

# Sudan National Biosafety Framework



**November 2005**

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**PREFACE**

For thousands of years, people have used various conventional breeding techniques to modify plants and animals to improve food production. Traditional fermentation techniques, for example, are still used to transform grains into bread and beverages, and milk into cheese. Another traditional form of genetic manipulation is selective breeding, which makes it possible to promote preferred traits, such as higher yields from crops and animals.

Today, these low-tech methods of genetic modification are being supplemented and even replaced by the sophisticated tools of modern biotechnology. Researchers can now take a single gene from a plant or animal cell and insert it into another species to give that species a desired characteristic, such as resistance to a destructive pest or disease. The result is commonly referred to as a genetically modified organism (GMO), or as a living modified organism (LMO), resulting from modern biotechnology.

The beneficial outcome of Biotechnology is yet to be realized, with products and services beyond our imagination now. We shall yet to witness greater breakthroughs of biotechnology in the continuous quest of Man towards the betterment of his life. But hard work is ahead and although optimism is great, we should not expect biotechnology to be a panacea for all our ailments. The Governments of Sudan has recognized that it has to reap the benefits of modern biotechnology under close monitoring. While advances in biotechnology have great potential for improving human well-being, it is widely recognized that LMOs must be subject to adequate safety measures. Such measures, known collectively as biosafety, seek to ensure the safe transfer, handling, use and disposal of LMOs. With the biotech industry growing by leaps and bounds, the international community agreed on the need to develop a legally binding biosafety protocol under the 1992 Convention on Biological Diversity. It is noteworthy that the Government of Sudan has acceded to the Cartagena Protocol on Biosafety.

It is therefore imperative to have the necessary legislative, administrative and policy instruments in place to minimize risks to the environment and human health that might emerge from applications of modern biotechnology. It should also be noted that successful development and application of biotechnology are possible only when a broad research and knowledge base about the manipulated organism are available. It is therefore, imperative that the country must have the necessary infrastructure, financial support and expertise.

On behalf of the people and Government of Sudan I am grateful to the Global Environment Facility (GEF) and the United Nations Environment Programme (UNEP) for their financing and technical assistance. It is this support that made the country's National Biosafety Framework (NBF) possible. Sudan has taken the practical steps towards developing its NBF.

## *Sudan National Biosafety Framework*

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This Framework addresses the national policies on biosafety, regulatory regime, administrative arrangements, risk assessment, risk management and monitoring and inspection as well as public participation.

Further steps are now needed for an efficient and operational Framework that will achieve the goals for which it is structured. The process of implementation is dynamic as long as advancements in modern biotechnology are on-going.

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## **ACKNOWLEDGEMENTS**

The process of developing the National Biosafety Framework (NBF) was an intensive important 18-months exercise that has involved stakeholders from different walks of life in Sudan. It involved among many others, individuals from academic and research institutions, relevant government departments, NGO and CBO members. It is therefore difficult to name everyone who contributed and/or participated.

We are indebted to the Minister of Environment and Physical Development for his continued support to the (NBF) Project. We would also like to show our appreciation to the Chairman of the National Coordinating Committee (NCC) of the (NBF) Project and the members of the Committee (Annex I) under the guidance and advice of whom the Project has achieved its goals.

We are grateful to the Task Force members; Professor Hamid Ahmed Dirar (Dean Faculty of Agriculture, University of Khartoum) Dr. Ahmed S. El Wakeel (Ex-Coordinator Biodiversity Project in Sudan), Dr. El Tahir Ibrahim Mohamed, Head, Unit of Genetic Resources, Agricultural Research Corporation (ARC) and Mr. Imad Eldin Bashir (Attorney General's Chambers) who were closely involved with the development and drafting of the NBF since its inception as a zero draft.

The great effort made by the National NBF Project Coordinator, Dr. Abdelbagi Mukhtar Ali need not be underscored. He was the one facilitating all the activities of the Project.

We are appreciative to the external reviewer Dr (Mrs) Martha Kandawa-Schuz, Namibia Biotechnology Alliance (NABA) whose input is well recognized during her visit to Sudan.

Our thanks are extended to the support staff of the Higher Council for Environment and Natural resources (HCENR) who assisted in organizing the national and state based workshops held by the Project.

Last but not least we wish to express our gratitude to UNEP-GEF for financing and technically assisting in the progress and implementation of the Project. We are particularly grateful to Mr. Charles Gbedemah, Regional Coordinator for Africa, UNEP-GEF Global Biosafety Project for his great help.

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**ABBREVIATIONS AND ACRONYMS**

<b>AIA</b>	<b>Advance Informed Agreement</b>
<b>BCH</b>	<b>Biosafety Clearing-House</b>
<b>CBD</b>	<b>Convention on Biological Diversity</b>
<b>CNA</b>	<b>Competent National Authority</b>
<b>DNA</b>	<b>Deoxyriboneucleic acid</b>
<b>GEF</b>	<b>Global Environment Facility</b>
<b>GMOs</b>	<b>Genetically Modified Organisms</b>
<b>HCENR</b>	<b>Higher Council for Environment and Natural Resouces</b>
<b>IBCs</b>	<b>Institutional Biosafety Committees</b>
<b>LMOs</b>	<b>Living Modified Organisms</b>
<b>NBC</b>	<b>National Biosafety Committee</b>
<b>NBF</b>	<b>National Biosafety Framework</b>
<b>NCABC</b>	<b>National Competent Authority Biosafety Committee</b>
<b>NFP</b>	<b>National Focal Point</b>
<b>NGOs</b>	<b>Non-Governmental Organizations</b>
<b>UNEP</b>	<b>United Nations Environment Programme</b>
<b>WTO</b>	<b>World Trade Organization</b>

**DEFINITION OF TERMS**

<b>Applicant</b>	means a natural or juristic person submitting an application, notification or petition pursuant to the provisions of this Act.
<b>Competent Authority</b>	means the entity responsible for implementation of this Act.
<b>Contained use</b>	means any operation or activity, undertaken within a facility, installation or other physical structure, which involves (GMOs) that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment and the general population.
<b>Export</b>	means the intentional transboundary movement from the area of national jurisdiction of Sudan to the area of national jurisdiction of another country.
<b>Import</b>	means the intentional transboundary movement into the area of national jurisdiction of Sudan from the area of national jurisdiction of another country.
<b>Genetically Modified Organism (GMO)</b>	An organism that has been transformed by the insertion of one or more transgenes.
<b>Modern biotechnology</b>	means the application of: <ul style="list-style-type: none"><li>(i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or</li><li>(ii) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection .</li></ul>
<b>Operator</b>	means any person conducting activities authorized or otherwise allowed under this Act.
<b>Placing on the market</b>	means making a GMO available to third parties on a commercial basis.

**SECTION ONE  
NATIONAL POLICY ON BIOSAFETY**

**1.1 Introduction**

- The Constitution of Sudan calls for the conservation of natural resources of the country and the protection of its diverse environment against any hazards.
- Sudan is party to the Convention on Biological Diversity (CBD) which recognizes modern biotechnology as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care.
- Sudan has acceded to the Cartagena Protocol on Biosafety, which regulates movement of genetically modified organisms (GMOs) across borders with the aim of protecting the environment, the biodiversity and also human health from possible adverse effects of the products of modern biotechnology.
- Sudan is member of the African Union and therefore respects the provisions of the African Model Law on Safety in Biotechnology.
- Sudan is in the process of acceding to the World Trade Organization (WTO) and will therefore abide by the requirements of its agreements.

Taking all the above into consideration, Sudan has set in place this National Policy on Biosafety, in accordance with its national, regional and international obligations.

**1.2 Basic Principles**

- The Policy shall be in harmony with regional and international agreements to which Sudan is party.
- Sudan's national laws should be consistent with the Biosafety Policy.
- As stipulated in Article 15 of the CBD, Sudan, like other parties to the convention, has sovereign rights to its biological resources and would protect them and protect human health against any possible harm posed by the applications of modern biotechnology.
- Sudan fully recognizes the great potential of modern biotechnology and strives to make full use of it but that should be under controlled conditions with the aim of reaping the fruits of this technology without incurring any harm to biological diversity or to human health.
- Sudan has an obligation to protect its vast agricultural land to

benefit its immediate population and the population of the region at large.

- Sudan shall seek to build its capacities with respect to biotechnology and biosafety in order to be able to carry out research and development and to deal with any adverse situations that may occur.
- Rules and regulations dealing with GMOs shall be developed such that research and applications of biotechnology are not in any way harmful to environment and human health.
- Research, applications, trade or any other activity dealing with GMOs shall be performed only after securing an authorization permit.
- Sudan shall follow the Precautionary Principle as stipulated in Principle 15 of the Rio Declaration which says that lack of scientific certainty does not warrant refusal to take action to protect the environment and human health.
- Sudan shall cooperate with relevant organizations and other countries in the area of biotechnology applications and biosafety.
- Transparency is of utmost importance in all dealings involving GMOs. Relevant information shall be fed into the Biosafety Clearing House of the CBD.
- Public participation is extremely important and the government has an obligation to seek avenues whereby the public is well informed of all activities in GMOs and involved, as well, in the decision-making process on such activities.

### **1.3 Scope**

The policy covers the following:

- Laboratory research and other contained uses of GMOs.
- Modern biotechnology applications to industry.
- Modern biotechnology applications to agriculture including trial and field releases.
- Trade in and transboundary movement of GMOs and their products.
- Food and feed involving GMOs, including relief and aid materials.

### **1.4 Objectives**

The policy aims at:

- Promoting the application of Biotechnology as a tool in the sustainable development of the country to benefit the people of the Sudan.

- Ensuring the judicious and wise use of modern biotechnology in order not to jeopardize the environment and human health.
- Protecting Sudan's Biological Diversity by preventing genetic contamination.
- Controlling the transboundary movement of GMOs and products thereof in accordance with the provisions of the Cartagena Protocol.

### **1.5 Implementation**

The following considerations shall be taken into account when implementing the policy:

- The government shall designate a Focal Point to liaise between the Government of Sudan and the Secretariat of the Cartagena Protocol.
- The government shall designate one Competent Authority to handle all matters concerning GMOs internally or externally including exemptions from regulations.
- Decision making shall be mainly based on risk assessment which is in turn based on scientific grounds and on Advance Informed Agreement (AIA) and the Precautionary Principle.
- Biosafety legislations and regulations are to be formulated to encompass all the above aspects and others including application, notification, risk assessment, risk management, institutional structures, release and containment, monitoring and enforcement, packaging, labeling, AIA, liability and redress, public participation, confidential information, decision making, compliance and other aspects .

## **SECTION TWO REGULATORY REGIME**

### **2.1 Purpose**

The regulatory regime is one of the biosafety framework tools that enable the transfer of the national obligations into domestic regulatory instrument that conforms to the international agreements. Therefore, the regime is to establish a transparent and predictable decision making process on genetically modified organisms and related activities, to establish the necessary administrative arrangements.

### **2.2 Challenges**

Certain challenges need to be addressed while developing the regulatory regime, such as:

- The involvement of all interested stakeholders.
- The effective coordination among all concerned sectors e.g. environment, agriculture, health, education ...etc.
- Synergies between relevant legislative frameworks.
- The ability to develop a regulatory regime that encompasses; clarity, transparency, consistency, sustainability, enforceability and adaptability to changes.

### **2.3 General structure**

The regulatory regime could be either a new legislative mechanism, a regulation based on an existing law or an organic law embodying all its characteristics. However, a national biosafety regulatory regime is to include:

- Objectives and Scope.
- Institutional and Administrative Arrangements.
- Handling request including risk assessment and management.
- Duties of the regulatory Agencies (monitoring and enforcement).
- Inspectorate System.
- Miscellaneous provisions (penalties, disclosure, public participation, liability and redress, regulations for inspection, certification of laboratories, permits for contained use, release into the environment and placement on the market).

## **2.4 Provisions**

Provisions of the regulatory regime include general, operational and other types of provisions.

### **2.4.1 General provisions**

The general provisions deal with the following aspects of the regulatory regime:

- Objectives.
- Scope.
- Definitions.
- Institutional provisions.
- General obligations.

The scope answers the question of WHAT does the regulatory regime cover? The answer has usually two parts, which are the activities and objects. Activities will include contained use, release into the environment and commercialization of GMOs, while objects refer to the GMOs that are either released into the environment or used as food and feed. Scope should also state what might be excluded such as pharmaceuticals and laboratory research.

### **2.4.2 Operational provisions**

These are the provisions of the regulatory regime that consist of the following elements:

- Procedures for permits and notifications.
- Risk assessment procedures.
- Risk management arrangements.
- Safety standards to be applied

### **2.4.3 Other provisions**

These are the provisions that help the system work such as provisions dealing with:

- Enforcement.
- Public participation.
- Monitoring.
- Confidentiality.
- Emergency measures.

**SECTION THREE**  
**ADMINISTRATIVE ARRANGEMENTS OF THE NBF**

**3.1 Structure of the Administrative Arrangements**

An administrative set-up is to be established in Sudan to enhance, guide, supervise and decide on matters related to the GMOs and biosafety. Such set-up is to be composed of the following:

- A National Focal Point (NFP).
- A National Competent Authority (NCA).
- A National Biosafety Committee (NBC).

**3.2 Functions of Entities in the Administrative Structure**

**3.2.1 National Focal Point (NFP)**

The Higher Council for Environment and Natural Resources (HCENR) shall be the body designated by the government of Sudan to be responsible for liaising with the secretariat of the Cartagena Protocol on Biosafety, and facilitating the exchange of information among the relevant bodies and authorities.

**3.2.2 National Competent Authority (NCA)**

It is proposed that this authority is to be designated by the government mainly to follow up, supervise and control the implementation of the regulatory regime. It has the following functions and duties:

- Setting criteria, standards, guidelines and regulations necessary for the fulfillment of the law objectives.
- Review and amend these regulations and guidelines as necessary.
- Taking decisions on the import, transit, contained use, release or placing on market of GMOs or a product of GMOs, according to the recommendation and guidelines of the National Biosafety Committee (NBC) .
- Keep GMOs and their products globally under constant review, and therefore, banning the transit of any GMO or its product suspected of posing a serious risk, and notifies the Clearing-House, customs and trade officials accordingly.
- Taking legal measures nationally or internationally to protect human health, biological diversity and in general the environment from risks that may be posed by GMOs or their products, *inter alia*, through enforcing the law and Protocol .
- Designation of inspectors and undertaking inspection as well as other measures to ensure compliance with the law.
- As soon as possible after the composition of the NBC it appoints a

suitably qualified and experienced person as Registrar.

- Given these functions of the NCA and the results of the consultations made during the workshops, the Ministry of Science and Technology has been selected as the most suitable CA in Sudan.

### **3.2.3 National Biosafety Committee (NBC)**

- To provide, as appropriate, guidance and policy recommendations to the NCA.
- Review applications and decide or suggest steps to be followed to carry out the work.
- Reviewing, making or having made risk assessments of GMOs or products GMOs of which the cost will be borne by the exporter when the GMOs or their products are to be imported
- Investigate and ensure that adequate testing of genetically modified materials has been performed in the country of origin before they are introduced to country of import.
- Determine the suitability of the physical and biological containment and decide on the appropriate control measures and procedures up to the level of assessed risk.
- To cause establishment of Institutional Biosafety Committee, or nomination of independent panels or any other body of experts, as technical and scientific advisors on issues of biosafety

### **3.2.4 Institutional Biosafety Committees (IBCs)**

These are committees established by institutions that are involved in the production, import, transit, export, handling, contained use, release or placing on a market of GMOs, or products of GMOs. These committees are to institute and control safety mechanisms and approval procedures at the institutional level.

The functions of an IBC include the following:

- a. Advise the institution on staff qualifications and experience necessary for any GMO work to be undertaken.
- b. Assist institutions in drawing up proposals that takes into consideration the applicable Biosafety measures.
- c. Advise institutions on cases where biotechnological activities should be reported to NCABC.
- d. Assist institutions in establishment of appropriate monitoring mechanisms of risk assessment and risk management.
- e. Collaborate with NCABC in ensuring the

- implementation of the safety measures stipulated in the guidelines.
- f. Monitor releases on sites, provide NBC with progress reports at the end of field trial and provide final reports.

## **SECTION FOUR RISK ASSESSMENT, RISK MANAGEMENT AND MONITORING AND INSPECTION**

### **4.1 Definitions and Concepts**

*Risk Assessment* may be defined as the exploring of the likelihood that an organism introduced into the environment may cause harm to that environment and also human health. Risk Assessment looks at two basic factors, hazard which is a potentially adverse outcome of an event or an activity and risk which is the probability of the hazard is occurring.

*Risk Management* is a strategy to regulate, manage and control the risks identified in the Risk Assessment.

Risk Assessment is based also on the Precautionary Principle in addition to the information provided as a requirement of the Advance Informed Agreement. Risk Assessment is undertaken in a scientifically sound manner. Information from other sources such as Biosafety clean House and new scientific research findings are also included in the gathering of information for Risk Assessment.

### **4.2 Objectives and Importance**

Risk assessment aims at anticipating detrimental effects, designing monitoring systems for the early detection of the outcome of the effects and planning intervention strategies to avert, mitigate or remediate adverse effects.

In dealing with GMOs and the products of Modern Biotech it is of utmost importance to carry out Risk Assessment before taking any decision on matters concerning these genetically manipulated products. The Cartagena Protocol empowers governments to decide whether or not to accept GMO imports on the basis of Risk Assessment as stipulated in Article 15. Under the Protocol Risk Assessment is meant to identify and evaluate the potential adverse effects of GMOs on the conservation and sustainable use of biological diversity and also on human health. The importance of Risk Assessment stems out of this point.

Risk Assessment in Sudan shall cover more than importation of GMOs. It should cover Research projects, Aid food, nucleic acids and releases of GMOs produced internally or from abroad into the environment, in addition to trans-boundary trade.

In the case of contained use of GMOs, Risk Assessment is

also very important because the design of the containment facility and defining the work condition will be based essentially on the outcome of Risk Assessment.

Risk Assessment is the backbone of Biosafely when dealing with modern biotechnology outputs.

Risk management shall have appropriate mechanisms and measures to ensure the safety of the various activities involving GMOs in the Country.

### **4.3 Steps and Procedures**

Risk Assessment is based on information provided by the applicant and is usually carried out by the applicant. Therefore, risk assessment shall be carried out by the applicant and the government authority will form a panel to evaluate the assessment. However, the government can carry out its own independent assessment. In this case the government can ask the applicant to bear the cost.

The broad steps to be followed in risk assessment shall include:

- A. Identification of the main hazardous characteristics of the GMOs:
  - Capacity to survive, establish and disseminates.
  - Potential of gene transfer.
  - Phenotypic and genotypic stability.
  - Examination of the characteristics of the receiving environment e.g. rainfall, temperature, soil type, etc.
- B. See if any of the hazards identified above is likely to be realized in that particular environment of release.
- C. Estimation of potential harmful effects, and their magnitudes, for each of the identified hazards in the given environment:
  - i. The magnitude is expressed quantitatively as severe, moderate, low or negligible harm.
- D. Assessment of the probability with which the potential harmful effects might be realized.
- E. Evaluation of the risk of each of the hazards identified as high, medium, low or negligible.
- F. Evaluation of overall risks to the environment and to human health as high, medium, low or negligible.
- G. If there are risks there will be identification of strategies and measures that would help manage those risks.
- H. Risk management is best carried out step-wise and case –by-case. A panel of experts with experience in the particular GMOs should carry out the Risk Assessment. Sometimes the panel might ask for

extra information to better evaluate the Risk Assessment given by him/her/it. There are many other ways of risk management. General regulatory management procedures include:

- i. All work with GMOs will be carried out only subject to the approval of the authorities concerned.
- ii. Experiments of transformation will be carried out under completely contained laboratory conditions.
- iii. In addition to the physical containment described above as Biosafety levels, biological containment techniques should be applied wherever possible.
- iv. Disposal of GMOs should be through incineration or by any other approved method.

There should be put in place by the concerned authority's contingency plans to deal with untoward effects when observed.

Management schemes are many and variable, depending on the kind of GMOs. For plants and Crops that are GMOs that are GMOs the common processes include the following:

- Use of isolation distances or buffer zones to the next field of the same crop to minimize pollen transfer.
- Use of border rows carrying non-transgenic plants to catch pollen.  
It is important to inactivate the remaining plants and seeds and specific soil treatments in order to prevent growth of and destroy volunteer plants after harvest of GMOs.

#### **4.4 Information needed for Risk Assessment**

The information on which risk assessment is made and is evaluated is usually asked for in the form of a questionnaire appended to the Regulations. The information could also be asked for in the application form as there are many aspects asked for in each of the two forms that are common between them.

At any rate as summary of the relevant questions for obtaining the necessary information for Risk Assessment is given below.

##### **4.4.1 Characteristics of the Recipient (Parent) Organism**

- Scientific name and taxonomy,
- Species it is related to,
- Degree of relatedness to the donor,
- Mode of reproduction,
- Methods of identification and detection,
- Generation time,

- Geographical distribution,
- Dissemination,
- Toxic effects on humans, animals or other organisms,
- Climatic Characteristics of original habitats, and
- Genetic stability.

#### 4.4.2 Characteristics of the Donor organism

- Scientific name and taxonomy,
- Degree of klatches to the recipient,
- Related species,
- Habitat,
- Etc. (mostly as for recipient).

#### 4.4.3 Characteristics of the vector and insert

- Identity of the vector,
- Origin of the vector,
- Host range of the vector,
- Sequence of the vector,
- Sequence of the insert, and
- Genetic characteristic of the insert.

#### 4.4.4 Characteristics of the GMO

- Method used for modification,
- Is inserted gene interoperated or extra-chromosomal,
- Protein coded by the insert,
- Genetic stability,
- Traits which have been introduced, and
- How GMO differs from recipient organism.

#### 4.4.5 Information on the Receiving Environment

- Location
- Geographic, climatic and ecological characteristics
- Biological diversity
- Centers of origin of plants & plants & crops
- Proximity to protected areas.

- Etc.

In the case of GMOs to be used in containment the design of the containment facility should be congruent with the level of risk identified. Commonly four levels of laboratory design are defined and are standardized internationally:

- Biosafety Level 1: This is the least stringent level.  
It does not require special laboratory equipment and does not involve use of microorganisms. This level is suited for moderate potential hazards.
- Biosafety level 2: Personnel should have Specific training in handling pathogenic agents. The laboratory should be supervised by a competent scientist.
- Biosafety Level 3: useful for clinical, diagnostic, research or production work. Suitable for organisms which may cause serious or potential lethal disease as a result of exposure by the inhalation route. Safety cabinets should be used.
- Biosafety Level 4: This level as the most stringent. Suited for work with dangerous and exotic agents which pose a high risk in life-threatening disease. Personnel should wear positive-pressure units.

#### **4.5 Monitoring and Inspection**

A system of contiguous monitoring of all the stages of a GMO project should be designed and executed with vigilance. This should give an idea of the extent to which the realization of the GMO project has an impact on the environment and on human health.

##### **▪ Techniques of monitoring**

Explicit surveillance and monitoring provisions, are to be made to observe, measure, evaluate and analyze, by recognized scientific methods, the risks or adverse effects of the GMO or its use for human health and the environment.

Certain techniques shall be adopted in monitoring to ensure compliance the biosafety policy or framework, these are:

**-Surveillance:** surveillance is the acquisition of data, mainly a scientific activity, on which further action such as monitoring may

be based. Surveillance includes taking samples of the affected environments. Once the information is gathered it must be assembled organized and analyzed by an appropriate agency or institution to which the information is sent.

**-Monitoring:** monitoring is the continuous assessment of information. It is a necessary instrument for gathering and evaluating data concerning the modified organism in order to see the extent, to which transgenic have impacted on the environment, and human health. Most releases which pose no zero risk to the environment will require appropriate monitoring to ensure that no harm results from the release .

**-Inspection:** inspection is another technique adopted. It is an important aspect of monitoring and evaluation. National Biosafety Framework must provide for the appointment of biosafety inspectors as well as their powers.

Powers of biosafety inspectors include the following:

- (a) Conduct an investigation to determine whether the provisions of the Act or regulations have been complied with .
- (b) Enter any premises, facility, vessel or property, which the inspector has reason to believe it is necessary for him to enter , in order to ascertain whether the requirements of the Act are being complied with .
- (c) Take with him any equipment or material required for any purpose for which the right of entry is being exercised.
- (d) Carry out such tests and inspections and make such recording as may in the circumstances be necessary .
- (e) Direct that any part of premise which he has power to enter, shall be left undisturbed for so long as is reasonably necessary for the purpose of testing or inspection.
- (f) Take appropriate samples of any organism, articles, substances found in any premises which he has power to enter for analysis.
- (g) in the case of anything found in the premises which he has power to enter, which appears to him to contain GMO which have adversely affected or are likely to adversely affect the environment, he may cause it to be dismantled or subjected to any process or test but not so as to damage or destroy it, unless it, is necessary.
- (h) Request any information regarding any activity or process from the owner or person in charge.

## **SECTION FIVE PUBLIC PARTICIPATION**

### **5.1 The Concept**

Public participation is defined as the process of encouraging all interested and affected parties to contribute to solving social problems, setting priorities, designing strategies, increasing ownership and taking on responsibilities for action. Therefore, public participation in a National Biosafety Framework means the encouragement of the public and interested stakeholders to be aware of, and contribute to the research, development, implementation and monitoring of such a framework.

### **5.2 Objectives**

Generally, the aim of participation in a national biosafety system is to build partnerships, so that it is possible to harness the collective energy and potential of all stakeholders both in developing and implementing a country's National Biosafety Framework.

Specifically participation helps to:

- Promote sustainability through a process of policy development and decision making that involves all sectors of society, thus helping to develop a sense of ownership amongst the public as stakeholders.
- Improved understanding of the different views held by various stakeholders about the safe use of GMOs through education and awareness resulting from public debate. The debate would assist in building trust and respect between different stakeholder groups with differing views.
- Ensure an inclusive process that involves all stakeholders so that different social and religious views can be taken into account in developing a common vision and purpose for the NBF.
- Promote improved decision making based on sound information and use of available national resources and expertise, thus helping to minimize risks and possible adverse effects .
- Promote transparency and accountability of the government's decision-making processes for GMOs, helping to build trust in the government and promote public commitment to biosafety.

### **5.3 Principles**

Two principles are to be respected in the processes of public awareness and participation in matters related to biosafety:

- Principle (1): Basic information on biotechnology and biosafety issues should be communicated to all stakeholders (the

public) in order to empower them for making informed decisions .

Principle (2): Employment of different communication means to reach the different stakeholders on case by case basis .

#### **5.4 Who are the public?**

In Sudan the public could be categorized into four groups:

- Governmental bodies.
- Non-governmental organizations.
- Private sector.
- Individual citizens.

##### 5.4.1 Governmental bodies

These include:

- Policy makers such as the related government institutions dealing with sectors like environment, agriculture, commerce, industry, health, planning, science and technology.
- Research institutes such as those active in agricultural research, animal research and natural resources and environment research.
- Regulatory and control bodies, including legislative councils, standards and metrology organization, customs authority and import and export authorities.
- Implementation agencies of which the examples are the different departments within the relevant government institutions (e.g. quality control, seeds and quarantine agencies).

##### 5.4.2 Non-governmental organizations

These include the civil society organizations such as the political parties, voluntary societies (e.g. Sudanese Environment Conservation Society, Consumer's Protection Society), professional organizations (e.g. Farmers Union, Pastoralists Union) and the local community leaders.

##### 5.4.3 Private sector

Representatives of the private sector, which is involved in activities related to the GMOs are to be involved in the awareness and decision making processes. They could be drawn from individuals, companies, unions and organizations.

## **5.5 Criteria of organizations to be involved**

Some criteria could be used to identify the most relevant organizations for involvement in awareness and decision making processes related to the GMOs and biosafety matters.

### 5.5.1 Criteria of governmental organizations

These are the organizations involved in one or more of the following activities / fields:

- Scientific research.
- Awareness.
- Information.
- Education.
- Trade.
- Legislation.
- Environment.
- Health.
- Training.
- Relief.
- Production.
- International cooperation.

### 5.5.2 Criteria of non-governmental organizations

The non-governmental organizations to be involved in such participatory activities are those meeting the following criteria:

- Big/ active with voluntary membership.
- Having wide geographical coverage.
- Democracy is practiced in the activities of the organization.
- Concerned with environmental issues as a priority and objective.

## **5.6 Mechanisms**

Different mechanisms could be employed to ensure the public participation. Such mechanisms depend, among others, on the type and level of participation envisaged, which could be either of the following:

- i. Empowerment, when people are empowered through training and access to resources to become decision makers themselves.
- ii. Interactive participation, when stakeholders are involved in analysis, planning and in

- working out ways to tackle issues and challenges. It is both right and responsibility.
- iii. Functional participation, when people are asked to participate in and support the implementation of the government plans, but final decisions are made by the government agency on behalf of the public.
  - iv. Consultation, when people are asked to give their views on particular issues or plans. It is effective when the results of the consultation help to form decisions or plans.
  - v. Passive participation, by including people's representatives in decision-making bodies to approve decisions.

#### 5.6.1 Mechanisms for awareness

It must be emphasized that raising awareness on biotechnology and GMOs and related biosafety issues is a major role that must be played by whatever national authorities or institutes concerned with biotechnology and biosafety issues. Several mechanisms could be used for raising the awareness of the public on issues related to biotechnology and biosafety. Examples of such mechanisms, which can also be used in Sudan, are the following :

- Surveys to collect baseline data to assist the governments in preparing the public information and awareness campaigns.
- Publication of information through pamphlets or internet sites or telephone lines using the local languages.
- Establishment of databases and monitoring of information on GMOs products. Such databases are to be made available for the public.
- Use of public information media such as newspapers, radio and television.
- Production of printed materials such as leaflets or fact sheets on biotechnology and GMOs, or other awareness materials on risks and precautionary measures to be taken.
- Use of theatre and drama and different types of art media.
- Use of informal meetings.
- Supporting the non-governmental and the civil society organizations for raising awareness and mobilizing efforts among groups of the society that might be difficult to be reached without cooperation with such organizations.
- Open field days and public demonstrations..
- Establishment of information bureaus that are specialized on the GMOs and serve as communication points for obtaining information and responding to inquires of the stakeholders.

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In Sudan, the following mechanisms and methods are recommended to be used for raising the awareness of the public on biotechnology and GMOs:

- Radio
- Television
- Cassettes and video tapes.
- Newspapers.
- Posters.
- Newsletters and printed materials.
- Scientific publications.
- Internet.
- Telephone lines .
- Education programs.
- Databases.
- Training programs.
- Direct personal contacts.
- Open lectures and symposia.
- Agricultural extension and information .
- Discussion sessions .
- Use of the community keys such as local leaders, religious leaders, educated groups, civil society organizations, scientific and research institutes and public institutes.

#### 5.6.2 Mechanisms for participation in decision making

Generally, the following mechanisms are used to ensure public participation in the decision making process:

- Legal frameworks that provide for the rights of the public to have access to information and to be consulted and involved when making decisions that affect their lives.
- Publishing applications for approval of GMOs in an official register as a routine work, giving the public the chance to comment within a specific period of time. This could be taken further by organizing meetings for consultation on the public comments before taking the final decision .
- Consultation could be carried out at different levels in the country including the local, state, regional and national levels.
- On-going reviewing of biosafety procedures by bodies formulated from the stakeholders.
- Formation of advisory committees those are independent from the government and industry with broad representation of the stakeholders.
- Convening workshops and seminars targeted to specific groups such as farmers, journalists, local council, residents,

consumers, industry representatives.

- Bottom-up participatory processes that are facilitated by credible and experienced NGOs, which can help to include stakeholders who risk being left-out of government led consultation processes.

#### I. How to inform the public?

In Sudan, the following mechanisms are proposed for informing the public on requests / applications for release or use of GMOs.

- applications could be published through:
  - a. Technical committees.
  - b. Different communication and information media.
- The risk assessment reports should be fully published for the public using all available media.

#### II. How the public can respond?

The comments and views of the public in Sudan are to be conveyed to the concerned authorities using the following methods.

- Questionnaires.
- The public can directly contact the official and parliamentary bodies to convey their comments and views.
- Organizations and societies can play a role in conveying the public opinions to the concerned authorities.
- Use of newspapers for publishing the comments and views of the public.
- Use of the radio and television programs.

#### III. How the public views can be taken into account?

The following methods are recommended for taking into account the public views and comments while making decisions on GMOs:

- Analysis of public comments and views.
- Technical committees.
- The lobbying and pressure exerted by the civil society organizations.

### **5.7 Roles of governmental and non-governmental organizations in awareness**

Different organizations are to play significant roles in raising the awareness of the public on the GMOs and biosafety matters.

#### 5.7.1 Governmental organizations

The governmental organizations can play a role in raising the awareness of the public on:

- Benefits and risks of the GMOs.
- Information on the GMOs products.

#### 5.7.2 Non-governmental organizations

The non-governmental organizations can play a role in raising the awareness of the public on:

- Biotechnology as a modern science.
- Different uses of biotechnology.
- Achievements of biotechnology in different fields.
- Actual benefits and expected risks/ hazards of GMOs.
- Regulations and precautionary measures to be taken.

#### 5.7.3 Target groups for awareness activities

The following groups are to be targeted by governmental and/or non-governmental organizations when carrying out their awareness activities:

- Top leaders and decision makers.
- Producers in both agricultural and industrial sectors.
- Consumers in general.
- Women as being more concerned with foods.
- Students as being effective on their families and close relatives.

### **5.8 Role of governmental and non-governmental organizations in decision making**

Both governmental and non-governmental organizations have roles to play while decisions are being made in the country on GMOs and biosafety matters.

#### 5.8.1 Governmental organizations

Governmental organizations can play a role to facilitate the decision making process on the GMOs through the following:

- Establishment of a national body for biotechnology with executive capabilities, under which specialized groups or committees can be formed.
- Issuing of legislations and regulations.
- Establishment of special attorneys and courts.

### 5.8.2 Non-governmental organizations

The non-governmental organizations can play a role in the decision making process on the GMOs through the following:

- Conducting preliminary and detailed surveys to assess the capacities of such organizations and extent of their understanding to issues related to biotechnology and biosafety.
- Use of questionnaires and opinion surveys and direct meetings to know the views and comments of the public on the GMOs.
- Feedbacks and direct and indirect responses of the public can also be used to know and understand the public views on GMOs.
- The participatory approach should be used within and between the NGOs in order to develop sound ideas based on scientific approach.
- Formation of joint teams with broad representation for enlightening the public and tackling all issues related to modern technologies and biosafety.
- Early informing the public on whatever activities related to modern biotechnology intended to be introduced in the country. This will give ample chances for carrying out discussions and dialogue on the matter.

### **5.9 Stages for public participation**

In Sudan the public are to be involved at different stages of the decision making process. Such stages can be outlined in the following:

- A selected technical committee should investigate applications upon their receipt in order to verify if an application is technically sound and perfect. At such stage the public need not be involved.
- A summary of the technical information submitted with an application should be made available for the public (stakeholders).
- The risk assessment reports should be made available fully to the public.
- A draft decision should be communicated to the public for further feedback and reaction before the final decision is made.
- The public should then be informed about the final decision.

### **5.10 Capacity building**

Capacity building is needed for empowering the public to play effective roles in the awareness and decision making process on GMOs. Areas for capacity building for the different types of organizations include the following:

- Capacities of governmental organizations should be built in the area of biotechnology and biosafety by:
  - a) Survey and assessment of the available capacities and needs for capacity building.
  - b) Provision of equipment, needs and aids for education, awareness activities and training.
  - c) Enhancing the international cooperation in this area and collaboration with foreign expertise.
- The capacities of the non-governmental organizations need to be built in both areas of awareness and decision making as could be outlined in the following:
  - a. Provision of information on modern biotechnology in different ways, methods and styles that could be understood by the different targeted groups.
  - b. Training and education programs for providing the basic information and skills of relevance.
  - c. Publication of available information to all sectors and social groups using different methods and approaches.
  - d. Provision of aids and equipment that enable the organizations to achieve their educational and training programs such as vehicles, communication aids...etc.
  - e. Coordination and networking between different civil society organizations in order to have common understanding on the different related issues with common objectives and to be able to use efficiently the available resources.
- Generally the public are to be empowered and their capacities should be built in order to enable them to participate effectively in making the right decisions on the GMOs. This could be achieved through:
  - Enlightening the public (citizens) of their rights and duties.
  - Democratic practice and behavior to be enhanced in the decision making process.
  - Enlightening people about the benefits and risks / hazards of the biotechnology products.
  - Encouraging the transparent and credible practice and behavior which enhance confidence and trust on the decisions taken.
  - Access to information should be looked at as one of the basic citizen rights.
  - High value should be given to opponent views.
  - Conducting surveys for public opinion on different issues.

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## Annex II

### THE BIOLOGICAL SAFETY BILL 2005

In exercise of the provisions of the Sudan Constitution 1998, the National Assembly, hereby passed and signed by the President of the Republic as follows :-

#### Chapter I

#### General Provisions

##### Title and Commencement

1. This Act may be cited as the Biological Safety Bill 2005, and shall come into force as from the date of signature.

##### Objectives

- 2.(a) In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Act is to ensure an adequate level of protection in the field of the safe transfer, handling, and use of genetically modified organisms (GMOs) resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity and human health.
- (b) To provide a transparent and predictable process for review and decision-making on such GMOs and related activities; and
- (c) To implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

##### Definitions

- 3.(a) “Applicant” means a natural or juristic person submitting an application, notification or petition pursuant to the provisions of this Act ;
- (b) “Competent Authority” means the entity responsible for implementation of this Act.
- (c) “Contained use” means any operation or activity, undertaken within a facility,

- installation or other physical structure, which involves (GMOs) that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment and the general population .
- (d) “Export” means the intentional transboundary movement from the area of national jurisdiction of Sudan to the area of national jurisdiction of another country.
  - (e) “Import” means the intentional transboundary movement into the area of national jurisdiction of Sudan from the area of national jurisdiction of another country.
  - (f) “Genetically” (GMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
  - (g) “Intentional introduction into the environment” means any deliberate use of (GMOs) subject to this Act that is not contained use including (GMOs) imported for direct use for food or feed or for processing.
  - (h) “Modern biotechnology” means the application of:
    - (i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
    - (ii) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection .
  - (i) “National Focal Point” means the entity designated to be responsible on behalf of Sudan for liaison with the Secretariat of the Cartagena Protocol.
  - (j) “Operator” means any person conducting activities authorized or otherwise allowed under this Act.
  - (k) “Person” means a juridical or natural person.
  - (l) “Placing on the market” means making a GMO available to third parties on a commercial basis.
  - (m) “Registry” means the compilation of (GMOs) or activities that are authorized, exempted or subject to simplified procedures in accordance with this Act and regularly published by the Competent Authority pursuant to Article
  - (n) “Risks to human health” means the potential impact on human beings as a direct

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result of an adverse effect on the conservation and sustainable use of biological diversity.

### Scope

- 4.(a) Subject to the exceptions set forth in this Act or provided for by regulation hereunder, this Act shall apply to the contained use, intentional introduction into the environment, and import and export of (GMOs) that may have an adverse effect on the conservation and sustainable use of biological diversity and human health .
- (b) This Act shall not apply to :
- (i) (GMOs) that are pharmaceuticals for human use;
  - (ii) (GMOs) in transit through but not destined for use in Sudan ; and
  - (iii) Any other (GMOs) or categories of (GMOs) that are exempted pursuant to Article 13 of this Act.

## Chapter II

### Institutional Arrangement

#### National Focal Point (NFP) (HCENR)

5. HCENR shall be the body designated or established by the government to be responsible on the government's behalf for:
- Liaising with the secretariat of the Cartagena Protocol on Biosafety and facilitate the exchange of information among the relevant bodies and authorities.

### Establishment of Competent Authority

6. (a) Ministry of Science and Technology shall be the Competent Authority for the purposes of the administration of this Act and any regulations promulgated hereunder .
- (b) The primary functions of the Competent Authority are :
- (i) to receive, respond to and make decisions on notifications pursuant to Article 11 and applications pursuant to Articles 9 respectively, in consultation with the National Biosafety Committee and in conformity with the requirements of this Act;

- (ii) To establish regulations and administrative mechanisms to ensure the appropriate handling, dissemination, and storage of documents and data in connection with the processing of applications and notifications and other matters covered by this Act; and
- (iii) To promote public awareness and education concerning the activities regulated under this Act, including through the publication of guidance and other materials that explain and elaborate on the risk assessment, risk management and authorization processes.
- (iv) To establish mechanisms for inspection and monitoring of approved GMOs

### Establishment of National Biosafety Committee

7. (1) A National Biosafety committee (NBC) shall be established by the Competent Authority for the purpose of conducting risk assessments and providing scientific and other technical advice and assistance to the Competent Authority .  
The responsibilities of the NBC shall include:
- (i) Conducting risk assessments;
  - (ii) Reviewing risk assessments provided in applications or notifications ;
  - (iii) Reviewing risk management measures ;
  - (iv) Recommending containment measures, limitations on the duration of authorizations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures; and
  - (v) Providing such other expert advice and assistance as the Competent Authority may request.
- (2) The NBC shall consist of a core group of scientific experts appointed by the Competent Authority from the following fields:
- (a) Government Ministries of:
    - (i) Science and Technology
    - (ii) Agriculture and Forestry,
    - (iii) Health,
    - (iv) Environment and Physical Development,

- (v) Animal Wealth,
  - (vi) Interior (Customs)
  - (vii) Foreign Trade,
  - (viii) Industry,
  - (ix) Investment.
  - (x) Justice
- (b) Government Corporations & departments:
- (i) Sudanese Standards & Metrology Organization
  - (ii) (Corporation) SSMO
  - (iii) Sea Ports Corporation (SPC)
  - (iv) Humanitarian Aid Commission ( HAC)
- (c) Public Universities
- (i) university of Khartoum
  - (ii) Gezira university
  - (iii) University of Juba
- (d) Research institutions:
- (i) Agricultural Research Corporation
  - (ii) Animal production Research Institute
  - (iii) Animal Resources Research Corporation (ARRC)
- (e) Stakeholders :
- (i) Sudanese Farmers' Union
  - (ii) Pastoralists' Union
  - (iii) Sudanese Environment conservation Society
  - (iv) Environmentalists Society
- (3) Internal procedures for the operation of NBC and its subcommittees shall be proposed by the NBC and shall be approved by the Competent Authority and established by regulation. Such regulations shall provide for all matters necessary for the effective and transparent operation of the NBC and any subcommittees established hereunder but shall prescribe the terms of reference and competence of the NBC and shall include, at a minimum, mechanisms and procedures for:

- (i) Designating members and chairpersons of the NBC and its subcommittees, appointing advisors and specifying rules of procedure for the NBC and its subcommittees, and for the participation of advisors in the NBC or its subcommittees;
- (ii) Ensuring the absence of conflicts of interest among members of the NBC and its subcommittees and advisors to the NBC and its subcommittees in conformity with paragraph (e);
- (iii) Providing appropriate remuneration for members of the NBC and its subcommittees and advisors to the NBC and its subcommittees; and
- (iv) Ensuring the protection of confidential information as required by Article 9 of this Act, including a declaration that any information attained by virtue of membership in the NBC or a subcommittee, or appointment as an advisor to the NBC or a subcommittee, shall not be disclosed to others or used for any research, development or commercial purpose without the express written authorization of the Applicant identifying the information as confidential pursuant to Article 12.

### Institutional biosafety Committee (IBC)

- 8.(1) There shall be established in any institution involved in the import , transit, export, handling, contained use, release or placing on the market of (GMOs) .The guidelines hold the management of an institution doing GM research responsible for ensuring that the environment is safe and recommend the establishment of an IBC, which should have a concise Biosafety Protocol .
- (2) Members of this committee include researchers from :
- (a) Experienced researcher in modern biotechnology applications who is familiar with biosafety requirements for rDNA work and facilities (Chairperson) .
  - (b) Three other scientists of relevant experience to genetic engineering

## Chapter III

### Notification and Authorization Requirements

- 9.(a) No person shall conduct any contained use activities involving (GMOs) or import (GMOs) for such purposes without the prior submission of a notification

- to the Competent Authority as set forth in this Article
- (b) A Notification of intent to conduct activities with GMOs under contained use pursuant to paragraph (a) shall be submitted at least sixty (60) days before the activities covered by the notification are due to begin .
- (c) The notification shall include :
- (i) The name and contact information for the Applicant ;
  - (ii) The location where contained use activities will be undertaken ;
  - (iii) The nature and identity of the GMO or GMOs involved;
  - (iv) The nature and purpose of the activities, including such activities as storing , transporting, producing, culturing, processing, destroying, disposing, or using the GMOs in any other way;
  - (v) A description of the containment measures to be provided and the suitability of those measures for the GMOs and activities to be undertaken;
  - (vi) A description of any potential risks associated with the GMOs and activities to be undertaken; and
  - (vii) A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the GMOs that may occur as a result of the activities to be conducted .
- (d) In response to the submission of a notification, the Competent Authority may, in consultation with the NBC , request additional information, including a risk assessment carried out in a scientifically sound manner, in accordance with Annex II and recognized risk assessment techniques. The competent Authority shall inform the Applicant in writing of the additional information sought and the procedure the Competent Authority will follow in taking further action on the notification.
- (e) Where additional information is sought by the Competent Authority under paragraph (d), a final written decision as to whether the proposed activities may proceed shall be provided by the Competent Authority to the Applicant receipt of the additional information. In the event the proposed activities are not permitted as requested in the notification, the Competent Authority shall include in its final written decision the reasons for the prohibition or any limitations or conditions

that may be placed on the proposed activities .

- (g) Regulations governing the conduct or contained use activities, including relevant definitions, risk classifications, waste and disposal requirements and procedures, and requirements for risk assessments, shall be promulgated pursuant to Article 28 of this Act.

### Authorization Requirements for Intentional Introduction into the Environment

10. (a) the following activities are prohibited unless authorized by the Competent Authority in conformity with this Act :

- (i) The intentional introduction into the environment of a GMO for purposes other than placing on the market; and
  - (ii) Placing on the market of a GMO.
- (b) No person shall import a GMO for activities subject to paragraph (a) without authorization under this Act.
- (c) Persons proposing to export GMOs covered by this Act from Sudan to another country party to the Cartagena Protocol shall:
- (i) Notify the Competent Authority of the proposed party of import in writing, prior to the first transboundary movement of the GMO for intentional introduction into the environment of the party of import by supplying, at a minimum, information specified in Annex I, in accordance with the Cartagena Protocol and any applicable domestic legislation;
  - (ii) Include a declaration that all information provided in such notification is factually correct; and
  - (iii) Prior to shipment, provide to the Competent Authority a copy of the authorization granted by the importing country where authorization is required under the Cartagena Protocol and/or the applicable laws of that country.

### Application Procedures for Intentional Introduction into the Environment

11.(a) Any person proposing to intentionally introduce an GMO into the environment

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shall submit to the Competent Authority an application that complies with the requirements of this Article and describes the activity or activities for which authorization is sought .

- (i) The information specified in Annex I, with the exception of any information the Competent Authority identifies as unnecessary in pre-application consultations;
  - (ii) A risk assessment in conformity with Annex III of the Cartagena Protocol, and
  - (iii) Any additional information applicants deem relevant to an assessment of the potential risks and/or benefits of the requested activity.
- (b) All applications shall include a declaration that the information contained therein is factually correct.
- (c) An Applicant may withdraw its application at any time prior to the issuance of a final decision by the Competent Authority without prejudice .

### Confidential Information

12.(a)The Competent Authority shall :

- (i) Permit the Applicant to identify information provided to the Competent Authority in accordance with the requirements of this Act and any regulations promulgated hereunder, including information contained in notifications, applications and other written submissions, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request;
  - (ii) Decide whether it accepts as confidential the information designated by the Applicant;
  - (iii) Prior to any disclosure of information identified by the Applicant as confidential, inform the Applicant of its rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure; and
  - (iv) In the event that an Applicant withdraws or has withdrawn an application, respect the Applicant's claims of confidentiality, including claims for that information on which the Competent Authority and the Applicant disagree as to its confidentiality.
- (b) The Competent Authority shall neither use nor permit the use of confidential information accepted as confidential under paragraph (a) for any purpose

- specifically authorized under this Act except with the written consent of the applicant and shall ensure that such information is protected by all persons involved in handling or reviewing applications or other written submissions under this Act.
- (c) Without prejudice to paragraph (a)(iv) above, the following information shall not be considered confidential :
- (i) The name and address of the Applicant ;
  - (ii) A general description of the GMO;
  - (iii) A summary of risk assessments performed on the GMO; and
  - (iv) Any methods and plans for emergency response.

### Acknowledgment and Preliminary Response

- 13.(a) Upon receipt of an application submitted under Article 8, the Competent Authority immediately shall refer the application to NBC for prompt screening for prima facie completeness.
- (b) Within thirty (30) days of receipt of the application, based on information provided by NBC, the Competent Authority shall acknowledge receipt of the application and respond, in writing, to the Applicant.
- (c) The preliminary response shall include:
- (i) The date of receipt of the application ; and
  - (ii) Whether the application, prima facie, contains the required information or, if not, what additional information within the scope of Annex I, is required.
- (d) If additional information is required, the number of days the Competent Authority must wait for the information shall not be included in calculating the timeframe for making a final decision under Article 15.

### Risk Assessment and Risk Management

- 14.(a) The Competent Authority shall ensure that appropriate and adequate risk assessments are carried out for all activities that require authorization under Article 10.
- (b) Risk assessment, including the auditing of risk assessments, shall be carried out in a scientifically sound manner, in accordance with Annex III and recognized risk

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- assessment techniques. Risk assessments shall be based on the information included in the application and any other available scientific evidence.
- (c) The NBC shall audit risk assessments submitted by the Applicant and shall conduct or cause to be conducted any additional risk assessments as required on a case-by-case basis. In carrying out its risk assessment and auditing activities, the NBC shall take into account any risk management measures proposed by the Applicant and any additional risk management measures that may be necessary to minimize any identified potential risks. Where additional risk assessments required, it may be undertaken by the Applicant, NBC or other experts at the discretion of the competent Authority.
  - (d) Upon conclusion of the risk assessment and auditing process, the NBC shall provide to the Competent Authority a risk assessment report that gives its opinion, with justifications, on the disposition of the application and indicates any measures or actions that need be taken to ensure the safe use of the GMO. The report should include a summary of the risk assessment that does not include any confidential information subject to protection under Article 9.
  - (e) The competent Authority shall ensure that appropriate mechanisms, measures or strategies are in place to regulate, manage and control potential risks identified during the risk assessment process and shall impose such mechanisms, measures or strategies to the extent necessary to prevent adverse effects of GMOs on the conservation and sustainable use of biological diversity including risks to human health.

### Decision-making and Communication of Decision

- 15.(a) Following receipt of the risk assessment report, the Competent Authority shall make a final decision concerning the authorization requested in the application submitted under Article 11.
- (b) Any decision rendered under paragraph (a) shall be based upon:
  - (i) The information submitted by the Applicant under Article 11.
  - (ii) The risk assessment report prepared by the NBC in accordance with Article 14(a).
  - (iii) Any relevant comments submitted by the public pursuant to Article 20.

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- (c) In reaching a decision, the competent Authority also may take into account, consistent with the international obligations of Sudan, socio-economic considerations arising from the impact of GMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
  - (d) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of living modified organism on the conservation and sustainable use of biological diversity including human health, shall not prevent the Competent Authority from making a decision, as appropriate, in order to avoid or minimize such potential adverse effects.
  - (e) A final decision shall be made and communicated to the Applicant within two hundred-seventy (270) days of receipt of an application.
  - (f) The final decision of the Competent Authority shall be recorded in a decision document that:
    - (i) Identifies the Applicant and summarizes the nature of the request ;
    - (ii) Describes the procedure followed in reviewing the application;
    - (iii) Includes the summary of the risk assessment conducted by the NBC
    - (iv) States whether the requested activity is authorized, with or without conditions, or whether the requested activity is prohibited ; and
    - (v) Provides the reasons for the decision.
    - (vi) Any specific conditions, limitations or requirements related to the authorization must be clear on the face of the decision document.

## Chapter IV

### Review Mechanisms

#### Review of Decisions

- 16.(a) The Competent Authority, in consultation with NBC , may review any decision under Article 8 and 9 at any time upon obtaining significant new scientific information indicating that the GMO or activities involved may adversely affect the conservation and sustainable use of biological diversity including risks to human health. The competent Authority shall inform the Applicant of its intent

- and reasons for initiating a review of the decision prior to undertaking the review.
- (b) Any applicant may request the Competent Authority to review its decision under Article 6, Article 9 or with respect to an activity conducted or proposed to be conducted by the Applicant where the Applicant considers that :
- i. a change in circumstance has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was based ; or
  - ii. Additional scientific or technical information has become available that may have a material effect on the decision including any conditions, limitations or requirements imposed under an authorization.
- (c) If upon review under paragraphs (a) or (b) in consultation with NBC, the Competent Authority finds that a change is warranted, it may issue an order changing the decision and/or the conditions in the authorization in a manner that is consistent with the validated scientific evidence or other accepted scientific methodology.
- (d) A written decision, pursuant to a review conducted under paragraph (a), shall be provided to the Applicant by the Competent Authority within ninety (270) days from the date the Applicant is notified of the review and shall set out the reasons for the decision.

### Right of Appeal

- 17.(a) any Applicant who is aggrieved by any decision of the Competent Authority under this Act may appeal to the Minister on either procedural or substantive grounds .
- (b) The Minister shall decide on such appeals within a reasonable time, not to exceed sixty (60)days, and shall communicate its decision and the reasons therefore in writing to the Competent Authority and the Applicant .
- (c) An Applicant who remains aggrieved following an appeal under paragraph (a) or who does not receive a response within the Time Frame stated in paragraph (b) shall have the right to appeal the decision of the Competent Authority to a competent court .

## Chapter V

### Safeguards

#### Monitoring and Submission of New Information

- 18.(a) Operators shall monitor their activities to ensure that they comply with the requirements of this Act and any conditions or requirements imposed in connection with the authorization or allowance of activities under this Act .
- (b) Operators that become aware of any significant new scientific information indicating that authorized activities with GMOs may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health, or pose potential risks not previously known or considered, shall immediately advise the Competent Authority of the new information and newly identified risks and of the measures put in place to ensure the continued safe use of the GMOs
- (c) Subject to the protection of confidential information in accordance with Article 9, Operators shall supply to the Competent Authority upon request and in accordance with regulations promulgated under the authority of this Act such information about their activities as is necessary for the Competent Authority to carry out its supervisory, monitoring or enforcement tasks under this Act or to deal with any emergency situations.

#### Unintentional Introduction into the Environment

- 19.(a) Any Operator with knowledge of an unintentional or unauthorized introduction into the environment of an GMO subject to this Act that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall, within 24 hours of when the Operator knew of the introduction, notify the Competent Authority of the occurrence .

- (b) A notification under paragraph (a) shall include the following :
  - (i) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMO .
  - (iii) Information on the circumstances and estimated date of the introduction;
    - (iii) Any available information about the possible adverse effect on the conservation and sustainable use of biological diversity, as well as available information about possible risk management measures ;
  - (iii) Any other relevant information; and
  - (iv) A point of contact for further information .
- (f) The Competent Authority, in consultation with NBC , shall consult with Operators providing notifications under paragraph (a) and determine whether any action is necessary to minimize any adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health .
- (g) Where it knows of an occurrence within its jurisdiction resulting in an introduction that leads or may lead to an unintentional transboundary movement of an GMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity and to human health, in another country, the Competent Authority shall notify affected or potentially affected countries, the Biosafety Clearing House, and, where appropriate, relevant international organizations .

### Cessation Orders

- 20.(a) The Competent Authority may issue an order for the immediate cessation of any activity covered by an authorization or which has been the subject of a notification submitted under this Act or for the immediate imposition of additional risk management measures with respect to such activity, if the Competent Authority determines that there is an imminent danger posed to the conservation and sustainable use of biological diversity and to human health, on the basis of :
- (i) One or more tests conducted and evaluated in a manner consistent with accepted scientific procedures, or

- (ii) Other validated scientific evidence.
- (b) The Competent Authority also may issue a Cessation Order upon the failure of any Operator to demonstrate substantial compliance, after a reasonable period of time, with an order issued under Article 16(c) or, with respect to an authorization granted or notification submitted under this Act, when there exists a material infringement of any provision of the Act or regulations made hereunder.
- (c) An order issued pursuant to paragraph (a) or (b) shall be withdrawn once the Competent Authority determines that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

## Chapter VI

### Public Information, Awareness and Participation

#### Public Awareness and Participation

- 21.(a) The Competent Authority shall promote awareness and education of the public and those conducting activities subject to the Act concerning biosafety matters through the publication and dissemination of this Act and regulations made hereunder, as well as guidance documents and other material aimed at improving understanding of biosafety and related authorization and notification requirements.
- (b) The Competent Authority shall publish, on a regular basis :
  - (i) Notices concerning proposals under Article 13(b) and (c) and
  - (ii) Proposed decisions on applications and petitions filed pursuant to Article 10.
- (c) Upon request, the Competent Authority shall make available to any person portions of any application or petition subject to paragraph (b)(ii) that does not qualify as confidential information under Article 9, without prejudice to Article 12 (a)(iv) .
- (d) Any person may submit written comments on a proposed decision for any application for placing a GMO on the market or any petition for an exemption within sixty (60) days from the date the notice is posted. Such comments shall be considered as part of the decision-making process in accordance with Article 15(b).

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Any comments received by the Competent Authority and responses thereto also shall be made available to the public upon request.

- (e) The Competent Authority shall publish notices of final decisions concerning all applications or petitions under Article 10 of this Act and notices concerning the final resolution of any compliance matters under Articles 23 and 26 in cases involving non-compliance with material provisions of this Act.
- (f) The Competent Authority shall establish and maintain a registry of:
  - (i) GMOs for which authorization is granted under Article 10 of the Act, including whether the GMO has been authorized for placing on the market; and
  - (ii) GMOs and activities that are exempted or subject to simplified procedures in accordance with Article 13(b), (c) or (h) of the Act .
- (g) any regulations proposed under Article 26 of this Act must be published and a period of sixty (60) days allowed for the submission of written comments by any person. Such comments shall be considered as part of the regulatory process in accordance with Article 26(a). Any comments received by the Competent Authority and responses thereto also shall be made available to the public upon request.

### International Information Sharing

- 22.(a) The Competent Authority shall notify the Biosafety Clearing House that its domestic regulations shall apply with respect to any imports of GMOs to the area of national jurisdiction of Sudan
- (b) The Competent Authority shall provide to the Biosafety Clearing House, with the information's required by the protocol.

## Chapter VII

### Enforcement

- 23.(a) The Competent Authority may appoint as inspectors such number of persons appearing to it to be qualified for the purposes of ensuring compliance with the Act and its regulations .
- (b) The powers of an inspector are :

- (i) at any reasonable time ( or, in a situation in which in the inspector's opinion there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking also into account risks to human health, at any time ) :
  - (A) to enter premises, including but not limited to a facility, vessel or property, which the inspector has reason to believe it is necessary for him to enter and to take with him any person duly authorized by the Competent Authority; and
  - (B) to take with him any equipment or materials required for any purpose for which the power of entry is being exercised.
- (ii) to carry out such tests and inspections 9 and to make such recordings), as may in any circumstances be necessary;
- (iii) to direct that any, or any part of, premises which he has power to enter, or anything in or on such premises, shall be left undisturbed ( whether generally or in particular respects ) for so long as is reasonably necessary for the purpose of any test or inspection ;
- (iv) to take samples of any organisms, articles or substances found in or on any premises which he has power to enter, and of the air, water or landing, ion, or in the vicinity of, the premises;
- (v) in the case of anything found in or on any premises which he has power to enter, which appears to him to contain or to have contained GMOs which have adversely affected or are likely to adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health, to cause it to be dismantled or subjected to any process or test ( but not so as to damage or destroy it unless this is necessary );
- (vi) in the case of anything mentioned in subparagraph (v) above or anything found on premises which he has power to enter which appears to be a GMO or to consist of or include GMOs to take possession of it and detain it for so long as is necessary for all or any of the following purposes , namely :
  - (A)to examine it and do to it anything which he has power to do under that subparagraph ;

- (B) to ensure that it is not tampered with before his examination of it is completed ; and
  - (C) to ensure that it is available for use as evidence in any proceedings for an offence under Article 26;
  - (vii) to require the production of, or where the information is recorded in computerized form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for him to see for the purposes of any test or inspection under this Article and to inspect, and take copies of , or of any entry in, the records;
  - (viii) to require any person to afford him such facilities and assistance with respect to any matters or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him by this Article ;
  - (ix) such other powers as may be necessary for the purposes mentioned in paragraph (a) above which is conferred by regulations made by the Competent Authority .
- (c) Where goods are seized by an inspector without reasonable cause, the aggrieved person may bring an action in any competent court for appropriate relief, in including an order for the return of the good seized, and, if the claim prevails, shall be entitled to the costs of such proceedings .

### 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.

### Regulations

- 26.(a) Consistent with the objective and scope of this Act, the Competent Authority shall propose and, after public notice and an opportunity for public comment pursuant to Article 21 (g), finalize and publish such regulations as may be necessary for implementing the provisions of this Act.
- (b) The Competent Authority shall publish a schedule of fees to cover administrative costs of processing notifications, applications and petitions submitted under this Act.
- (c) The Competent Authority should decide on the labeling criteria of GMOs.