.
- 4) The publication of a written or oral description of a biological resource and its associated knowledge and information, or the presence of these resources in a genebank or any other collection, or its local use, shall not preclude the local community from exercising its community intellectual rights in relation to those resources.

#### PART V – FARMERS' RIGHTS

#### Recognition of 24.

#### Farmers' Rights

- 1) Farmers' Rights are recognized as stemming from the enormous contributions that local farming communities, especially their women members, of all regions of the world, particularly those in the centres of origin or diversity of crops and other agro-biodiversity, have made in the conservation, development and sustainable use of plant and animal genetic resources that constitute the basis of breeding for food and agriculture production; and
- 2) For farmers to continue making these achievements, therefore, Farmers' Rights have to be recognized and protected.

#### Application of 25.

#### the Law on Farmers' Varieties

- 1) Farmers' varieties and breeds are recognized and shall be protected under the rules of practice as found in, and recognized by, the customary practices and laws of the concerned local farming communities, whether such laws are written or not.
- 2) A variety with specific attributes identified by a community shall be granted intellectual protection through a variety certificate which does not have to meet the criteria of distinction, uniformity and stability. This variety certificate entitles the community to have the exclusive rights to multiply, cultivate, use or sell the variety, or to license its use without prejudice to the Farmers' Rights set out in this law.

#### Farmers' Rights

#### **26**.

- 1) Farmers' Rights shall, with due regard for gender equity, include the right to:
- a) the protection of their traditional knowledge relevant to plant and animal genetic resources;
- b) obtain an equitable share of benefits arising from the use of plant and animal genetic resources;
- c) participate in making decisions, including at the national level, on matters related to the conservation and sustainable use of plant and animal genetic resources;
- d) save, use, exchange and sell farm-saved seed/propagating material of farmers' varieties;
- e) use a new breeders' variety protected under this law to develop farmers' varieties, including material obtained from genebanks or plant genetic resource centres; and
- f) collectively save, use, multiply and process farm-saved seed of protected varieties.
- 2) Notwithstanding sub-paragraphs c) and d), the farmer shall not sell farm-saved seed/propagating material of a breeders' protected variety

in the seed industry on a commercial scale.

3) Breeders' Rights on a new variety shall be subject to restriction with the objective of protecting food security, health, biological diversity and any other requirements of the farming community for propagation material of a particular variety.

## Certification of Farmers' Varieties

#### 27

- 1. Any product derived from the sustainable use a biological resource shall be granted a certificate or label of recognition.
- 2 A certificate of fair trade shall be granted to a product derived from a biological resource or knowledge or technology, when a significant part of the benefits derived from the product go back to the local community.

#### PART VI - PLANT BREEDERS' RIGHTS

Recognition of 28.

Plant Breeders' Rights

Plant Breeders' Rights stem from the efforts and investments made by persons/institutions for the development of new varieties of plants, as defined in Article 41, being the basis for providing recognition and economic reward

Characteristics 29.

of New Varieties

A variety will be considered new if it:

- a) is, by reason of one or more identifiable characteristics, clearly distinguishable from all varieties the existence of which is a matter of common knowledge at the effective date of application for the grant of a Plant Breeders' Rights.
- b) is stable in its essential characteristics, in that after repeated reproduction or propagation or, where the applicant has defined a particular cycle of reproduction or multiplication, at the end of each cycle, remains true to its description;
- c) is, having regard to its particular features of sexual reproduction or vegetative propagation, a sufficiently homogenous variety or is a well-defined multiline.

Rights of 30.
Plant Breeders 1)

- Plant Breeders 1) A Plant Breeders' Rights, in respect of a new variety, is:
  - a) the exclusive right to sell, including the right to license other persons to sell plants or propagating material of that variety;
  - b) the exclusive right to produce, including the right to license other persons to produce, propagating material of that variety for sale;
  - 2) A Plant Breeders' Rights in respect of a plant variety is subject to the conditions provided in Part V, the Farmers' Rights Part of this Act.

Exemptions to 31. the Rights of 1)
Breeders

- 1) Notwithstanding the existences of Plant Breeders' Rights in respect of a plant variety, any person or farmers' community may:
- a) propagate, grow and use plants of that variety for purposes other than commerce;
- b) sell plants or propagating material of that variety as food or for another use that does not involve the growing of the plants or the propagation of that variety;
- c) sell within a farm or any other place at which plants of that variety are grown any plants or propagating material of that variety at that place.
- d) use plants or propagating material of the variety as an initial source of variation for the purpose of developing another new plant variety except where the person makes repeated use of plants or

propagating material of the first mentioned variety for the commercial production of another variety.

- e) sprout the protected variety as food for home consumption or for the market.
- f) use the protected variety in further breeding, research or teaching.
- g) obtain, with the conditions of utilization, such a protected variety from genebanks or plant genetic resources centres.
- 2) Farmers will be free to save, exchange and use part of the seed from the first crop of plants which they have grown for sowing in their own farms to produce a second and subsequent crops subject to conditions specified in Part V, the Farmers' Rights Part of this Act.

#### Application of 32.

#### Breeders' Rights

- 1) Subject to this Act, a breeder of a new plant variety may make an application to the National Competent Authority for a Plant Breeders' Rights in respect of the variety.
- 2) A breeder of a new variety, or his successor, has the right to make an application for a Plant Breeders' Rights in respect of that variety, whether or not the breeder is a citizen or foreigner, or is resident or not and whether the variety was bred locally or abroad.
- 3) Where two or more persons are entitled to make an application for a Plant Breeders' Rights in respect of a new variety, whether by reason that they bred the plant variety jointly or independently or otherwise, those persons or some of those persons may make a joint application for those rights.
- 4) Where two or more persons breed a new plant variety jointly, one of those breeders or a successor of one of those breeders shall not make an application for a Plant Breeders' Rights in respect of that variety otherwise than jointly with, or with the consent in writing of, the other person, or each other person, entitled to make an application for those Rights.
- 5) In the case of both public-financed and private institutions, the application can be made in the name of the institution.

#### Restrictions to 33.

#### Plant Breeders' Rights

- 1) Where the Government considers it necessary, in the public interest, the Plant Breeders' Rights in respect of a new variety shall be subject to conditions restricting the realization of those rights. These restrictions may be imposed, *inter alia*:
- a) where problems with competitive practices of the Rights holder are identified;
- b) where food security or nutritional or health needs are adversely affected;
- c) where a high proportion of the plant variety offered for sale is being imported;

- d) where the requirements of the farming community for propagating material of a particular variety are not met; and
- e) where it is considered important to promote public interest for socio-economic reasons and for developing indigenous and other technologies;
- 2) Where restrictions are imposed on a Plant Breeders' Rights:
- a) the grantee shall be given a copy of the instrument setting out the conditions of the restriction;
  - b) a public notice shall be given;
- c) the compensation to be awarded to the holder of the Rights shall be specified;
- the Rights-holder may appeal against the compensation award.
- 3) In particular, and without prejudice to the generality of the foregoing provisions, the relevant Government authority shall have the right to convert the exclusive Plant Breeders' Rights granted under this Act to non-exclusive Plant Breeders' Rights (compulsory licence of right).

**Duration** of Plant Breeders' Rights

34.

Subject to this Act, a Plant Breeders' Rights in respect of a plant variety shall exist for a period of 20 years in the case of annual crops and 25 years in the case of trees, vines and other perennials commencing on the day on which the successful application for a Plant Breeders' Rights in respect of the plant variety was accepted.

Dispute Settlement **35**.

Where conflicts arise on whether a plant variety qualifies as a new plant variety under the Act, they will be handled administratively through the National Competent Authority, an ad hoc tribunal and finally through the court of law.

Infringements 36. of Plant Breeders' Rights

- 1) An action or proceedings for an infringement of a Plant Breeders' Rights may be instituted in writing in a court or, if agreeable to both parties, it may be submitted to a binding arbitration.
- 2) A defendant in an action or proceeding for an infringement of a Plant Breeders' Rights in respect of a variety may apply by way of counter-claim for the revocation of that Plant Breeders' Rights:
  - on the grounds that the variety was not a new plant variety;
- b) on the grounds that facts exist which, if known to the National Competent Authority before the grant of that Plant Breeders' Rights, would have resulted in the refusal of the grant.
- 3) If, in an action or proceedings for an infringement of a Plant

Breeders' Rights in respect of a plant variety in which a defendant has applied by way of counter-claim for the revocation on the grounds referred to in paragraph 2)a) or b), the court is satisfied that the grounds exist, the court may revoke that Plant Breeders' Rights.

4) Where, in an action or proceedings for an infringement of a Plant Breeders' Rights, the court, on an application by the defendant by way of counter-claim, revokes the Plant Breeders' Rights, the court shall order the defendant to serve on the National Competent Authority a copy of the order revoking that Plant Breeders' Rights.

#### National Competent Authority

#### **37**.

The State shall designate or establish a National Competent Authority which shall implement and enforce the provisions on Plant Breeders' Rights in this Act.

#### Registration of 38.

Plant Breeders' Rights

The National Competent Authority shall:

- a) receive and examine applications for the registration of Plant Breeders' Rights;
  - b) carry out the required trials for testing the applicant's variety;
  - c) register and issue certificates for Plant Breeders' Rights;
- d) publish applications for Plant Breeders' Rights in the Official Gazette;
- e) hear opposition on the registration of any Plant Breeders' Rights;
  - f) maintain the Register for Plant Breeders' Rights.

#### Register of

**39**.

Plant Breeders' Rights

The National Competent Authority shall keep a National Register of Plant Breeders' Rights in which shall be entered particulars required by this Act or regulations.

#### Plant Genetic 40.

Resources Centres

The Government shall declare or gazette specified plant genetic resources centre(s), as suitable centre(s) for storage and maintenance of germplasm material for the purpose of this Act.

## Filing of Applications

#### **41**.

- 1) Where an application is filed in respect of a Plant Breeders' Rights:
- a) the application is accepted if the National Competent Authority is satisfied that:
- i) the application complies with the requirements of Article 29; and

- ii) the specified fees have been paid; or
- b) the application is rejected if the National Competent Authority is satisfied that it does not fulfil the prescribed requirements.
- 2) Where the National Competent Authority accepts an application it shall, within 30 days after accepting the application, given written notice to the applicant stating that the application has been accepted and it shall give public notice of the application.
- 3) Where the National Competent Authority rejects an application, it shall, within 30 days after rejecting the application, give written notice to the applicant stating that the application has been rejected and stating the grounds for rejection.

## Uniform Testing and Assessment Procedures

#### **42**.

- 1) On the acceptance of an application, the National Competent Authority shall stipulate the quantity of seed/planting material that should be made available by the applicant for trials and testing.
- 2) The National Competent Authority shall arrange to get statistically valid trials conducted to evaluate the suitability of the variety for national release.
- 3) The assessment criteria shall include important economic, physiological, ecological and nutritive quality attributes.
- 4) The fees with respect to a Plant Breeders' Rights shall be fixed on the basis of the administrative and examination costs incurred.

#### Characteristics 43.

of Plant Varieties Originating from Outside the Country

For the purpose of this Act, where a plant variety in respect of which an application has been accepted has originated from outside the country, the variety shall not be taken to have a particular characteristic unless:

- a) statistically valid, multi-locational, variety trials carried out in the country for at least three growing seasons have demonstrated that the variety has the specific characteristic as claimed by the applicant; or
- b) an exceptional crises in food production so requires and the National Competent Authority is satisfied that:
- i) statistically valid trials on the variety carried out outside the country have demonstrated that the variety has that specified characteristic; and
- ii) the natural environment outside the country under which the statistically valid trials were carried is similar to the environment in the country.

### Plant Varieties 44. Trials

1) Where, in dealing with an application in respect of a plant variety,

the National Competent Authority considers it necessary that there should be a statistically valid trial or a further statistically valid trial of the variety, trials shall be carried out:

- a) for the purpose of determining whether the plant variety is distinct, homogenous or stable;
- b) for the purpose of determining whether the variety will, if grown in the country, exhibit the claimed distinctiveness, homogeneity and stability;
- c) requiring the applicant to supply sufficient seed or propagation material of the variety, as the case requires, and with any necessary information, to enable the variety to be test grown for the purpose so specified.
- 2) After the completion of the trials on a plant variety, any plants or propagation material of plants used in, or resulting from, the trials that are capable of being transported shall be removed by the applicant for a Plant Breeders' Rights in respect of that plant variety.

#### Withdrawal of 45. **Application**

- 1) An application may be withdrawn by the applicant at any time before the publication of the application.
- 2) Where an application is withdrawn after its publication in the Official Gazette, but before the granting of a Plant Breeders' Rights, the National Competent Authority shall forthwith publicise that withdrawal

#### **Provisional Protection**

#### 46.

- 1) Where an application for a Plant Breeders' Rights in respect of a plant variety has been accepted, the applicant shall be deemed to be the owner of a Plant Breeders' Rights in respect of that plant variety during the period commencing on the date of filing of the application and ending on whichever of the dates specified in a) and b) occurs first:
  - a) when the application is disposed of; or
- b) where the National Competent Authority has given the applicant a notice at the expiration of the prescribed period, after the notice is given.
- 2) Steps to protect genetic materials of new varieties under testing will be taken, so as to prevent their use for non-research purposes.

#### Opposition to 47.

Breeders' Rights

- Grant of Plant 1) Where official gazettement of an application for a Plant Breeders' Rights in respect of a plant variety or of the variation of such a variety is given, any person who considers that:
  - a) commercial or public interests would be negatively affected by the grant of those rights to the applicant;
  - b) the application in relation to that variety does not fulfil

the prescribed criteria for granting a Plant Breeders' Rights;

may within 6 months after publication of the application, or any further time before the application is disposed of, lodge with the National Competent Authority a written objection to the granting of the Rights setting out the particulars of the objection.

- 2) Where an opposition to the grant of a Plant Breeders' Rights is lodged under paragraph 1), the National Competent Authority shall cause a copy of that opposition to be given to the applicant for that Plant Breeders' Rights.
- 3) Any person may inspect an application, or an opposition lodged, at any reasonable time and is entitled, upon payment of such fee as is prescribed, to be given a copy of the application or of the opposition.

#### Grant of Plant 48.

#### Breeders' Rights

- 1) Subject to this Article, an application for a Plant Breeders' Rights in respect of a plant variety is granted if the National Competent Authority is satisfied that:
  - i) there is such a plant variety;
  - ii) the plant variety is a new plant variety;
  - iii) the applicant is entitled to the application;
- iv) the grant of those rights to the applicant is not prohibited by this Act;
  - v) those rights have not been granted to another person;
- vi) there has been no earlier application for those rights that has not been withdrawn or otherwise disposed of; and
- vii) all fees payable under this Act in relation to the application have been paid;
- 2) If the National Competent Authority is not satisfied that the conditions in paragraph 1) above have been fulfilled, the National Competent Authority shall refuse to grant that Plant Breeders' Rights to the applicant.
- 3) The National Competent Authority shall not grant, or refuse to grant, a Plant Breeders' Rights in respect of a plant variety unless a period of six (6) months has elapsed since the publication of the application in the official gazette, or, if the application has been varied in a manner that the National Competent Authority considers to be significant, a period of 6 months has elapsed since the publication of particulars of the variation, or of the last such variation, as the case requires.
- 4) The National Competent Authority shall not refuse to grant a Plant Breeders' Rights unless it has given the applicant for that Plant Breeders' Rights a reasonable opportunity to make a written submission in relation to the application.
- 5) Where an opposition to the grant of a Plant Breeders' Rights has been lodged, the National Competent Authority shall not grant the

Plant Breeders' Rights unless it has given the person who lodged the opposition a reasonable opportunity to make a written submission in relation to the objection.

- 6) A Plant Breeders' Rights shall be granted and issued by the National Competent Authority to the applicant in the form specified in its regulations.
- 7) Where a Plant Breeders' Rights over one variety is granted to persons, that Plant Breeders' Rights shall be granted to those persons jointly.
- 8) Where a Plant Breeders' Rights is granted to a public or private institution, it shall accrue to the institution represented by the designated person or persons.
- 9) Where the National Competent Authority refuses to grant a Plant Breeders' Rights in respect of a plant variety, the National Competent Authority shall, within 30 days after refusing, give written notice of the refusal to the applicant clearly setting out the grounds for the refusal.

#### Entry of Plant 49.

Breeders' Rights in the Register

- 1) When the National Competent Authority grants a Plant Breeders' Rights in respect of a plant variety, it shall enter in the Register:
- a) a description, or a description and photograph, of the plant variety;
  - b) the name of the variety;
  - c) the pedigree of the variety (where possible);
  - d) the name of the grantee;
  - e) the name and address of the breeder;
- f) the address for the service of documents on the grantee for the purpose of this Act, which is shown on the application for the Rights;
  - g) the date on which the Plant Breeders' Rights was granted;
- h) a description of the communities/localities in the country entitled to Farmers' Rights in relation to the variety;
- i) such other particulars relating to the grant as the National Competent Authority considers appropriate.

## Publication of Grant of Plant

**50**.

Breeders' Rights Where a Plant Breeders' Rights has been granted, the National Competent Authority shall, within 30 days after granting, publish that Plant Breeders' Rights in the official gazette. The publication will also make reference to the entitlements under Farmers' Rights.

#### Effect of Grant on Certain Persons

**51**.

1) Where a Plant Breeders' Rights in respect of a plant variety has been granted to a person, another person who was entitled to make an application for that Plant Breeders' Rights, whether or not a person who developed that variety independently of the breeder, or the successor of such another person, is not entitled to any interest in that Plant Breeders' Rights because of the entitlement to make the application or because of the grounds of the entitlement, but nothing in this Article prevents a person from applying to the National Competent Authority for the revocation of that Plant Breeders' Rights or from instituting proceedings before a court in respect of that Plant Breeders' Rights.

#### 2) Where:

- a) a Plant Breeders' Rights in respect of a new plant variety has been granted to a person, and
- b) another person (in this paragraph referred to as the 'eligible person') was entitled, at a law or in equity to have the right to make an application for that Plant Breeders' Rights assigned to the eligible person, then the eligible person is entitled to have that Plant Breeders' Rights assigned to her/him.

Nature of Plant Breeders' Rights

#### **52**.

- 1) A Plant Breeders' Rights is personal property and, subject to any conditions imposed under other paragraphs, is capable of assignment or of transmission by will or by operation of law.
- 2) An assignment of a Plant Breeders' Rights does not have effect unless it is in writing, signed by or on behalf of the assignor.

Assignment of 53.

Plant Breeders' Rights

- 1) Where a Plant Breeders' Rights is assigned or transmitted to a person, that person shall, within 30 days after acquiring it, inform the National Competent Authority in writing that the person has acquired that Plant Breeders' Rights, giving particulars of the manner in which it was acquired, and the National Competent Authority, if satisfied that the Plant Breeders' Rights has been so assigned or transmitted, shall enter the name of that person on the Register as the grantee of that Plant Breeders' Rights.
- 2) Where in accordance with paragraph 1), the National Competent Authority enters on the Register as the grantee of a Plant Breeders' Rights the name of a person who claims to have acquired that Plant Breeders' Rights, it shall, within 30 days after entering the name in the Register, give written notice to the person newly entered and to the person who was the grantee before the new entry was made stating that the entry has been made.
- 3) Where the National Competent Authority is not satisfied that a Plant Breeders' Rights has been assigned or transmitted to a person who has informed the National Competent Authority in accordance with paragraph 1) that that Plant Breeders' Rights has been thus assigned or transmitted to the claimant, the National Competent Authority shall forthwith:
  - a) give written notice to the claimant:

- i) stating that the National Competent Authority is not satisfied; and
- ii) setting out the grounds on which the National Competent Authority is not so satisfied; and
  - b) give written notice to the grantee of those rights:
- i) setting out particulars of the information given by the claimant:
- ii) stating that the National Competent Authority is not satisfied; and
  - iii) setting out the grounds on which it is not so satisfied.
- 4) A person who informs the National Competent Authority in accordance with paragraph 1) that a Plant Breeders' Rights has been assigned or transmitted to her/him shall give written notice to the National Competent Authority of an address in the country for the service of documents in accordance with this Act; and
- a) where the National Competent Authority enters the name of that person on the Register in accordance with paragraph 1) and that address is different from the address already entered in the Register, it shall amend the Register so that the address so given is entered in the Register as the address for service of documents on the grantee for the purpose of this Act; or
- b) where the National Competent Authority is not satisfied that those rights have been assigned or transmitted to that person, the notice to that person under paragraph 3)a) shall be given by being posted.

#### Supply of Propagating Material

#### **54**.

- 1) A Plant Breeders' Rights in respect of a plant variety is subject to the condition that the grantee of the Rights shall comply with any notice given to her/him by the National Competent Authority.
- 2) Where a Plant Breeders' Rights are granted in respect of a plant variety, the National Competent Authority may give the grantee of the Plant Breeders' Rights written notice requiring the grantee, within 14 days of the giving of the notice or any other time that is allowed, to cause a specified quantity of propagating material of that variety to be delivered, at the expense of the grantee, to a specified plant genetic resources centre and a herbarium.
- 3) The quantity of the propagating material of a variety specified in a notice under paragraph 2) shall be the quantity that the National Competent Authority considers would be sufficient to enable that variety to be kept in existence if there were no other propagating material of that variety.
- 4) Where the propagating material is delivered to a plant genetic resources centre in accordance with the conditions imposed on Plant Breeders' Rights by paragraph 1), the National Competent Authority shall, subject to paragraph 6), cause that material to be stored at a

specified plant genetic resources centre.

- 5) The delivery and storing of the propagating material in accordance with this paragraph does not affect the ownership of the material but that the material shall not be dealt with otherwise than for the purposes of this Act.
- 6) The propagating material stored at a plant genetic resources centre may be used by the National Competent Authority for the purposes set out in this Act
- 7) Without limiting paragraphs 5) and 6), where, the propagating material is stored at a plant genetic resources centre as gazetted by the Government according to Article 39 of this Act, the material shall not form part of the national collection, and shall not be used for the purposes of that collection, until a decision on the application for a Plant Breeders' Rights is taken. Once the variety is accorded recognition, the propagating material can be provided for purposes of further research and breeding under the intimation of the depositor of the material.

#### Revocation of 55.

Plant Breeders' Rights

- 1) The National Competent Authority shall revoke a Plant Breeders' Rights in respect of a plant variety if:
- a) it is satisfied that the plant variety was not new or that facts exist which, if known before the grant of that Plant Breeders' Rights, would have resulted in the refusal of the grant; or
- b) the grantee has failed to pay a prescribed fee payable in respect of that Plant Breeders' within 90 days after having been notified that the prescribed fee was due for payment.
- 2) The National Competent Authority may revoke a Plant Breeders' Rights if it is satisfied that:
- a) the grantee has failed to comply, in relation to that Plant Breeders' Rights, with the prescribed conditions; or
- b) a person to whom that Plant Breeders' Rights has been assigned or transmitted has failed to comply with the provisions of this Act.
- 3) Where the National Competent Authority revokes a Plant Breeders' Rights in respect of a plant variety in accordance with this Article, it shall, within 7 days after the decision is taken, give written notice of the revocation to the grantee setting out the grounds for the revocation.
- 4) The National Competent Authority shall not revoke a Plant Breeders' Rights in accordance with this Article unless and until it has given the grantee and any person to whom it believes that Plant Breeders' Rights has been assigned or transmitted, particulars of the grounds for the proposed revocation and given the grantee and any such person a reasonable opportunity to make a written submission in relation to the proposed revocation.

- 5) The revocation of a Plant Breeders' Rights in respect of a plant variety in accordance with this Article takes effect:
- a) subject to paragraph 4), at the expiration of the period within which an application may be made to a court for a review of the revocation; or
- b) if such an application is made to the court, at the time when the application is withdrawn or finally determined by a court.
- 6) Nothing in this Article shall be taken to affect the powers or the legal system.
- 7) Any person whose interests are affected by the granting of a Plant Breeders' Rights in respect of a plant variety may apply to the National Competent Authority for the revocation of that Plant Breeders' Rights in accordance with this section.
- 8) The National Competent Authority shall consider any application under paragraph 7) for the revocation of a Plant Breeders' Rights. The decision of the National Competent Authority not to revoke the Plant Breeders' Rights shall be communicated to the applicant by a written notice within 7 days after the decision is taken, setting out the grounds for the decision.

Surrender of Plant Breeders' Rights

#### **56**.

- 1) Subject to paragraph 2) of Article 34, a grantee of a Plant Breeders' Rights may at any time, by giving notice to National Competent Authority, offer to surrender that Plant Breeders' Rights: the National Competent Authority, after giving public notice of the offer and giving all interested parties an opportunity to make a written submission in relation to the offer, may, if it finds fit, accept the offer and revoke those rights.
- 2) Where an action or proceeding in respect of a Plant Breeders' Rights is pending in a court, the National Competent Authority shall not accept an offer for the surrender of, or revoke, that Plant Breeders' Rights, except by leave of the court or by consent of the parties to the action or proceeding.

#### PART VII - INSTITUTIONAL ARRANGEMENTS

Establishment 57.

**Competent** 

Authority

of the National The State shall designate or establish a National Competent Authority which shall implement and enforce the provisions of this legislation. Its duties shall include those set out in Article 29.

**Duties** of the National **Competent** Authority

The duties of the National Competent Authority are, while ensuring gender equity, to:

- create and operate a regulatory mechanism that will ensure effective protection of Community Intellectual Rights and Farmers' Rights, and the regulation of access to biological resources;
- ii) carry out the process of consultation and participation of local communities, including farming communities, in the identification of their rights as provided for under the customary practices and laws of the communities;
- iii) identify types of Community Intellectual Rights and Farmers' Rights;
- iv) identify and define the requirements and procedures necessary for the recognition of Community Intellectual Rights and Farmers' Rights;
  - develop criteria and mechanisms to standardise procedures;
- vi) develop a system of registration of items protected by Community Intellectual Rights and Farmers' Rights according to their customary practices and law;
- vii) issue licenses for the exploitation and commercialisation of biological resources, including protected species, varieties or lineages, and community innovations, practices, knowledge and technologies;
- viii) identify relevant technical institutions that will assist local communities, including farming communities, in the categorisation and characterisation of their biological resources, innovations, practices, knowledge and technologies.

Establishment 59. of National Inter-Sectoral Co-ordination

**Body** 

A National Inter-Sectoral Co-ordination Body at the highest level, composed of representatives from relevant public sectors, scientific and professional organizations, non-governmental and local community organizations, shall be created as a body to co-ordinate and follow-up the proper implementation of this legislation by the National Competent Authority.

Functions of the National Inter-Sectoral Co-ordination

The functions of the National Inter-Sectoral Coordination Body shall

#### **Body**

- ensure that the minimum conditions for agreements with collectors are strictly observed and complied with;
- ii) ensure that the rights of local communities, including farming communities, are protected, with due regard for gender equity, wherever the activities relating to the accessing, collection or research on biological resources, community innovations, practices, knowledge and technologies are conducted, including verifying that the requirements of prior informed consent by the local communities are complied with;
- iii) recommend policies and laws on the sustainable use of biological resources including new laws on intellectual property rights, Community Intellectual Rights and Farmers' Rights over their biological resources, innovations, practices, knowledge and technologies; and
- iv) perform such other functions as may be necessary for the effective implementation of this legislation.

#### **Composition**

Inter-Sectoral Co-ordination **Body** 

of the National The National Inter-Sectoral Co-ordination Body shall be composed of the following persons:

> Here the functional composition of the body can be outlined, the qualifications, fields of expertise or specialisation, public interest qualities, industry, community based organizations and persons from relevant areas and fields with due regard for gender equity. This section seeks to fulfil the requirements set out in Article 29 above.

#### Appointment of Technical Advisory Body

**62**.

61.

It is hereby appointed a body to be known as the Technical Advisory Body to support the work of the National Inter-Sectoral Co-ordination Body.

#### Functions of the Technical Advisory Body

**63**.

The functions of the Technical Advisory Body shall be to:

- formulate policy options that promote the protection of Community Intellectual Rights, Farmers' Rights, gender equity and the regulation of access to biological resources;
- ii) prepare lists of taxa threatened by deterioration and/or extinction and of the places threatened by serious loss of biological diversity;
- iii) monitor and evaluate, at regular intervals, the implementation of this legislation or actual or potential threats to biological diversity and the likely impacts on the pursuit towards sustainable development;
- iv) develop and recommend a mechanism to enable the identification and dissemination of information regarding threats to biological resources; and
  - v) perform such other functions as may be necessary to imple-

ment this legislation.

#### Establishment 64. of a National Information System

- It is hereby established that there shall be a National Information System with regard to biological resources, which includes the activities set out in the following Article.
- Local communities may also establish databases on their biological resources together with their components and derivatives. and the knowledge and technologies of those communities.
- Access to information in the National Information System and databases shall be regulated by a charter setting out the rights of the owners of the data

#### Activities of the National Information System

The activities of the National Information System shall include inter alia the following:

- the compilation and documentation of information on Community Intellectual Rights, Farmers' Rights, gender equity and access to biological resources, community innovations, practices, knowledge and technologies;
- ii) the maintenance of an up-to-date system of information about -research and development activities on biological resources and community innovations, practices, knowledge and technologies; and
- iii) the compilation of information on piracy of biological resources, community innovations, practices, knowledge and technologies, and the disseminating of this information to all relevant and concerned bodies.

#### Establishment 66.

#### of a **Community** Gene Fund

- 1) The Community Gene Fund shall be established as an autonomous Trust. A Director shall be appointed to administer the Fund. The Director shall report to the National Competent Authority.
- 2) There shall be an autonomous Trust to administer a Community Gene Fund deriving its funds from the shares due to local farming communities under Article 27.1(b) in Part V on Farmers' Rights. The Fund, which will be exempted from income tax, can receive contributions from national and international bodies and others interested in strengthening genetic conservation by local communities.
- 3) A royalty to be fixed by the National Competent Authority based on the gross value of the Breeders' Rights protected seeds sold shall be credited to the Community Gene Fund for the benefit of farming communities whose farmers' varieties have been the basis for the breeding of breeders' varieties.
- 4) The gene fund shall be used to finance projects developed by the farming communities, ensuring equity for women, with or without the participation of experts to help them, aimed at solving their felt problems, including, but not restricted to, the development,

conservation and sustainable use of agricultural genetic resources.

- 5) All salaries and administrative expenses relating to the establishment and administration of the Community Gene Fund will be met by the Government, in order to ensure that the entire proceeds of the Fund go to the farming local communities.
- 6) The Community Gene Fund will have a Fund Management Committee, comprising representatives of farming local communities, professionals, non-governmental organizations, and the public and private sector.

#### PART VIII - ENABLING PROVISIONS

#### Sanctions and 67.

#### **Penalties**

- 1) Without prejudice to the existing agencies and authorities, the State shall establish appropriate agencies with the power to ensure compliance with the provisions of this law.
- 2) Without prejudice to the exercise of civil and penal actions which may arise from violations of the provisions of this legislation and subsequent regulations, sanctions and penalties to be provided may include:
  - i) written warning;
  - ii) fines;
  - iii) automatic cancellation / revocation of the permission for access;
  - iv) confiscation of collected biological specimens and equipment;
- v) permanent ban from access to biological resources, community knowledge and technologies in the country.
- 3) The violation committed shall be publicized in the national and international media and shall be reported by the National Competent Authority to the secretariats of relevant international agreements and regional bodies.
- 4) When the collector conducts his/her operations outside of national jurisdiction, any alleged violations by such a collector may be prosecuted through the cooperation of the government under whose jurisdiction the collector operates based on the guarantee that the latter has provided.

#### Appeals 68.

Decisions on approval, disapproval or cancellation of agreements regarding access to biological resources, community knowledge or technologies may be appealed through appropriate administrative channels. Recourse to the courts shall be allowed after exhaustion of all administrative remedies.