THE GOVERNMENT OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

ENVIRONMENTAL PROTECTION AUTHORITY

BIOSAFETY FRAMEWORK

FINAL DRAFT

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1. General Introduction

In November 2000, the 16th GEF Council approved the UNEP/GEF Global Project entitled "Development of National Biosafety Frameworks", which aimed at assisting 100 developing countries to prepare their national biosafety frameworks in accordance with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

Ethiopia, being a party to the Cartagena Protocol and one of the eligible countries, has prepared its Nation Biosafety Framework (NBF) through financial assistance from GEF. This NBF comprises of policy, legal, administrative and technical instruments that have been developed in order to ensure an adequate level of safety in the field of the safe transfer, development, handling and use of Living Modified Organisms (LMOs), also referred to as Genetically Modified Organisms (GMOs) and their products that emanate from modern biotechnology and may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Though NBFs vary from country to country, they all share common elements. These are:-

- A Government **policy on biosafety**,
- A **regulatory regime** for biosafety, which is designed to address issues of safety in the area of biotechnology. This includes laws, directives, regulations and guidelines which regulate the transboundary movements of LMOs/GMOs and products thereof,
- A **system to handle notifications or requests for authorizations** to be engaged in LMO/GMO related activities. This may includes import, export, transit, handling, release, contained use, transport, placing on the market, of LMOs/GMOs or products thereof,
- Systems for **enforcement and monitoring for environmental effects** and
- Mechanisms for **public awareness, education and participation**.

The Ethiopian biosafety framework is a combination of:-

- **Government policy provisions on Biosafety in various policy documents**. The current policy direction to the framework is in the Environmental Policy of Ethiopia. The policy incorporates sectoral as well as cross sectoral environmental policy provisions which are set in place to ensure the sound management and use of natural resources and the environment. This Environmental Policy is based on the Constitution and the Conservation Strategy. The National Biotechnology Policy and the Science and Technology policy are also consistent with the Environmental Policy.
- A **regulatory regime** which is based on the *Precautionary Principle* set to protect human and animal health, biological diversity and the environment at large by preventing or managing down to levels of insignificance the adverse effects of GMOs and products thereof. This includes a biosafety law and directives governing the movement of GMOs and their products.
- An **administrative system to handle notification or request for authorization** from the designated Authority after submitting an application along with a risk assessment report for all research and development activities, import, export, transit, handling, release, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, or use as food, feed or for processing of any GMO or products thereof.
- A **mechanism for enforcement and monitoring** that needs to be incorporated on any application to be engaged in GMO related activities. This includes a clear and sequential description of all the steps to be taken during the implementation of a project that uses GMOs or their products, monitoring and evaluation that will be made at the end of each step, methods of waste disposal as well as emergency measures in cases of accidental release.

- A **mechanism for public awareness and participation** which ensures that the public is made aware and take part in decision making for any application of a GMO or a products thereof.

1.1. Introduction to the NBF

The UNEP/GEF Project on the Development of the National Biosafety Framework for Ethiopia was started in September 2002 and ended in ------ 2007. This project assisted Ethiopia in raising awareness and building technical and scientific capacity as well as in the development of a legal framework that deals with risks emanating from GMOs and products thereof, and in making informed decisions on biosafety.

The National Executing Agency for the UNEP/GEF project was

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The National Coordinating Committee (NCC) consisted of thirty three (33) persons drawn from diverse professions serving in Regional and Federal offices, universities and research institutions. These institutions were:-

1. Gambella Peoples National Regional State Plan and Economic Development Bureau
2. Afar National Regional State Plan and Economic Development Bureau
3. Somali National Regional State Finance and Economic Development Bureau
4. Beneshangul Gumuz Environmental Protection Authority
5. Tigray National Regional State Finance and Economic Development Bureau
6. Dire Dawa Administration Plan and Economic Development Office
7. Harrari Peoples National Regional State Plan and Economic Development Bureau
8. Regional Government of Oromia Environmental Protection Office
9. Southern Nations, Nationalities and Peoples Environmental Protection Authority
10. Amhara Naitonal Regional State Environmental Protection and Land Administration and Use Authority
11. Debre Zeit National Veterinary Institute
12. Ethiopia Drug Administration and Control Authority
13. Ethiopian Customs Authority
14. Ethiopian Manufacturing Industries Association
15. Institute for Sustainable Development
16. Ethiopian Agricultural Research Organization
17. Armauer Hansen Research Institute
18. Quality and Standards Authority of Ethiopia
19. Ethiopian Consumers' Protection Association
20. Ethiopia Seed Enterprise
21. Ethiopian Science and Technology Commission
22. Ministry of Health
23. National Agricultural Input Authority
24. City Government of Addis Ababa Environmental Protection Authority
25. Institute of Biodiversity Conservation and Research
26. Ministry of Trade and Industry
27. Ministry of Justice

28. Ethiopian Health and Nutrition Research Institute
29. Forum for Environment
30. Alemaya University
31. Mekelle University
32. Addis Ababa University Department of Biology
33. Debre Zeit Faculty of Veterinary Medicine

2. Description of the National Biosafety Framework (NBF)

2.1. Biosafety Policy

A policy is recognized as a document that conveniently packages a public will or mandate regarding certain identified issues. It enables clear ideas to be developed or formulated about what actions are required to address an identified problem. A Biosafety policy could stand-alone be a part of a more general policy or a combination of policies, e.g., on biodiversity conservation, environmental protection, science and technology and sustainable development. The concern revolving around GMOs and products thereof entails the possible presence of adverse side effects, and biosafety controls are, therefore, necessary to anticipate such possible negative impacts.

2.1.1. National Biosafety Policy for Ethiopia

Currently there is no stand-alone biosafety policy for Ethiopia. However, based on the definition given to the term 'policy' we could say there are indeed policies which address the major issues of a biosafety policy. The 1994 Constitution of the Federal Democratic Republic of Ethiopia provides for general directions and actions relevant to address the problems identified in relation to biosafety. The Environmental Policy of Ethiopia, which emanated from the Conservation Strategy, addresses biosafety concerns. This policy was prepared by the Environmental Protection Authority in collaboration with the Ministry of Economic Development and Cooperation in April 1997. It was then approved by the Council

of Ministers. In addition, the National Science and Technology Policy of Ethiopia provides guidance for the development of science and technology in Ethiopia. The National Biotechnology Policy, the National Biodiversity Conservation and Research Policy and the Agricultural Research Policy are also relevant documents which incorporate elements that can contribute to the biosafety policy of the country. All these policies are necessary to control the importation and export of biotechnology products and to make use of the technology in a safe and responsible way.

A) The Constitution of the Federal Democratic Republic of Ethiopia

The Constitution of the Federal Democratic Republic of Ethiopia provides the overriding principles and legal provisions for the legislative frameworks in the country. The concepts of sustainable development and environmental protection are enshrined in the following articles of the Constitution that stipulate the rights of peoples in Ethiopia.

Article 43: The Right to Development: - states that the Peoples of Ethiopia as a whole have the right to improved living standards and to sustainable development. It also guarantees the right of Ethiopian nationals to participate in national development and be consulted with respect to policies and projects that affect their community.

Article 44: Environmental Rights: - provides all persons the right to live in a clean and healthy environment. This provision also ensures the right to commensurate monetary or alternative means of compensation, including relocation with adequate state assistance, to all persons who have been displaced or whose livelihoods have been adversely affected as a result of state programs.

Article 92: Environmental Objectives: puts an obligation on citizens and the Government to protect the environment. It requires that all design and implementation of programs and projects of development made by the Ethiopian Government be environment friendly. In line with Article 43, this provision gives citizens the right to full consultation and to the expression of their views in the planning and implementation of environmental policies and projects that affect them directly.

These constitutional provisions have served as guiding principles for all activities that are related to policy formulation, strategy development and legislative and institutional frameworks for environmental protection as well as sustainable development of the country.

B) The National Science and Technology Policy

The National Science and Technology Policy, issued in 1994, provide direction for the growth and enhancement of science and technology and its utilization in Ethiopia's development. The policy document comprises of policy objectives and strategies to be followed, and the priority sectors and programs to be undertaken. Environment and biodiversity are among the sectors and programs that are given priority by the policy.

The main objectives of the policy are to build national capability to generate, select, import, develop, disseminate and apply appropriate technologies for the realization of the country's socio-economic objectives and to rationally conserve and utilize its natural and manpower resources, to improve and develop the knowledge, culture and the scientific and technological awareness of the peoples and to make Science and Technology activities more productive, efficient and development oriented. Its major elements focus, among other issues, on

collection, conservation, sustainable use of the country's biodiversity and on the promotion of research and publication.

C) The National Biodiversity Conservation and Research Policy

The National Biodiversity Conservation and Research Policy was approved in April 1998 by the Council of Ministers. The policy focuses on the conservation, development and sustainable utilization of the country's biodiversity. The overall objective of this policy is to ensure the effective conservation, rational development and sustainable utilization of the country's biodiversity. It also ensures that the country's plant, animal and microbial genetic resources and ecosystems as a whole are conserved, developed, managed and sustainably utilized. In addition, the policy calls for a legal recognition, fostering and augmenting of the indigenous knowledge and methods relevant to the conservation, development and sustainable use of biodiversity and the promotion and use of new and emerging technologies such as biotechnology.

D) Agricultural Research Policy

The overall objective of the agricultural research policy is to give a clear direction and guidance for agricultural research and the application of research results for the development of agricultural science and technology.

The specific objectives are:-

- To choose and generate agricultural technologies that will improve the productivity of the agricultural sector and that would enable the country to be self-sufficient in food production.
- To build capacity, direct and coordinate agricultural research programs so as to solve the major problems and sustainably raise agricultural production and protect the environment.

- To to disseminate research results to users thereby contribute to the national economy.

Among the various strategies of the policy, those that need mentioning in the context of biosafety include:-

- In the effort to raise the productivity of the agricultural sector and to be self-sufficient in food production, agricultural research shall focus on generating and choosing technologies that will improve the productivity of the peasant sector, which constitutes the major part of agricultural production.
- The country's natural resources are dwindling with time. Research will be conducted to choose and generate technologies which will conserve, protect and sustainably use the country's agricultural and natural resources.
- To resolve urgent problems of the economic sector within a short period of time, agricultural research activities shall focus mainly on applied research and on programs that will bring change within a short period of time. However, research on basic, strategic and new and emerging technologies, e.g. biotechnology, will also be undertaken as deemed necessary.

E) Plan for Accelerated and Sustained Development to End Poverty (PASDEP)

Ethiopia is, with a view to reversing the rampant problem of environmental degradation and poverty, currently engaged in the massive task of developing a ten-year development programme. The document outlining the effort is what is known as a Plan for Accelerated and Sustainable Development to End Poverty (PASDEP).

Ethiopia's strategy for the next five years therefore consists of the following **eight pillars**:

- Building an all-inclusive implementation capacity;

- A massive push to accelerate growth;
- Creating the balance between economic development and population growth;
- Unleashing the potentials of Ethiopia's women;
- Strengthening the infrastructure of the country;
- Strengthening human resource development;
- Managing risk and volatility; and,
- Creating employment opportunities.

Environmental management is a core subject treated in the document. The Vision of the country is stated in the document as:

"Our vision is a self-reliant Ethiopian population with a high quality of life in a productive environment, which assures equity between genders and among generations."

This Environmentally Sound Development Vision of Ethiopia can be achieved by ensuring social, economic and environmental sustainability in development. The Strategic goals set for the realization of this vision are:

GOAL A: Ensure community-led environmental protection and the sustainable use of environmental resources for gender equity and improved livelihood;

GOAL B: Rehabilitate affected ecosystems;

GOAL C: Enhance capacity of ecosystems to deliver goods and services, particularly biomass for food, feed and household energy;

GOAL D: Remove the adverse impacts of municipal waste;

GOAL E: Prevent Environmental pollution;

GOAL F: Ensure proactively the integration of environmental and ethical dictates especially mainstreaming gender equity in development.

F) The Environmental Policy of Ethiopia

1. The Policy Goal, Objectives and Guiding principles

1.1. Overall Policy Goal

The overall policy goal is to improve and enhance the health and quality of life of all Ethiopians and to promote sustainable social and economic development through sound management and use of natural, human-made and cultural resources and the environment as a whole so as to meet the needs of the present generation without compromising the ability of future generations to meet their own needs.

1.2. Specific Policy Objectives

The Policy, among other things, seeks to ensure that essential ecological processes and life support systems are sustained, biological diversity is preserved and renewable natural resources are used in such a way that their regenerative and productive capabilities are maintained and where possible enhanced so that the satisfaction of the needs of future generations is not compromised. The policy is also designed to identify and develop natural resources that are currently underutilized by finding new technologies, and/or intensifying existing uses which are not widely applied. With regard to public awareness and participation, the environmental policy of Ethiopia aims to ensures the empowerment and participation of the people and their organizations at all levels in environmental management activities and to raise public awareness and promote understanding of the essential linkages between environment and development.

1.3. Key Guiding Principles

Establishing and clearly defining these guiding principles is seen by the Environmental Policy as very important as they will shape all subsequent policy, strategy and program formulation and their implementation. Sectoral and cross-sectoral policy provisions and environmental elements of other macro policies are seen as requiring to be checked against these principles to ensure consistency.

The Key Guiding Principles of the Environmental Policy that are related to biosafety are:

a) Every person has the right to live in a healthy environment;
b) The development, use and management of renewable resources shall be based on sustainability;
c) Appropriate and affordable technologies which use renewable and non-renewable resources efficiently shall be adopted, adapted, developed and disseminated;
d) Full environmental and social cost (or benefits forgone or lost) that may result through damage to resources or the environment as a result of degradation or pollution shall be incorporated into public and private sector planning and accounting, and decisions shall be based on minimizing and covering these costs;
e) Local, regional and international environmental interdependence shall be recognized;
f) Species and their varieties have the right to continue existing, and are, or may be, useful now and/or for generations to come.

I. Sectoral Environmental Policies

The sectoral environmental policy provisions that are of relevance to Biosafety are the following:

i) Genetic, Species and Ecosystem Biodiversity

The policy provisions for the conservation of the ecosystem biodiversity are designed to

promote *in-situ* systems (i.e. conservation in a natural reserve, farmer's fields etc) as the primary target for conserving both wild and domesticated biological diversity, and *ex-situ* systems (i.e. conservation outside the original or natural habitat in gene banks, farms, botanical gardens, ranches and zoos) as supplementary to *in-situ* conservation. They also aim to ensure that the

importation, exportation and exchange of genetic resources is subject to legislation for or ensuring the safe guarding of community and national interests, the fulfillment of international obligations, quarantine etc. *(See Annex I)*

ii) Soil Husbandry and Sustainable Agriculture

These policy provisions target to base, where possible, increased agricultural production on sustainably improving and intensifying existing farming systems by developing and disseminating technologies which are biologically stable, appropriate under the prevailing environmental and socio-cultural conditions for farmers, economically viable and environmentally beneficial. They also aim to put a mechanism to safeguard human and environmental health by producing adequate regulation of agricultural (crop and livestock) chemicals. The policy provisions are based on use the precautionary principle for assessing potentially damaging impacts when taking decisions that affect social and economic conditions, natural resources and the environment, especially in the pastoral areas, which are perhaps the least studied in the country. *(See Annex I)*

iii) Forest, Woodland and Tree Resources

The policy provisions for forest resources conservation aim to ensure that forestry development strategies integrate the development, management and conservation of forest resources with those of land and water resources, energy resources, ecosystems and genetic resources, as well as with crop and livestock production. Moreover, they aim to promote changes in agricultural and natural resource management systems which will limit the need for free range grazing of animals. *(See Annex I)*

iv) Urban Environment and Environmental Health

The policy provisions for the urban environment address the integration of human-produced and natural elements in the development and management of urban areas in order to maintain the natural ecosystems. They ensure that improved

environmental sanitation is placed highest on the federal and regional agendas for achieving sustainable urban development. *(See Annex I)*

v) Control of Hazardous Material and Pollution from Industrial Waste

The policy provisions adhere to the *precautionary principle* so as to minimize and where possible prevent discharges of substances, biological materials or their fragments from industrial plants and personal or communal appliances or any other external sources that could be harmful and aim to disallow discharge when it is likely to be hazardous. They also create by law an effective system of control, distribution, utilization and disposal after use or expiry of chemicals, biological organisms or fragments of organisms that could be hazardous but are required for use. In addition, these policy provisions prohibit from importation to and from transit through Ethiopia hazardous materials, organisms of fragments of organisms as agreed by African states under the Bamako Convention. *(See Annex I)*

II. Cross- Sectorial Environmental Policies

i) Community Participation and the Environment

The policy provisions in this regard are to develop effective methods of popular participation in the planning and implementation of environmental and resource use and management projects and programs, to develop the necessary legislation, training and financial support to empower local communities so that they may acquire the ability to prevent the manipulated imposition of external decisions in the name of participation, and to ensure genuine grassroots decisions in resources and environmental management. They also aim to ensure information flow among all levels of organization including the federal and regional states and the people at the grassroots level. *(See Annex I)*

ii) Environmental Research

Under environmental research, the policies adopted are to develop strategic environmental research which aims at identifying the social, economic and technical factors which influence resource management. Funds are to be allocated to support such kinds of programs and projects. The policy provisions aim to support research on appropriate technologies for environmental management and sustainable development through partnership between scientists and potential end users. They also aim to co-opt traditional systems of research and learning into a new system which incorporates both modern and traditional components. *(See Annex I)*

iii) Environmental Impact Assessment (EIA)

The policy provisions on EIA aim to ensure that environmental impact assessments consider not only physical and biological impacts but also addresses social, socio-economic, political and cultural conditions. They aim to ascertain that public and private sector development programs and projects predict any likely negative environmental impacts and incorporate their containment into the development design process. In addition, they aim to ensure that an environmental impact statement always includes mitigation plans for environmental management problems and contingency plans in case of accidents. Environmental audits for monitoring, inspection and record keeping should take place at specified intervals during project implementation. *(See Annex I)*

iv) Environmental Education and Awareness

The policy provisions aim in this regard are considered crucial for the proper implementation of the other policies. The policies related to biosafety are designed to target the public, particularly those involved in public and private sector activities that have significant environmental impacts, for environmental education and awareness programs. These polices recognize the important role that the mass media play and to effectively use them in creating and promoting

environmental awareness in view of the physical problems of access and communications in Ethiopia. *(See Annex I)*

Policy Implementation

i) Institutional Framework, Responsibilities and Mandates

The policies in this respect are adopted to determine institutional arrangements for the formulation of conservation and natural resource development and management strategies, legislation, regulation, monitoring and enforcement using the criteria under the policy document annexed. *(Annex I)* The intention is to avoid conflicts of interest by assigning responsibilities to separate organizations for environmental and natural resource development and management activities on the one hand, and environmental protection, regulation and monitoring on the other.

ii) Monitoring, Evaluation and Policy Review

The policy provisions aim to ensure that the monitoring of the overall impacts of the implementation of the Environmental Policy of the country is consistent with the institutional arrangement specified under the Conservation Strategy of Ethiopia is responsive to popular opinion. They oblige the Environmental Protection Authority to carry out the overall monitoring of the Policy implementation and be responsible for proposing modifications, in consultation with the mandated line ministries and/or the opinion of stakeholder communities and groups, and to have them approved by the Government. Each line ministry and regional and lower level bureau is also required to monitor the overall impact of the implementation of the Environmental Policy on those sectors and elements for which it has the legal mandate. *(Annex I)*

G) Environmental Policy and Conservation Strategy

The primary need in preparing a national policy and strategy document on environmental matters was for at determining the objectives and strategies which

should be used in order to ensure the respect for environmental values, by taking into account the prevailing economic, social and cultural situations of the country. In this context, with a view to further amplifying the Constitutional provisions on environmental protection, the Environmental Policy and the Conservation Strategy of Ethiopia have been prepared. These policy and strategy documents recognized and addressed environmental issues in a holistic manner.

The primary concerns of biosafety strategy plan are creating a coordinated and integrated approach and a participatory decision making culture among resource users, and implementing the ideals of the biosafety policy elements. The objective of biosafety planning, as further amplified by the Conservation Strategy of Ethiopia, is to materialize the security of tenure on land and the natural resources thereof by supporting sustainable:

- agricultural development;
- pastoral development;
- forestry , fisheries production; and
- urban environment.

Ethiopia, as a center of biodiversity, gives due attention to biosafety concerns. It has ratified the Convention on Biological Diversity (CBD) through Proclamation No. 98/1994. It became a signatory of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity on May 24, 2000 and ratified it on September 22, 2003 through Proclamation No. 362/2003.

As can be observed from the regulatory regime of Ethiopia, the major focus is the precautionary principle, in order to benefit from the technology by avoiding or mitigating the potential risks that may emanate from modern biotechnology. The country’s priorities are to develop a national framework that will assist Ethiopia in complying with its international obligations under the Cartagena Protocol on

Biosafety and also ensure safety together with sound environmental management and sustainable use of modern biotechnology.

2.2. Regulatory Regime

Genetic engineering is a very new field for Ethiopia. Therefore, biosafety should be a major concern in order to avoid or reduce the possible adverse impacts of GMOs on the conservation and sustainable use of biological diversity, human health as well as the socio-economic condition of Ethiopians. Putting a National Biosafety Law in place is mandatory not only for nationally implementing the Cartagena Protocol and thus for ensuring national safety from negative impacts of imported GMOs but also because the laws of neighboring countries could affect national safety since, once released, GMOs, could simply cross boundaries.

Before the commencement of the Biosafety Project, there was no specific biosafety law or enactment that regulates the transboundary movement of GMOs. Therefore, the need for the drafting of a new law which strictly governs the movement of GMOs and products thereof arises. In line with this, currently a biosafety regulatory regime has been developed in Ethiopia to regulate the transboundary movement of GMOs to avert their possible risks on biodiversity, human health and the environment in general.

The major regulatory regime for biosafety in Ethiopia comprises of the Draft Biosafety Proclamation and its six (6) directives.

2.2.1. Biosafety Proclamation

(i) Status: Draft

(ii) Scope: The draft biosafety proclamation regulates transactions including the import, export, transit, contained use, release, handling, transport or placing on the market of any GMO or its products whether intended for release into the environment, for use as a pharmaceutical, for food, feed or processing.

(iii) Brief summary of the draft biosafety proclamation

The objective of this draft proclamation is to protect human health, biological diversity and the environment by preventing or managing the adverse effects of new organisms developed through modern biotechnology *(Article 4)*. Its major foundation emanates from the *precautionary principle* in that it states the need for precaution if there is scientific uncertainty about the risk emanating from a GMO or its products *(Article 5)*. This precaution is taken when authorized persons take due care and reasonable measures to ensure that all transactions regarding GMOs and products thereof are carried out in conformity with the provisions of this law.

The initial step that should be taken in relation to any transaction of GMOs or products thereof is obtaining an advance informed agreement (AIA) of the Environmental Protection Authority (EPA) *(Article 8)*. For the purposes of the Draft Biosafety Proclamation, the Federal Environmental Protection Authority (EPA) is referred as “Authority” which has the sole responsibility for authorizing any transactions relating to any GMO or products thereof. The AIA as per this law is an explicit written consent granted by the Authority based upon full disclosure of all relevant information regarding the GMO or its products by the applicant seeking authorization to be engaged in any transaction relating to that GMO or any product thereof. Authorization on any transaction relating to GMO or products thereof is given only when the conditions for application are fulfilled as per the provision of the law.

Risk assessment report forms the basis for the AIA and the authorization of any transaction of a GMO or its product by the Authority. Expert opinions as well as public comments are also to be solicited regarding the risk assessment report and decision is made accordingly. Authorization is given only when it is duly determined by the Authority that the transaction relating to the GMO or product thereof will benefit the country without causing significant risk to human health,

biodiversity or the environment *(Article 8).* The adverse impacts on socio-economic considerations are also assessed during decision making.

Any GMO or product thereof in storage or transport shall be clearly identified, packed and labeled in both English and Amharic specifying the scientific name, the common name if available, the unique identifier and the transformation event and relevant traits and characteristics given in sufficient detail for purposes of traceability in accordance with the directives issued by the Authority. *(Article 23)*

Any authorization given may be revoked or subjected to conditions in addition to those originally imposed, if in the opinion of the Authority, new information obtained or a review of existing information about the GMO or product thereof indicates any unacceptable risk.

In addition to EPA, Licensing Agencies are other responsible institutions in the implementation of this law. These are organs of government empowered by law to issue an investment or trade permit or an operating license or work permit for any kind of activity or to register a business organization. Licensing Agencies prior to issuing any type of license to an applicant to be engaged in any transaction relating to a GMO or its product are required to ensure that the Authority has granted it authorization to do so *(Article 20)*. These agencies should also cancel or suspend licenses following the final decision of the Authority to that effect.

2.2.2. A Directive to determine the contents of an application on transactions involving genetically modified organisms (GMOs) and products thereof

(i) Status: Draft

(ii) Scope: The directive is issued to determine the information required for application to authorize the release of a GMO or its products to the environment, including use in a closed system (contained use), import for food, feed or processing, and as a pharmaceutical.

(iii) Brief summary of the directive: Any application on GMO related transactions is required to include:

- General information
- Information related to the genetically modified organism (GMO) or products thereof
- Information relating to the conditions of release and the receiving environment
- Information relating to the interactions between the GMO(s) or products thereof and the environment
- Information on monitoring, control, waste treatment and emergency response plans and
- Other additional information required in the case of notification for placing a commodity consisting of GMOs or products thereof on the market

2.2.3. A Directive on risk assessment parameters of genetically modified organisms (GMOs) or their products

(i) Status: Draft

(ii) Scope: This Directive is issued to determine risk assessment parameters of GMO or their product. The user of the GMO or its products shall carry out an assessment prior to the use or release of the GMOs or products thereof as regards the risks to human or animal health, biological diversity, the environment or to the socio-economic and cultural wellbeing of local communities and the country.

(iii) Brief summary of the directive: The risk assessment, in addition to those stated under the draft biosafety proclamation, should take the following parameters into consideration.

- Characteristics of donor and recipient organisms
- Characteristics of the constructs used vector(s), promoter(s), terminator(s), marker gene(s)
- Characteristics of genetically modified organism (GMO)

- Characteristics of resuscitated organism(s) or gene(s) from fossil DNA sequences or synthesized DNA sequences incorporated in the GMO
- Characteristics of any Nano-particle incorporated on its won or as a part of a DNA or RNA sequence
- Safety considerations for human and animal health
- Environmental considerations
- Socio-economic considerations

2.2.4. A Directive for Risk Management Schemes

(i) Status: Draft

(ii) Scope: The Directive is issued to determine the procedures for risk management strategy development to protect human health, biological diversity and in general the environment from accidents in the use of GMOs and their products.

(iii) Brief summary of the directive: The directive puts an obligation on the user of the GMO or product thereof to employ risk management schemes and procedures from the development, through all stages of testing of the GMO or its product to its intended use or commercialization. It requires the release of a GMO or its product to be monitored appropriately and requires an emergency plan in cases of accidental release to be put in place. The directive governs:-

- Imported products of GMOs used for human or animal health
- Genetically modified microbial organisms imported for human or animal health
- GMOs imported for contained use
- Products of a locally produced GMO
- GMOs made locally for use as human or animal vaccines
- Genetically modified plant, microbial or animal organisms imported for release

- Genetically modified plant, microbial or animal organism produced locally for eventual release

2.2.5. A Directive on application for the transport of genetically modified organisms (GMOs) or products thereof by road

(i) Status: Draft

(ii) Scope: The Directive is issued to determine the procedures for the transport of GMOs or products thereof by road.

(iii) Brief summary of the directive: This directive requires a driver who is engaged in the transport of GMOs or products thereof to be licensed and certified in accordance with the procedures and requirements to be established by the concerned licensing agency and approved by the Federal Environmental Protection Authority (EPA). Any person who wishes to transport any GMO shall apply in writing to the competent authority responsible for transport as well as to EPA. When licensing or registering drivers, the competent authority for transport may require the driver to carry adequate insurance to cover any harm to human health or the environment that may result from an accidental release of any GMO or products thereof, that are being transported by road. However, when the authority believes that a GMO or products thereof cannot cause any risk to human or animal health or the environment, it may exempt any GMO or products thereof, from these procedural requirements on transportation.

2.2.6. A Directive for the storage of genetically modified organisms (GMOs) or products thereof

(i) Status: Draft

(ii) Scope: The directive is issued to determine procedures for the storage of GMOs or products thereof.

(iii) Brief summary of the directive: Any premise or facility in order to store or process a GMO or its products should be registered and licensed by EPA in consultation with the agency responsible for health and labor

affairs. The person in charge of any premise that is to be used for the storage or processing of any GMO or products thereof shall apply in writing to EPA for permission to use such a premise for such a purpose. EPA, after its receipt of the application, shall inspect the premise to determine if

b) adequate facilities exist for the safe storage or processing of the specified GMO or products thereof,
c) adequate security, segregation and safety measures exists at the premise and
d) employee training in the management of GMOs and products thereof has been undertaken.

Upon completion of the inspection, EPA may refuse permission for the storage or processing of a GMO or its product or issue permit with condition or without condition or may require additional information. After issuing a permit, EPA should lodge the copy of the permit with the National Biosafety Clearing-House. In undertaking the licensing and registration of premises, EPA shall require such premises to carry adequate insurance to cover any foreseeable liability for harm to human health or the environment.

The Authority may for just cause, at any time, cancel the permit that has been issued if any requirement or condition contained in a permit is not strictly compiled with, or order the immediate cessation of the storage or processing of the GMO or products thereof as may be considered appropriate. Notwithstanding the provisions of this directive, the Ministries of Labor and Health may carry out inspections of premises to ensure compliance with any permit, standard and procedures established in this directive and for this purpose are empowered to execute spot checks to ensure compliance with any of such requirements.

2.2.7. A Directive for Emergency Measures for accidental release of genetically modified organisms (GMOs) and products thereof

(i) Status: Draft

(ii) Scope: This directive is issued to determine response to accidental release of GMOs and products thereof.

(iii) Brief summary of the directive: An Accidental Release Control Group, which comprises representatives from relevant institutions capable of undertaking risk management measures, is to be established by EPA in order to be ready to give direct response to any accidental release of GMOs or products thereof. This group has to develop appropriate systems for the detection and reporting of accidental releases or of incidents related to the transport and use of GMOs or products thereof which could result in such accident. It should also ensure that prompt response is made in the event of an accidental release of any GMO or product thereof to prevent damage to biodiversity, the environment or human health. The Accidental Release Control Group shall be the sole authority responsible for response to any accident, and shall direct the activities of agencies or parties that may offer assistance in the event of an accident.

3. System to Handle Notifications or Requests for Authorization

As per the draft biosafety law, requests for authorizations regarding any import, export, transit, contained use, release, handling, transport or placing on the market of any GMO or its products whether intended for release into the environment, for use as a pharmaceutical, for food, feed or processing are made via a written application to the Authority. The applicant is required to undertake risk assessment to identify any significant risks, specify the means of the prevention or containment of those risks and submit the Authority the risk assessment report together with any other documents determined necessary. Upon receipt of the risk assessment report, the Authority shall disseminate it to

experts as well as avail it to the public through appropriate means of communication and solicit comments on it. The risk assessment report is to be evaluated on a case-by-case basis. The Authority shall make decision on approval or rejection of the report within 15 days after receipt of the experts' opinion and public comments. It shall ensure that the comments made by the public, and in particular by the communities likely to be affected by the transaction, are considered in taking its decision. A copy of the final decision shall be lodged with the National Biosafety-Clearing House.

Licensing Agencies, based on the mandates empowered to them by law, shall, prior to issuing any type of license to any applicant to be engaged in any transaction relating to GMO or its products, ensure that the Authority has granted the applicant an authorization to do so.

Procedural Chart

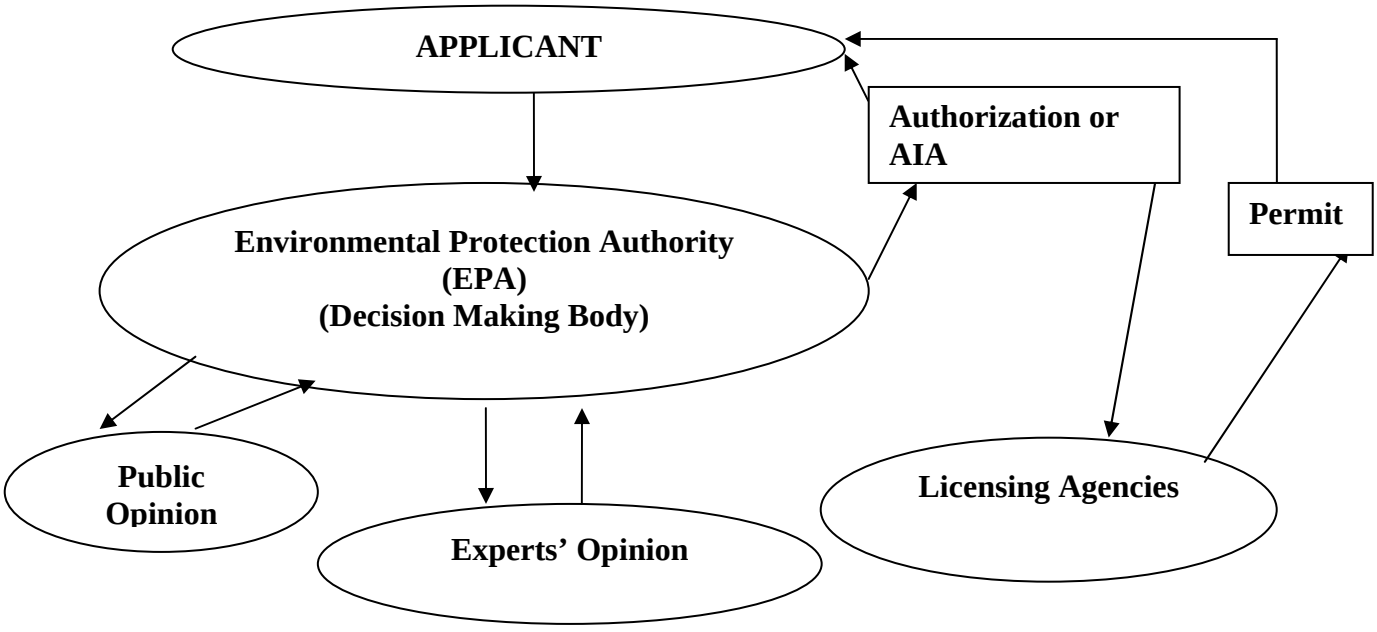

Fig. 1. System for Handling Application for Authorization

Future Plans

Key elements in national biosafety legislation, which would plug the gaps in the Protocol, would include requiring approvals/authorizations for all activities relating to all GMOs and their derived products on a case by case basis. Authorizations should also be required for every stage of GMO development---from research in contained condition to field trials and to full scale deliberate releases. In all cases risk assessment should include a cost-benefit or socio-economic analysis with a view to determining the need for GMOs and if there are alternative but appropriate technologies. The Authority should, based on the precautionary principle, assess the risk assessment report submitted to it and grant or refute authorization to the proponent to be engaged in GMO related activities. The final decision will be posted on the National Biosafety Clearing-House. The National BCH will contain all applications, roaster of experts, list of GMOs that have been approved and rejected for import or export, applicable laws, directives, guidelines concerning the handling, transport, use, transfer and release of GMO and products thereof and the Authority's final decisions. This is to ensure transparency and public participation in decision making.

Biosafety cannot be assured without the necessary scientific and technical capacity to monitor developments, adapt and adopt the useful ones, and pre-empt the harmful ones among them and chart new developments seen as necessary by considering national interests. The risk assessment requirements, AIA procedure and a clearing-house mechanism will only be effective if regulatory agencies are able to benefit from such arrangements and facilities. In this context, EPA should promote international cooperation to build the human resources and institutional capacity that help use biotechnology safely and regulate it efficiently. The support sought will include but not be limited to training, transfer of technology, know-how and financial resources.

4. Monitoring and Enforcement

4.1. Monitoring

Monitoring is to be carried out by the applicant and is part of the application for the authorization of GMO related activities as clearly stipulated under the Ethiopian biosafety law. As stated above, any person who wishes to carry out any transaction in relation with GMO or products thereof should submit an application in writing to the Authority. The application, among other things, should include a clear and sequential description of the steps to be taken during implementation of the project which uses the GMO or its products and the monitoring and evaluation that will be made at the end of each step, and the method of disposing of any waste (Art. 10(g) of the Proclamation. Furthermore, the risk assessment report should incorporate the consequences of unintentional (accidental) release of GMO or its products and emergency response plans to address it. The applicant is required to develop, maintain and implement a risk management strategy to protect human or animal health and the environment in general from risks that might arise from the authorized transaction.

Moreover, after an authorization is granted, the authorized person should maintain a register to record the type, quantity, country of origin and transaction of any GMO or its products and other information required by EPA (Art. 19(2) of the Proclamation. He/she is also required to submit to the EPA, every three months, a written report regarding the transactions involving any GMO or product thereof that is under his/her custody.

4.2. Enforcement

Enforcement for compliance with the regulatory regime is undertaken by the Authority (EPA). According to the biosafety law, the Authority will appoint inspectors and provide them with signed identity cards to exercise the monitoring functions referred to under the Proclamation. An inspector has the power to enter

any place or facility without any need for prior notice or court order which he or she has reason to believe that contraventions any of the provisions of the law are taking place and can take any corrective measures on any GMO transaction carried out in that place or facility. If upon inspection the transaction is determined to be in contradiction with the law or with any of the directives issued by the Authority, the Authority may order that the GMO or its product be re-exported or destroyed. Furthermore, inspectors are empowered to take, free of charge, samples of any GMO or its products as required and carry out or cause to be carried out tests or examinations to determine whether or not it poses any risk of harm to human or animal health, biodiversity or the environment at large(Art. 21 of the Proclamation).

Furthermore, any GMO or its products is destined to be under constant review by the Authority even when it has issued authorization. Whenever any GMO or product thereof is suspected of posing serious risk to human health, biodiversity or the environment, it will be banned from the territories of Ethiopia. The Authority may require any GMO or product thereof to undergo a period of observation commensurate with its life-cycle or generation time, at the cost of the applicant, before and after it is put to its intended use (Art. 22(4) (a) of the Proclamation).

The Authority may also withdraw the authorization or order the cessation of any transaction relating to the GMO or its product in the case of imminent and serious danger to human or animal health, biodiversity, the environment or socio-economic conditions and when the transaction has been undertaken in violation of any of the provisions of the draft biosafety Proclamation. In this case, the Authority may require the person responsible for the transaction to take measures as may be necessary to prevent or limit the harm or to restore the environment to its previous state. Following the final decision of the Authority to do so, licensing agencies have the power to suspend or cancel licenses that they have already granted using the powers vested upon them by law (Art. 20(2) of the Proclamation).

In cases of occurrence of serious and imminent danger to human health, biological diversity, the environment, socio-economic conditions or cultural norms of local communities or the economic condition of the country caused by any GMO or products thereof, the Authority may take measures as necessary to avert the danger at the cost of the person responsible for causing such danger.

Inspections at ports of entry on GMOs are also conducted to ensure compliance with the regulatory regime. Any person in possession of any GMO or its products is obliged to declare such a possession to the Customs Officer on duty at the port of entry or exit upon arrival or departure. If a Customs Officer suspects that any person is in possession of a GMO or product thereof for which there is no valid authorization, the officer may require the said person to surrender the organism or its product which will immediately be sent to the Authority. The Authority may then dispose of the seized organism or its product. The Authority may charge the attendant costs of disposal, housing or re-export to the owner or the person who had possession of the GMO or its product. However, if the organism surrendered to Customs Officer or inspector is determined by the Authority not to be a GMO or product thereof, it will be returned to the person who surrendered the specimen except for that part of it which might have been used up during any investigation (Art. 27 of the Proclamation).

Further, a person who is engaged in any transaction relating to the GMO or its product shall be strictly liable for any harm caused. Liability also extends to the provider, supplier or developer of the GMO or its product that has caused harm to human health, biodiversity or the environment. Thus liability is joint and several and should be fully compensated (Art. 29 of the Proclamation).

4.3. Future plans for monitoring and enforcement systems

The duty to prevent harm implies the application of measures to avoid harm and reduce or eliminate risks of harm. In this context the undertaking of monitoring

based on the collection of reliable information, continuous assessment and comparing it with approved parameters are crucial. The prime purpose of monitoring should be to help the implementation of the substantive provisions of the Proclamation by assisting and working together with communities, non-state actors and any interested individuals. For this to happen, there should be commitment to promote awareness, access to information and consultation in decision making. Enforcement actions should be designed to respond to non-compliance. The inspectors should get all the required trainings which will empower them to conduct the inspection in a scientifically sound manner.

5. Mechanisms for promoting and facilitating public awareness, education and participation

Public awareness and participation is to be facilitated by the Authority. The Authority as per the law would ensure that the public is made well aware by allowing reasonable time for public interaction. Upon receipt of an application for any transaction of a GMO or products thereof, the Authority should make it accessible to the public and relevant government agencies and solicit comments on it. The Authority shall also ensure that the comments made by the public and in particular by the communities likely to be affected by the transaction are incorporated in taking or reviewing decision (Art. 24 of the Proclamation). The final decision, either granting or denying of approval should also be made available to the public. The National Biosafety Clearing- House will serve as a public awareness instrument in that all information regarding GMOs and products thereof in Ethiopia will be posted there, including decisions given on every application for transaction.

The current policies on community participation and the environment are to ensure that all phases of environmental and resource development and management, from project conception through planning and implementation to monitoring and evaluation are undertaken taking into account the views of the resource users and managers. Environmental education and awareness policies

are to be designed to promote the teaching of environmental education on a multi-disciplinary basis and to integrate it into the ongoing curricula of schools and colleges. The policies in this regard also aim to target the public, particularly those of it that are involved in public and private sector activities that have significant environmental impacts. Existing policies provide for the formulation of environmental awareness programmes in such a way as to address specific environmental problems of particular localities in view of the extreme variability of environmental conditions and problems in Ethiopia

5.1. Future plans for systems for public awareness, education and participation

Participatory process in the formulation and implementation of a biosafety regulatory infrastructure is particularly important in achieving compliance and enhancing the legitimacy of the norms to be adopted. In line with this, the National Biosafety Clearing-House is to be developed by the Authority in order to facilitate the exchange of scientific, technical, environmental as well as legal information on GMOs and products thereof. As per the biosafety law, all information and documents in relation to biosafety and biotechnology in Ethiopia will be posted on the National BCH. This is to ensure the participation of the public in decision making process. Public awareness materials have also been prepared and there is also a plan to create more public education programs. Though the resources to conduct the programs throughout the country are going to be inadequate, the capacity has to be rectified through a biosafety capacity building program.

The mass media are recognized to play an important role and effective use in creating and promoting environmental awareness in view of the physical problems of access and communication in Ethiopia. Likewise, existing higher level training and education institutions would be strengthened so that they can offer programmes and courses in sustainable resource and environmental management for economists, planners, lawyers, engineers, sociologists and medical practitioners as well as for

natural resource and environmental scientists. Local development of environmental awareness associations would also be encouraged and the involvement of local community and religious leaders in programmes to promote environmental awareness will be supported.

5.2. The National Biosafety Database

Through the support of the UNEP/GEF National Biosafety Framework (NBF) Development project, Ethiopia is in the process of developing a National Biosafety Clearing-House to make accessible all the relevant information regarding modern biotechnology, biosafety and all transactions relating to GMO and products thereof. All relevant legislations will also be placed on the BCH. The Federal Environmental Protection Authority as a focal point to the NBF project has signed a Memorandum of Understanding (MoU) with UNEP to take part in the project, “Building Capacity for Effective Participation in the Biosafety Clearing-House (BCH)”. As per the MoU agreed upon, EPA has already established a National BCH Task Force with members drawn from key stakeholder institutions to assist in the implementation of the project at the national level. This task force meets once every month. EPA has also conducted a National Inception and launch workshop on the BCH project.

Future Plan for establishment of BCH

EPA, as a National Executing Agency to the BCH project will be the chair of the Task Force and decision will be make by the task force based on a consensus and according to the Rules of Procedures to be drawn by the first meeting of the Task Force members. Competent National Authorities will provide information to EPA, which after validation by the designated focal person, will transmit the respective information to the BCH Central Portal. EPA will be responsible for communicating information to the BCH Central Portal as well as to Competent National Authorities. This entails information on decisions on GMOs, new Competent Authorities, new national laws and regulations, etc.

Under this project, EPA has planned to conduct Training Workshops for the BCH Task Force on the BCH system and its management. This is to help the BCH Task Force to understand how to access and use it. It is also to train the Task Force on identification of and access to required information for national decision making, in-depth application of case studies for BCH Central Portal usage capacity building. Finally there will be a review and demonstration of the implantation status of the BCH to crate awareness and promote public participation.

ANNEXES

Annex I - Environmental Policy of Ethiopia

I. SECTORAL ENVIRONMENTAL POLICIES

1. Soil Husbandries and Sustainable Agriculture

The Policies are:

a. To foster a feeling of assured, uninterrupted and continuing access to the same land and natural resources on the part of farmers and pastoralists so as to remove the existing artificial constraints to the widespread adoption of, and investment in, sustainable land management technologies;

b. To base, where possible, increased agricultural production on sustainably improving and intensifying existing farming systems by developing and disseminating technologies which are biologically stable, appropriate under the prevailing environmental and socio-cultural conditions for farmers, economically viable and environmentally beneficial;

c. To promote the use of appropriate organic matter and nutrient management for improving soil structure, nutrient status and microbiology in improving soil conservation and land husbandry;

d. To safeguard the integrity of the soil and to protect its physical and biological properties, through management practices for the production of crops and livestock which pay particular attention to the proper balance in amounts of chemical and organic fertilizers, including green manures, farm yard manures and compost;

e. To promote effective ground cover as one of the most important factors in soil erosion control, taking advantage of the wide range of sustainable agronomic, pastoral and silvicultural approaches used in various areas of Ethiopia as potentially flexible alternatives to mechanical soil conservation systems;

f. To promote in drought-prone and low rainfall areas water conservation which is as important as physical soil conservation for more secure and increased biomass production, including crop production?

g. To ensure that, for reasons of cost and acceptability, improvements in land husbandry are made with an appreciation of existing husbandry systems, technologies and knowledge;

h. To ensure that, given the heterogeneous environment of the Ethiopian highlands, agricultural research and extension have a stronger focus on farming and land use systems and support an immediate strengthening of effective traditional land management systems;

i. To promote, for the relatively more environmentally uniform Ethiopian lowlands, a long-term approach to agricultural research programmes to develop appropriate farming and land management systems that yield high outputs;

j. To ensure that planning for agricultural development incorporates in its economic cost-benefit analysis the potential costs of soil degradation through erosion and Stalinization as well as soil and water pollution;

k. To ensure that inputs shall be as diverse and complementing as the physical, chemical and biological components of the soil require, and shall not focus solely on a quick and transitory increase in plant nutrients to the long-term detriment of soil structure and microbiology;

l. To institute the stall feeding of domesticated animals through a combination of providing agricultural residues, on-farm produced forage and fodder as well as the cutting and carrying of grass and browse from meadows and hillsides in order to encourage revegetation of grazing lands and the reduction of soil erosion;

m. To develop forestry on the farm, around the homestead and on eroding and/or eroded hillsides in order to increase the stock of trees for fuel wood, construction material, implements and crafts, for forage and for other tree products ;

n. To shift the emphasis in crop breeding from single line plant varieties and animal breeds to multiple lines involving as many different but

adapted lines as possible in order to increase both plasticity in adapting to environmental variations, and resistance to pests and diseases;

o. To use biological and cultural methods as well as resistant or tolerant varieties or breeds, pheromones or sterile male techniques in an integrated manner as a pest and disease management method in preference to chemical controls;

p. To safeguard human and environmental health by producing adequate regulation of agricultural (crop and livestock) chemicals;

q. To use the precautionary principle in assessing potentially damaging impacts when taking decisions that affect social and economic conditions, natural resources and the environment, especially in the pastoral areas, which are perhaps the least studied in the country;

r. To ensure that new technical recommendations are compatible with existing pastoral and agricultural systems, agro-ecological conditions and the prevailing socio-economic environment; and

s. To undertake full environmental, social and economic impact assessments of all existing irrigation schemes in the rangelands and wherever needed establish programmes of correcting their negative environmental, social and economic impacts.

2. Forest, Woodland and Tree Resources

The Policies are:

a. To recognize the complementary roles of communities, private entrepreneurs and the state in forestry development;

b. To encourage all concerned individuals and communities as well as the government to actively involve in the planning and implementation of forestry programmes to ensure sustainability, minimize cost, and forestall conflict;

c. To ensure that forestry development strategies integrate the development, management and conservation of forest resources with those of land and water resources, energy resources, ecosystems and genetic resources, as well as with crop and livestock production;

d. To ensure that afforestation with exotic species be restricted to backyard woodlots, to peri-urban plantations and to plantations for

specific industrial and other projects; otherwise until reliable information and knowledge on exotic species are available afforestation shall use local species as these are in tune with the environment and thus ensure its well-being;

e. To assist the natural process of afforestation of uncultivable areas by controlling felling and grazing and by planting judiciously selected local species, as well as by other affordable interventions.

f. To adhere to the principle that "sustainable forest management" is achieved when social acceptability and economic viability have been achieved and the volume of wood harvested in a given period is about equal to the net growth that the forest is capable of generating;

g. To pursue agricultural and other policies and programmes that will reduce pressure on fragile woodland resources and ecosystems; and

h. To promote changes in agricultural and natural resource management systems which will limit the need for free grazing of animals in protected forest areas.

i. To find substitutes for construction and fuel wood whenever capabilities and other conditions allow, in order to reduce pressure on forests.

3. Genetic, Species and Ecosystem Biodiversity

The Policies are:

a. To promote *in situ* systems (i.e. conservation in a nature reserve, farmer's fields, etc.) as the primary target for conserving both wild and domesticated biological diversity; but also promote *ex situ* systems (i.e. conservation outside the original or natural habitat) in gene banks, farms, botanical gardens, ranches and zoos as supplementary to *in situ* conservation;

b. To promote *in situ* conservation of crop and domestic animal biological diversity as well as other human made and managed ecosystems through the conscious conservation of samples of such ecosystems, even when change as a whole is taking place;

c. To ensure that the importation, exportation and exchange of genetic and species resources is subject to legislation, e.g. to ensure the safeguarding of community and national interests, the fulfilling of international obligations, quarantine, etc. Above all biological material which is self-regenerative and impossible to control once allowed to

get out of control may result in the most insidious and damaging form of pollution which is biological pollution, thus the importation and use of biological material including those genetically engineered should be under stringent regulations;

d. To ensure that factors such as the level of vulnerability, uniqueness, importance and economic and environmental potential of the genome be taken into account in determining priorities in conservation;

e. To ensure that the conservation of genetic resources *in situ* maintains a dynamic system of genetic variability in an environment of constant selection pressure that is normally present in the natural or human made ecosystem as the case may be;

f. To promote the involvement of local communities inside and outside protected areas in the planning and management of such areas;

g. To ensure that the conservation of biological diversity outside the protected area system be integrated with strategic land use plans, local level plans and sustainable agricultural and pastoral production strategies;

h. To include in protected areas as wide a range of ecosystems and habitats as possible and where appropriate to link them by corridors of suitable habitats along which species can migrate;

i. To ensure that pricing policies and instruments support conservation of biological diversity;

j. To ensure that park, forest and wildlife conservation and management programmes which conserve biological diversity on behalf of the country allow for a major part of any economic benefits deriving there from to be channelled to local communities affected by such programmes; and

k. To recognize that certain animal and plant species are vermin or pests or may be a reservoir of disease to humans, crops and livestock, and to control them.

4. Human Settlements, Urban Environment and Environmental Health

The Policies are:

a. To incorporate rural urban migration, human settlement and environmental health concerns which arise from urbanization created

by social and economic development into regional, wereda and local level planning and development activities;

b. To integrate harmoniously, human-produced and natural elements in the development and management of urban areas in order to maintain the natural ecosystems;

c. To ensure that improved environmental sanitation be placed highest on the federal and regional agendas for achieving sustainable urban development;

d. To promote the construction by individual families of their own houses and create conducive conditions for communities and individual families to make improvements to their immediate habitats as well as to provide human and domestic waste disposal facilities;

e. To recognize the importance of and help bring about behavioural change through education and public awareness of environmental sanitation problems in trying to achieve demand-driven community led programmes of improved urban environments as well as the sustainable use and maintenance of sanitation facilities;

f. To bring about a sound partnership between the government and communities in the development of an integrated sanitation delivery system, and to foster the supplementary role of NGOs;

g. To ensure that housing and sanitation technologies and regulatory standards are set at a level and cost that are within reach of the users and flexible enough to be adaptable to the very varied socio-economic, epidemiological, climatic and physical site conditions which are found in urban areas;

h. To give priority to waste collection services and to its safe disposal;

i. On the one hand to recognize the importance of adequate water supply as an important component in achieving a sustainable and healthy urban environment, and on the other hand to recognize the minimization of the need for water as an important factor in the choice of sanitation technologies;

j. To construct shared VIP latrines in the low income and very high density housing areas of Addis Ababa and the older towns with frequent emptying by tankers integrated with programmes on user education, health and hygiene, with follow up maintenance and cleaning, all implemented as a component of a broader urban environmental upgrading programme including storm water drainage;

k. To ensure the construction of family latrines in lower density urban and peri-urban areas as a conditionality of the house plot lease and to integrate this with health and hygiene awareness programmes;

l. To create conducive conditions for families, housing groups and communities to construct latrines and for private entrepreneurs to undertake latrine emptying as well as waste collection and disposal services;

m. To undertake studies which identify suitable sanitary landfill sites in the major cites and towns of Ethiopia;

n. To plan and create green spaces within urban areas, including community forests and woodlands for fuel wood as well as for recreational amenity, providing habitats for plants and animals and ameliorating urban micro climates;

o. To promote the development of sewerage systems and sewage treatment facilities in urban centres; and

p. To the extent possible to recycle liquid and solid wastes from homesteads and establishments for the production of energy, fertilizer and for other uses.

5. Control of Hazardous Materials and Pollution from Industrial Waste

The Policies are:

a. To adhere to the precautionary principle of minimizing and where possible preventing discharges of substances, biological materials or their fragments from industrial plants and personal or communal appliances or any other external sources that could be harmful, and to disallow the discharge when they are likely to be hazardous;

b. To adopt the "polluter pays" principle while endorsing the precautionary principle since pollution is likely to occur, and ensure that polluting enterprises and municipalities and Woreda councils provide their own appropriate pollution control facilities;

c. To establish clear linkages between the control of pollution and other policy areas including water resources, agriculture, human settlements, health and disaster prevention and preparedness;

d. To provide adequate regulation of agricultural (crop and livestock) chemicals and micro- organisms;

e. To ensure that pollution control is commensurate with the potency, longevity and potential to increase or reproduce of the pollutant;

f. To establish safe limits for the location of sanitary landfill sites in the vicinity of wells, bore holes and dams, and issue regulations to enforce them;

g. To review and develop guidelines for waste disposal, public and industrial hygiene and techniques to enable the cost-effective implementation of defined standards of control, and to issue regulations to enforce them;

h. To formulate and implement a country-wide strategy and guidelines on the management of wastes from the medical, agriculture and other sectors that may use potentially hazardous biological organisms, their fragments or chemicals, and to issue the necessary regulations to enforce them;

i. To establish a system for monitoring compliance with land, air and water pollution control standards and regulations, the handling and storage of hazardous and dangerous materials, mining operations, public and industrial hygiene, waste disposal, and water quality;

j. To maintain an up-to-date register of toxic, hazardous and radioactive substances, and to make the information available on request;

k. To maintain regular environmental audits to ensure the adoption of environmentally sound practices in all public and private development activities including industrial and mining operations;

l. To enforce the exhaustive labelling and detailing of the contents usage and expiry date of foods, drugs, cosmetics, other chemicals, and when any of the contents are poisonous or dangerous in any other way, the fixing of strikingly visible labels to that effect;

m. To promote waste minimization processes, including the efficient recycling of materials wherever possible;

n. To create by law an effective system of control, distribution, utilization and disposal after use or expiry of chemicals, biological organisms or fragments of organisms that could be hazardous but are required for use;

o. To prohibit from importation to and from transit through Ethiopia hazardous materials, organisms or fragments of organisms as agreed by African states in Bamako;

p. To hold as legally liable an employer who deploys employees in using or handling hazardous materials without adequately training them on how to deal with the hazard and without adequate equipment to protect each one of them for physical harm or disease that is caused by working conditions whether the harm or disease starts in the place of work or away from it;

q. To foster better understanding of the dangerous effects of chemicals and organisms and their fragments through the provision of information in a form understandable to users, and provide or enforce the provision of information on the appropriate methods and technologies for the treatment and disposal of wastes.

6. Community Participation and the Environment

The Policies are:

a. To ensure that all phases of environmental and resource development and management, from project conception to planning and implementation to monitoring and evaluation are undertaken based on the decisions of the resource users and managers;

b. To reorient management professionals employed in natural resource and environmental extension programmes to embrace participatory development, and to strengthen their communication skills so as to more effectively disseminate both the results of scientific research and the practical experience of local farmers;

c. To develop effective methods of popular participation in the planning and implementation of environmental and resource use and management projects and programmes;

d. To develop the necessary legislation, training and financial support to empower local communities so that they may acquire the ability to prevent the manipulated imposition of external decisions in the name of participation, and to ensure genuine grassroots decisions in resources and environmental management;

e. To authorize all levels of organization to raise funds locally from the use of natural resources to fund the development, management and sustainable use of those resources;

f. To greatly increase the number of women extension agents in the field of natural resource and environmental management; and

g. To ensure information flow among all levels of organization including the Federal and Regional States and the people at the grassroots level by developing a two way mechanism for data collection and dissemination.

7. Environmental Research

The Policies are:

a. To develop strategic environmental research which aims at identifying the social, economic and technical factors which influence resource management;

b. To promote the training and the improvement of the working conditions of researchers so that they become technically competent and familiar with the agro-ecological and socio-economic conditions of the potential end users;

c. To put in place an appropriate information exchange system and institutional structure which facilitate closer interaction among farmers, pastoralists, government professionals, development NGO's, and researchers;

d. To support research on appropriate technologies for environmental management and sustainable development through a partnership between scientists and potential end users so as to benefit from the universal knowledge of the former in science and technology and the unique knowledge of the latter in the very often site specific conditions under which the technology is to be used;

e. To co-opt existing traditional systems of research and learning into a new system which incorporates both modern and traditional components;

f. To allocate funds to support strategic, applied and adaptive research programmes and projects; and

g. To establish Science and Technology Associations in all communities to identify and support their traditional systems of research and development and provide a channel for feedback of information concerning the suitability or otherwise of research outputs;

7. Environmental Impact Assessment (EIA)

The Policies are:

a. To ensure that environmental impact assessments consider not only physical and biological impacts but also address social, socio-economic, political and cultural conditions;

b. To ensure that public and private sector development programmes and projects recognize any environmental impacts early and incorporate their containment into the development design process;

c. To recognize that public consultation is an integral part of EIA and ensure that EIA procedures make provision for both an independent review and public comment before consideration by decision makers;

d. To ensure that an environmental impact statement always includes mitigation plans for environmental management problems and contingency plans in case of accidents;

e. To ensure that, at specified intervals during project implementation, environmental audits regarding monitoring, inspection and record keeping take place for activities where these have been required by the Environmental Impact Statement;

f. To ensure that preliminary and full EIA's are undertaken by the relevant sectoral ministries or departments, if in the public sector, and by the developer, if in the private sector;

g. To create by law an EIA process this requires appropriate environmental impact statements and environmental audits for private and state development projects;

h. To establish the necessary institutional framework and determine the linkages of its parts for undertaking, coordinating and approving EIAs and the subsequent system of environmental audits required to ensure compliance with conditionalities;

i. To develop detailed sectoral technical guidelines in EIAs and environmental audits;

j. To ensure that social, socio-economic, political and cultural conditions are considered in environmental impact assessment procedures and included in sectoral guidelines; and

k. To develop EIA and environmental audit capacity and capability in the Environmental Protection Authority, sectoral ministries and agencies as well as in the regions.

8. Environmental Education and Awareness

The Policies are:

a. To promote the teaching of environmental education on a multi-disciplinary basis and to integrate it into the ongoing curricula of schools and colleges and not treat it as a separate or additional subject, though this should also be done at the tertiary level;

b. To target the public, particularly those involved in public and private sector activities that have significant environmental impacts, for environmental education and awareness programmes;

c. To formulate environmental awareness programmes in such a way as to make them address specific environmental problems of particular localities in view of the extreme variability of environmental conditions and problems in Ethiopia;

d. To recognize the important role the mass media play and to effectively use them in creating and promoting environmental awareness in view of the physical problems of access and communications in Ethiopia;

e. To strengthen existing higher level training and education institutions so that they can offer programmes and courses in sustainable resource and environmental management for economists, planners, lawyers, engineers, sociologists and medical practitioners as well as for natural resource and environmental scientists;

f. To provide in-service training in such specialized subjects as environmental economics, environmental law, environmental monitoring, geographical information systems (GIS), pollution monitoring and control, and hazardous waste management;

g. To encourage the local development of environmental awareness associations and programmes specific to particular agro-ecological zones and support them with scientific inputs;

h. To develop environmental awareness programmes for urban environments for dissemination by the mass media and foster the development of urban environmental awareness associations; and

i. To initiate, encourage and support the involvement of local community and religious leaders in programmes to promote environmental awareness.

POLICY IMPLEMENTATION

1. Institutional Framework, Responsibilities and Mandates

The Policies are:

a. To give political and popular support to the sustainable use of natural, human-made and cultural resources and environmental management for effectiveness at the federal, regional, zonal, Woreda and community levels;

b. To ensure that legally established coordination and management bodies from the federal down to the community level handle the sectoral and cross sectoral planning and implementation issues identified as the responsibilities of concerned line ministries commissions, authorities and bureaus, as applicable to the level of organizations, including those of the relevant federal executive organs as well as regional and municipal governments, elected councillors, non-governmental organizations, community representatives, representatives of professional or other environmental associations and the private sector;

c. To use to the maximum, whenever possible, existing institutional structures;

d. To determine institutional arrangements for the formulation of conservation and natural resource development and management strategies, legislation, regulation, monitoring and enforcement using the following criteria:

   (i) conformity with the Constitution, especially with respect to the decentralization of power;
   (ii) harmonization of sectoral interests;
   (iii) integration of environmental planning with development planning;
   (iv) minimization of incremental financial requirements;

e. To avoid conflicts of interest by assigning responsibilities to separate organisations for environmental and natural resource development and management activities on the one hand, and environmental protection, regulation and monitoring on the other;

f. To ensure that enforcement of government laws and regulations with respect to environmental protection remain the responsibility of federal and regional courts and administrations; nevertheless, where government's own development activities are controlled by laws and regulations, the monitoring of such laws and regulations to ensure compliance of specific ministries and other government entities should be carried out by the government organization responsible for environmental protection and regulation.

2. *Legislative Framework*

The Policies are that the Law should:

a. To provide a framework for encouraging participation by the people of Ethiopia in the development of federal and regional policies, laws and plans for the sustainable use and management of the natural, human-made and cultural resources and the environment;

b. To enable the creation of programmes that motivate the peoples of Ethiopia into restoring, protecting, managing and sustainably using the natural, human-made and cultural resources and the environment of the country;

c. To ensure agreement with the constitution and the prevailing, political, social, cultural and economic policies, laws and practices and to harmonize these with the principle of sustainable development;

d. To be consistent with Article 44 of the Constitution and assure all people living in the country of their fundamental right to an environment adequate for their health and well-being;

e. To create the conditions for formulating, reviewing and updating sectoral regulations on, and procedures for, the restoration, protection, management and sustainable use of the natural, human-made and cultural resources and the environment; and

f. To provide a broad framework for both punitive and incentive measures.

3. *Monitoring, Evaluation and Policy Review*

The Policies are:

a. To ensure that individual programme and project monitoring becomes the responsibility of the appropriate federal and/or regional implementing and/or mandated agencies;

b. To ensure that the monitoring of the overall impacts of the implementation of the Federal Environmental Policy on the country's renewable natural resources and environmental support systems, and that the compilation of recommendations for any modification that is required, should be consistent with the institutional arrangement specified in the CSE and also be responsive to popular opinion;

c. To ensure that the Environmental Protection Authority carries the overall monitoring of the Policy implementation and is responsible for proposing modifications, in consultation with the mandated line ministries and/or the opinion of stakeholder communities and groups, and for having them approved by the Inter-Ministerial Environmental Protection Council;

d. To ensure that line ministries and regional and lower level bureaus and branches of bureaus monitor the overall impact of the implementation of this Federal Environmental Policy on those sectors and elements for which they have the legal mandate;

e. To ensure that, starting with the Community Environmental Coordinating Committee and aggregating upwards through the appropriate level offices of Water Resources, Mines and Energy, Agriculture, and Economic Development and Cooperation, reviews of the status of natural resources and the environment, including evaluation of the implementation of this Federal Environmental Policy, are completed annually at the appropriate levels; and to ensure that the Environmental Protection Authority will be responsible for prompting the compilation of the reports and for reporting on the process;

f. To ensure that, at least annually, meetings held by communities at the village level with their Community Environmental Coordinating Committees then successively from the Woreda and the Regional Environmental Coordinating Committees through to the Environmental Protection Council, evaluate these reviews and make their

recommendations; the Environmental Protection Authority will be responsible for prompting that the evaluation takes place and for reporting on the process.

Annex II- Draft Biosafety Law

Whereas**,** modern biotechnology might have much promise for the improvement of human well-being if its potential adverse effects on human health, biological diversity and in general the environment are addressed;

Whereas**,** ensuring human and animal health, the safety of the environment and the quality of socio-economic and cultural conditions from the risks arising from genetically modified organisms and products thereof fosters the implementation of the environmental rights and obligations enshrined in the Constitution of the Federal Democratic Republic of Ethiopia;

Whereas**,** it is the prime responsibility of the government to achieve the Sustainable Development Vision of the country and to enhance the national capacity to cope with the risks associated with genetically modified organisms and or products thereof;

Now, therefore**,** in accordance with Article 55(1) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follows:

PART ONE

1. Short Title

This Proclamation may be cited as the "Biosafety Proclamation No.____/____".

2. Definitions

For the purpose of this Proclamation:

1. **'Advance Informed Agreement'** means an explicit written consent granted by the Authority for a transaction. When the transaction involves the importation of any genetically modified organism or product thereof, the consent shall be based upon the taking of full responsibility by the competent national authority of the exporting country for the complete and accurate disclosure of information on any genetically modified organism and on any product thereof before any transaction is undertaken. When the transaction is Ethiopian, the consent shall be based upon the taking of full responsibility by the applicant for the complete and accurate disclosure of information on any genetically modified organism and on any products thereof before any

transaction is undertaken.

2. **‘Applicant’** means any licensed person who submits an application in writing to the Authority seeking authorization to be engaged in a transaction relating to genetically modified organisms or products thereof pursuant to the provisions of this Proclamation.
3. **'Authority'** means the Environmental Protection Authority of the Federal Democratic Republic of Ethiopia established pursuant to Proclamation No. 295/2002.
4. **'Authorized person'** means any person who has been given an authorization by the Authority to engage in any transaction based upon an Advance Informed Agreement.
5. **‘Cartagena Protocol on Biosafety’** means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity ratified during the under Proclamation No 362/2003.
6. **‘Competent National Authority’** means the national institution of a country of export of any genetically modified organisms or products thereof to Ethiopia designated by the state of that exporting country to carry out the functions described in Articles 7-12 of the Cartagena Protocol on Biosafety;
7. **‘Contained use’** means any operation in which genetically modified organisms or products thereof are produced, grown or developed, stored, destroyed or used in some other way including for research, in a closed system not exceeding the requirement stated in the appropriate directives issued by the Authority, in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to effectively prevent their contact with, and their impact on, humans and the external environment.
8. **‘Development’** means the production of a genetically modified organism through the use of modern biotechnology;
9. **‘Deliberate release’** or **‘release’** means any intentional introduction into the environment of a genetically modified organism or a product thereof; this includes releases for commercial purposes, for distribution as aid food, for remediation, for research purposes in field experiments, for use in greenhouses, for aqua-culture facilities, for feed or medical use by animals, for animal accommodation unless the facility is approved as constituting contained use, for use as part of an approved laboratory or other installations unless that installation has been approved as constituting contained use, for disposal of genetically modified organisms or products thereof or waste containing genetically modified organisms or products thereof unless that disposal system has been approved as constituting contained use, for import, export or transport of genetically modified organisms or products thereof.
10. **‘Genetically modified organism’** means any biological entity in which the genetic material or its expression, and includes plants, animals, micro-organisms (viruses, bacteria, fungi, cell cultures, all vector systems including plasmids, viruses, transposons, artificial chromosomes), and naked nucleic acids including viroids, DNA, RNA sequences or other heritable molecules.
11. **'Inspector'** means a person appointed by the Authority to undertake inspection and

other control measures to ensure compliance with this Proclamation and any directives issued under it.

12. **'Licensing agency'** means any organ of government empowered by law to issue an investment, a trade permit, an operating license, or a work permit or to register a business organization using any genetically modified organisms or products thereof, as the case may be.

13. **'Modern biotechnology'** means a scientific technique that includes any of the following:

a) Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules extracted from any organism, biochemically synthesized, or produced by whatever means outside an organism into a virus, bacterium, plasmid, trnasposon or other vector, and their incorporation through the use of the vector into a host organism in which they are capable of replication in whole or in part;

b) Techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

c) Cell fusion techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells, or

d) Any other way of modifying the chemistry of any nucleic acid of a target organism.

14. **'National Biosafety Clearing-House'** means a system of acquisition and management of, and access to, information established by the Authority based on the Clearing-House Mechanism established under Article 20 of the Cartagena Protocol on Biosafety in order to facilitate the exchange of scientific, technical, environmental and legal information and experience with genetically modified organisms or products thereof.

15. **'Person'** includes any natural or juridical person.

16. **‘Placing on the market’** means supplying or making available to third parties a genetically modified organism or products thereof whether there has been monetary exchange or not, and includes the giving as aid food.

17. **‘Product of a genetically modified organism or product thereof’** means any material produced by, derived by the processing of, or produced howsoever otherwise from, any genetically modified organism.

18. **‘Significant Risk’** means unacceptable or imminent, direct or indirect, short, medium or long-term danger to human or animal health, biological diversity, the environment, socio-economic conditions or cultural norms of local communities or to the economic condition of the country from any transaction involving genetically modified organisms or products thereof.

19. **‘Risk assessment’** means the evaluation of the direct and indirect, short, medium and long-term risks that may arise from transactions involving any genetically modified organism or any product thereof.

20. **‘Socio-economic impact’** means the direct or indirect effect of a genetically modified organism or products thereof on social or cultural conditions, the livelihood or indigenous knowledge systems or technologies of a local community or communities, including on the economy of the country.

21. **'Transaction'** means any research and development, import, export, transit, handling, release, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism or products thereof.

3. Scope

1. This Proclamation shall apply to any transaction whether intended for release into the environment, contained use, transit, for use as a pharmaceutical for humans or animals, or for food, feed or processing.

2. This Proclamation shall not apply to any transaction of a pharmaceutical for humans, or a commodity for food, feed or processing listed under any regulations as exempted from this Proclamation.

4. Objective of the Proclamation

The objective of this Proclamation is to protect human and animal health, biological diversity and the environment at large by preventing or managing down to levels of insignificance the adverse effects of genetically modified organisms and products thereof.

5. Precautionary Principle

1. Any government organ shall, in the implementation of this Proclamation, take into account the need for caution, particularly where there is scientific uncertainty about a risk emanating from any transaction. When faced with any uncertainty in any risk, it shall assume that that risk can occur and shall act to prevent or contain it.

2. Any authorized person shall, in the implementation of this Proclamation, take due care and implement measures to ensure that all transactions are carried out in conformity with the provisions of this Proclamation.

PART TWO

Regulation of Genetically Modified Organisms and products thereof

6. Prohibition

1. Any transaction of a genetically modified organism or product thereof with the intention of causing harm to human health, biological diversity, the environment, or property, or with the intention of any other hostile act, is prohibited.

2. Any transaction of a genetically modified organism or products thereof with the intention of peaceful application which causes significant risk to human health, biological diversity, the environment, or property which has not been given an

Advance Informed Agreement in writing by the Authority is prohibited.

7. Restrictions on Transactions

1. No person shall engage in any transaction except as provided under this Proclamation.
2. Any transaction is subject to inspection by an Inspector authorized by the Authority.
3. If, upon an inspection carried out in accordance with the provisions of sub–article 2 of this Article, the Inspector determines that the transaction is not in compliance with this Proclamation or with any directives issued under it, the Authority may subsequently order that the genetically modified organism or product thereof be re-exported or destroyed.
4. Where imported genetically modified organisms or products thereof remain unclaimed at the port of entry for more than two weeks, the Authority, together with the Customs Authority or other concerned government body, may take action to dispose of them in an environmentally sound manner.
5. The costs of, and responsibility for, any action taken under sub-articles 2 to 4 of this Article shall be borne by the person carrying out the transaction, except where, for reasons of expediency, the Authority decides to cover the cost.

8. General Provisions on Advance Informed Agreement and Authorization

1. No person shall be engaged in any transaction without obtaining an Advance Informed Agreement from the Authority.
2. No authorization shall be given unless it is considered and determined by the Authority that the transaction will benefit the country without causing significant risk.
3. The Authority shall, as a condition to granting authorization, require the applicant to furnish evidence of insurance cover sufficient to meet its obligations under this Proclamation.

9. Duties of an Applicant

1. The applicant shall undertake a risk assessment to identify potential risks, specify the means of prevention or containment of the identified risks, and submit to the Authority the risk assessment report, together with any other documents determined as necessary by the Authority.
2. Besides a detailed technical analysis, a risk assessment report shall include a brief statement summarizing the report in non-technical terms, and shall indicate the completeness and accuracy of the information given in the report.
3. An applicant shall ensure that qualified persons that meet the requirements specified under the appropriate directives issued by the Authority prepare the risk assessment.

4. The cost of carrying out a risk assessment and writing a risk assessment report shall be borne by the applicant.

10. Application for Import Authorization

1. Any person who wishes to carry out any import of a genetically modified organism or any product thereof shall submit an application in writing to the Authority.
2. The application shall include:
   (a) A full and accurate description of the genetically modified organisms or products thereof to be imported, which shall include the technical and common names and a statement of the quantities;

   (b) The name of the importer that is to receive the genetically modified organisms or products thereof and documentary proof that such person possesses the technical capacity and the facilities to ensure that the transaction does not cause risks;

   (c) A risk assessment report including the consequences of unintentional release and emergency response plans to address it;

   (d) Information relating to the conditions of intended transaction, and where appropriate, the receiving environment for the genetically modified organism or products thereof, including in case of accidental release;

   (e) Information from previous or current transactions of the genetically modified organism or products thereof in the country of export and in any other country;

   (f) Information on previous approvals and refusals of transaction of the genetically modified organism or products thereof by any other country;

   (g) A clear and sequential description of the steps to be taken in the implementation of the project which uses the genetically modified organism or product thereof intended for import, and the monitoring and evaluation that will be made at the end of each step, and the method of disposing of any waste;

   (h) The place where and the purpose for which the genetically modified organism or product thereof is planned to be transacted, including detailed instructions for handling and use and a proposed labeling and packaging scheme in accordance with the relevant provisions of this Proclamation and directives issued under it,

   (i) A description of the intended transaction and any risk management measures put in place;

(j) Any other item of information specified under appropriate directives;

(k) A declaration confirming that the information provided is correct including, where appropriate, an undertaking from the originator of the information affirming its accuracy and completeness.

3. Without prejudice to sub-articles (1) and (2) of this Article, any person that engages in a transaction for food, feed or processing shall submit an application in writing to the Authority with a reference to the information on the item found in the Biosafety Clearing-House according to Article 25 of this Proclamation.

11. Development and other forms of Contained Use

1. Any person that develops a genetically modified organism or products thereof shall take into account the characteristics of the organisms used, the research site and the surrounding environment, and apply scientifically acceptable and environmentally sound practices in order to minimize possible risks.
2. The user of any genetically modified organism or products thereof for contained use shall ensure that the necessary safety precautions are taken to prevent any risk, including measures to limit the detrimental effects of any unintentional release of a genetically modified organism or product thereof.
3. The user of any genetically modified organism or product thereof under contained conditions shall keep records of all the development or use made as well as of any unforeseen event encountered.
4. The contained use of any genetically modified organisms or product thereof shall take place in accordance with directives issued by the Authority.

12. Transit

1. The Authority shall place any genetically modified organisms or products thereof that it deems too dangerous to transit through Ethiopia, in the Biosafety Clearing-House of the Cartagena Protocol on Biosafety.
2. Any person who wishes to carry out any transit of a genetically modified organism or product thereof through a territory of Ethiopia shall ensure that the transit of that genetically modified organism or prod thereof has not been prohibited by the Authority and shall notify the Authority of the intended transit before that transit takes place.

13. Export Authorization

1. Any person who intends to export or re-export a genetically modified organism or product thereof shall provide to the Authority the Advance Informed Agreement of the concerned agency of the importing country.

2. The presentation of the Advance Informed Agreement by an exporter shall in no way absolve the exporter from complying with any other laws governing foreign trade.
3. The submission of the Advance Informed Agreement shall not preclude the Authority or any other appropriate government agency from taking into account other considerations in deciding whether or not to approve the export.

14. Risk Assessment Report

1. A risk assessment report shall be prepared by a qualified person who is competent to determine whether the genetically modified organism or products thereof cause any risk; it shall be prepared according to the appropriate directives issued by the Authority and shall contain a risk management plan.
2. An approved risk assessment report shall remain valid for the period specified by the Authority during its approval.

PART THREE

Decision Making on a Risk Assessment Report

15. Expert Opinion and Public Comments

1. The Authority shall, upon receipt of the risk assessment report, disseminate it to experts and solicit opinions on it.
2. Within two weeks of the receipt of any risk assessment report, the Authority shall, through appropriate means of communication, avail the risk assessment report to the public and solicit comments on it for a period of not more than one month.
3. The public notice under sub-Article 2 above shall provide a description of the genetically modified organism or any product thereof together with a statement of the intention of the Authority either to grant or refuse authorization of the transaction involving that genetically modified organism or product thereof.
4. A copy of the public notice referred to under sub-Article 3 of this Article shall be lodged with the National Biosafety Clearing-House maintained by the Authority.
5. The Authority may establish a consultative process with all stakeholders, including but not restricted to, the academic and business communities and the civil society concerning the proposed authorization or refusal of the transaction.
6. Comments on the proposed authorization or refusal of the transaction may be made in writing by any person within a one month’s period after the public notification made by the Authority under sub-Article 2 of this Article.

16. Decision making

1. Evaluation of a risk assessment report shall be carried out on a case-by-case basis.

2. The Authority shall verify the information presented by the applicant or found in the Biosafety Clearing-House, as the case may be, by taking into account expert opinions and public comments, and shall make its decision on the application.
3. The Authority may, prior to taking a decision, request for further information as it may deem necessary and any applicant who fails to supply the required further information shall be deemed to have withdrawn her/his application.
4. The Authority shall, within 15 days after it has received experts' opinion as well as public comments and thus within 2 months after it has received an application, evaluate the risk assessment report and:
   a) Approve the report without conditions and issue authorization if it is convinced that the transaction will not cause unacceptable risk; or,
   b) Approve the report and issue authorization with conditions that must be fulfilled in order to eliminate or reduce risks if it is convinced that such risks can be effectively contained; or,
   c) Require the applicant to provide more information to enable better-informed decision making; or
   d) Reject the report and deny authorization.
5. Authorization shall not be given unless there is a firm and sufficient evidence that the genetically modified organism or product thereof does not entail any significant risk.
6. Within a week of issuing a decision under this article, the Authority shall lodge a copy of the decision with the National Biosafety Clearing-House.

17. Review of Decision

1. Any authorization given may be revoked or subjected to conditions in addition to those originally imposed, if, in the opinion of the Authority, new information obtained or a review of existing information about the genetically modified organism or product thereof indicates any unacceptable risk.
2. Where information becomes available to the applicant after authorization on possible significant risks, the applicant shall immediately notify the Authority.
3. The Authority may, if at any time it deems it warranted, cancel an authorization that has been issued under sub-Article 2 of this Article.
4. If any requirement or condition contained in an authorization is not strictly complied with, the Authority may take any action that it may consider appropriate for the immediate cessation of the, transaction including the destruction of the genetically modified organism or product thereof.
5. Any application to reconsider a refusal of authorization of a transaction of any genetically modified organism or product thereof shall be treated as a new application if it is accompanied by new scientific information. Otherwise a refusal shall be final.

18. Validity of Authorization

1. An authorization shall be presumed to have expired if the transaction has not been performed within the time frame set out for it during its approval.
2. Any applicant who wishes to challenge the appropriateness of sub-Article 1 of this Article may submit an application to that effect to the Authority.
3. Within 30 days from the receipt of an application pursuant to sub-Article (2) of this Article, the Authority shall, unless special circumstances so dictate, decide whether to extend the validity of the authorization or to order the revision or the redoing of the risk assessment.

19. Duties of Authorized Persons

1. Every authorized person engaged in any transaction shall take measures consistent with regulations and directives issued under this Proclamation pertaining to the transaction, labeling, displaying, or advertising, of any genetically modified organism or product thereof.
2. Every authorized person shall maintain a register to record the type, quantity, and country of origin and transaction of any genetically modified organism or product thereof and other relevant information required by the Authority.
3. Every authorized person shall immediately, whenever any genetically modified organism or product thereof ceases to be under her/his custody without her/his knowledge, inform the Authority.
4. An authorized person may not, against the terms and conditions of the authorization, transfer any genetically modified organism or product thereof to any other person.
5. Any authorized person shall develop, maintain and implement a risk management strategy to protect human and animal health and the environment from risks that might arise from the authorized transaction.
6. Any authorized person shall, every three months, submit to the Authority a written report regarding the transactions involving any genetically modified organism or products thereof that is under her/his custody.
7. Where there is any significant threat that an accidental release of any genetically modified organism or product thereof may occur, the owner or the person in charge shall immediately and by the quickest available means report the matter to the Authority.

20. Duties of Licensing Agencies

1. Licensing Agencies shall, prior to issuing any type of license to any applicant to be engaged in any transaction, ensure that the Authority has granted the applicant an authorization to do so.
2. All licensing agencies shall suspend or cancel licenses following the final decision of the Authority to do so, issued in line with the provisions of this Proclamation.

21. Inspectors

1. The Authority may appoint Inspectors to exercise and perform the functions referred to under this Proclamation.
2. Every Inspector shall be given an identity card signed by the head of the Authority, stating that he or she has been appointed as Inspector.
3. An Inspector shall exercise due diligence and impartiality in the discharge of her/his powers and duties under this Proclamation.
4. Without any need for prior notice or court order, an Inspector may:
   a) Enter any place or facility in respect of which she or he has reason to believe that a contravention of any provision of this Proclamation is taking place;
   b) Inspect and order the taking of any corrective measures on any transaction carried out in the place or facility;
   c) Request and obtain any information from any person carrying out or in charge of the carrying out of any transaction;
   d) Seize any appliance, book, statement or other document which appear to provide proof of contravention of any provision of this Proclamation; and
   e) Take free of charge samples of any material or substance as required and carry out or cause to be carried out tests she/he considers appropriate.

PART FOUR

Risk Management

22. Risk Management

1. The provisions of this section shall apply in addition to any other risk management measure that may be required in any authorization issued by the Authority.
2. No transaction shall be carried out unless it has been packed, labelled or handled, as the case may be, in accordance with the requirements set out under the relevant directives issued pursuant to this Proclamation.
3. All genetically modified organisms or products thereof that are transacted upon, or exported shall be accompanied by the document of authorization issued, which shall at all times be available for inspection by an Inspector.
4. The Authority may, for the implementation of the provisions of this Article,
   (a) require any genetically modified organism or product thereof to undergo a period of observation commensurate with its life-cycle or generation time, at the cost of the applicant, before and after it is put to its intended use; this period of observation may be determined by the Authority at the time of authorization or at any later time;
   (b) rescind the authorization or order the cessation of any transaction, if it decides that the genetically modified organism or product thereof contains characteristics or specific traits which pose risks;

(c) order the cessation of any transaction, which is being undertaken in violation of any of the provisions of this Proclamation, directives made under it or the terms or conditions of an authorization;

(d) require the person responsible for any transaction under this Proclamation to take such measures as may be necessary to prevent or limit any harm to human health, biological diversity, the environment, or socio-economic conditions or cultural norms of local communities or the economic condition of the country, or to restore the environment to its previous state;

(e) undertake or initiate the undertaking of safety measures, as necessary, at the cost of the person responsible, in the event that the person responsible fails to undertake those measures;

(f) take measures, as necessary, in the case of imminent and serious danger to human health, biological diversity, the environment, socio-economic conditions or cultural norms of local communities or the economic condition of the country caused by a genetically modified organism or its product, at the cost of the person responsible for causing such danger; or

(g) require the authorized person to submit reports periodically of the monitoring and evaluation of risks carried out when the transaction is taking place.

23. Identification and Labeling

1. Any genetically modified organism or product thereof in storage or transport shall be clearly identified and labeled in both Amharic and English as such, and the identification label shall specify the scientific name, the common name when available, the unique identifier and the transformation event, and relevant traits and characteristics given in sufficient detail for purposes of traceability in accordance with the directives of the Authority.
2. The labelling of any genetically modified organisms or products thereof that is being transported shall also state the name, address and telephone number of both the sender and the receiver.
3. Every label affixed to packaged genetically modified organisms or products thereof that are being transported or placed on the market shall be in such a manner that the nature of the consignment is readily recognisable.

II. PART FIVE
Public Participation

24. Public Participation

1. The Authority shall, upon receipt of an application for any transaction of genetically modified organisms or products thereof, make it accessible to the public and relevant government agencies and solicit comments on it.
2. The public may submit the Authority its comments within the period specified under Article 15 of this Proclamation in such a manner as determined by the Authority.
3. The Authority shall ensure that the comments made by the public, and in particular by the communities likely to be affected by the transaction, are incorporated in taking or reviewing its decision.
4. The Authority shall make available to the public information on any transaction, which has been granted or denied authorization.

25. Establishment of a National Biosafety Clearing-House

1. The Authority shall, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, genetically modified organisms and products thereof, establish a National Biosafety Clearing-House.
2. Any information determined confidential under Article 26 of this Proclamation shall not be placed on the National Biosafety Clearing-House.
3. The National Biosafety Clearing-House shall, without affecting the generality of sub-Article 1 of this Article, contain information on:
   a) A roster of experts that shall include the names, contact particulars and relevant information of all individuals in Ethiopia with expertise in genetically modified organisms and products thereof and risk assessment and management;
   b) A list of genetically modified organisms or products thereof that have been approved and rejected for import or export;
   c) Applications lodged pursuant to the provisions of this Proclamation;
   d) Applicable guidelines and codes of practice concerning the handling, transport, use, transfer and release of any genetically modified organisms or products thereof;
   e) Any national emergency response plan to manage the accidental release of any genetically modified organisms or products thereof;
   f) Any existing laws, regulations and directives for the implementation in Ethiopia of the Cartagena Protocol on Biosafety, as well as information required by the Authority for the Advance Informed Agreement procedure;
   g) Any relevant bilateral, regional and multilateral agreements and arrangements;
   h) The Authority's final decisions regarding the importation or release of genetically modified organisms or products thereof; and
   i) Such other information as may be required to implement this Proclamation.
4. The public shall have access to any record or document filed in the National Biosafety Clearing-House.

26. Confidential Information

1. Every applicant shall have a right to notify the Authority specifying the information to be treated as confidential.
2. The Authority shall protect information which is not essential for biosafety and which it determines as confidential following a request to that effect made in writing by the applicant.
3. However, in no case may the following information supplied by the applicant be kept confidential:
   a) Description of the genetically modified organism or its products, names and addresses of the applicant, purpose and location of the transaction;
   b) Methods and plans for monitoring the genetically modified organism or product thereof and for emergency response; and
   c) The evaluation of possible effects, in particular any pathogenic and/or ecologically disruptive effects.
4. If the applicant withdraws the application before approval, the authority shall respect the confidentiality of the information except for that part referred to under the provisions of sub-Article 3 of this Article.

PART SIX

Enforcement and Compliance

27. Inspections at Ports of Entry and Exit

1. Every person in possession of any genetically modified organism or product thereof as part of his or her personal effects or baggage shall, on arrival or departure**,** declare such possession to the Customs Officer on duty at the port of entry or exit.
2. Where a Customs Officer suspects that any person is in possession of a genetically modified organism or product thereof for which there is no valid permit, she/he shall require the said person to surrender such organism or product thereof.
3. Any genetically modified organism or product thereof surrendered to a Customs Officer pursuant to sub-article 2 shall be sent to the Authority immediately.
4. Without prejudice to the provisions of Article 7 of this Proclamation, if any organism surrendered to a Customs Officer or Inspector is determined by the Authority not to be a genetically modified organism or product thereof, such organism or product thereof shall be returned to the person who surrendered the specimen.

28. Confiscation of Genetically Modified Organisms and products thereof

1. Where a Customs Officer or inspector finds any material less than 1 kilogramme by weight and she/he suspects that it might contain any genetically modified organism or product thereof which is being transported in contravention of the

provisions of this Proclamation, she/he shall seize it and call the Authority to come and destroy it.

2. Any Customs Officer or Inspector seizing any genetically modified organism pursuant to sub-article 1 of this Article, may also seize any container, packing case, box, or other form of receptacle holding the genetically modified organism or product thereof; and any thing which the officer has reason to believe may be used as evidence of a breach of the provisions of this Proclamation.
3. Where a Customs Officer or Inspector finds any consignment which is 100 Kilogram's or more by weight and she/he suspects that it might contain any genetically modified organism or product thereof, she/he shall impound the consignment and notify the Authority.
4. The Authority shall store the consignment, referred to under sub-Article 3 of this Article, in such a manner that risks to biodiversity, the environment or human health are minimized.
5. The Authority shall not be held liable for any deterioration in storage in the condition of the contents of the consignment under this Article.
6. If the consignment under this Article is not taken out of Ethiopia within 4 weeks, the Authority shall destroy it by incineration or by any other method it deems appropriate.
7. All costs and expenses attendant upon any disposal, housing, safe-keeping, or re-export of any consignment of genetically modified organisms or products thereof that has been seized or confiscated shall be borne by the owner or the person who had possession thereof.

29. Liability and Redress

1. Approval for any transaction by the Authority does not exonerate the applicant from liability.
2. A person who is engaged in any transaction shall be strictly liable for any harm caused by such a genetically modified organism or products thereof. The harm shall be fully compensated.
3. Without prejudice to sub-Article 2 of this Article, exemption from liability shall be granted only when it is verified that it is the victim himself or a third person for whom the proponent is not responsible that has caused the damage.
4. Liability shall attach to the person responsible for the transaction, which results in the damage, injury or loss as well as to the provider, supplier or developer of the genetically modified organism or product thereof.
5. If there is more than one person responsible for the damage, injury or loss, then the liability shall be joint and several.
6. In the case of harm to the environment or biological diversity, compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the costs of preventive measures.
7. In the case of harm to human health, compensation shall include:
   a) All costs and expenses incurred in seeking and obtaining the necessary and appropriate medical treatment;

b) Compensation for any disability suffered, for diminished quality of life, and for all costs and expenses incurred in reinstating, as far as possible, the quality of life enjoyed by the person before the harm was suffered;

c) Compensation for loss of life and all costs and expenses incurred for funeral and other related expenses;

8. Liability shall also extend to harm or damage caused directly or indirectly by the genetically modified organism or its product to:

a) The livelihood or indigenous knowledge systems of local communities,

b) Technologies of a community or communities,

c) Damage or destruction arising from incidence of public disorder triggered by the genetically modified organism or product thereof,

d) Disruption or damage to production or agricultural systems,

e) Reduction in yields,

f) Soil contamination,

g) Damage to the biological diversity,

h) Damage to the economy of an area or community, and

i) Any other consequential economic, social or cultural damages

9. The right to bring any civil action in respect of harm caused by a genetically modified organism or a product thereof shall, having due regard to the laws on limitations of rights, commence from the date on which the affected person(s) or the community or communities could reasonably be expected to have learned of the harm, taking due account of:

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

b) the time that it may reasonably take to correlate the harm with the genetically modified organism or the product thereof, taking into consideration the situation or circumstance of the person(s) or community or communities affected.

10. Any person, group of persons, or any private or state organization is entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision of this law, including any provision relating to damage to human health, biological diversity, the environment, or to socio-economic or cultural conditions of local communities or to the economy of the country,

a) in that person's or group or class of persons' interest;

b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;

c) in the interest of, or on behalf of, a group or class of persons whose interests are affected;

d) in the public interest; and

e) in the interest of protecting the environment or biological diversity.

11. No costs shall be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting human health, biological diversity or the environment.
12. The burden of proving that an action was not instituted out of public interest or in the interest of protecting human health, biological diversity or the environment rests on the person claiming thus.

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

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

31. Offences and Penalties

1. Without prejudice to the provisions of the 2005 Criminal Code of Ethiopia, any person who;
   (a) is involved in any transaction under this Proclamation without the authorization of the Authority;
   (b) violates any conditions attached to the grant of authorization under this law;
   (c) fails to furnish any information as required by the provisions of this law;
   (d) withholds information that has become available to her/him after the authorization of her/his application, and that could change the evaluation of the risk posed by her/his project;
   (e) provides false, misleading or deceptive information in order to secure an authorization;
   (f) does not label, package or identify any genetically modified organism or its product in accordance with this law and the directives issued by the Authority;
   (g) labels, packages or identifies any genetically modified organism or its product in a manner that is false, misleading or deceptive or in contravention of any regulation made under this law;
   (h) exports a genetically modified organism or its product without the advance informed agreement of the importing country;
   (i) participates in any proceedings related to decision taking in respect of a subject matter covered by this law in which she/he has any direct or indirect interest of any kind;
   (j) violates any other provision of this law or any directives issued by the Authority;
   (k) uses a genetically modified organism or product thereof for hostile purposes;

(l) obstructs or fails to assist the Authority or other authorized officers in the performance of their duties under this Proclamation;

(m) refuses or fails to furnish information or to give an explanation or to reply to the best of her/his ability to any question lawfully demanded from her/him by any Inspector in the performance of her/his functions as determined by this Proclamation;

(n) falsely holds herself or himself out to be an Inspector or any other officer appointed under this Proclamation,

(o) fails to inform the Authority of any accident or emergency involving a genetically modified organism or product thereof;

Commits an offense and is liable on conviction to imprisonment for a term not less than ----- years or to a fine of ----- or both.

2. Any person shall upon conviction of any offense under this Proclamation be prohibited from engaging in any activity in relation to genetically modified organisms or products thereof. Such order of prohibition shall extend to any governmental or non-governmental entity.
3. Where the offense is committed by a governmental or a non-governmental entity, and where the court feels that a custodial sentence ought to be imposed, the executive officer in charge at the time the offense is committed shall be liable to imprisonment.

32. Civil Claims for Environmental Damage

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

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

PART SEVEN

Miscellaneous Provisions

33. Power to Issue Regulations

The Council of Ministers may issue Regulations necessary for the effective implementation of this Proclamation.

34. Power to Issue Directives

The Authority may issue Directives necessary for the effective implementation of this Proclamation.

35. Duty to Cooperate

Any person shall have the duty to cooperate in the implementation of this Proclamation.

36. Effective Date

This Proclamation shall come into force as of _____ day of _____.

Annex III- Directives

DIRECTIVE No. ONE

DIRECTIVE ISSUED TO DETERMINE THE CONTENTS OF AN APPLICATION ON TRANSACTIONS INVOLVING GENETICALLY MODIFIED ORGANISMS (GMOs) AND PRODUCTS THEREOF

WHEREAS it is important to determine the major elements of any application in a transaction involving Genetically Modified Organisms or products thereof to bring about consistency in procedural application and harmonization of the system internationally,

WHEREAS, the Environmental Council has agreed upon the information needed to be included in every application;

THEREFORE, this directive is issued in accordance with Article of the Biosafety Proclamation No. ----------

1. **Designation**

This directive may be cited as ‘’Directive No. 01/ 2007 issued to determine the content of an application on transactions in genetically modified organisms and products thereof.

2. **Transactions subject to these Directives**

A transaction subject to these directives shall include any research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism or products thereof.

3. INFORMATION TO SUBMIT AN APPLICATION FOR ANY KINDS OF TRANSACTIONS RELATING TO GMOs OR PRODUCTS THEREOF

3.1 APPLICATION INFORMATION

Following is the information required for application to authorize the release to the environment of a GMO or products thereof, including its use in a closed system in quantities exceeding 500ml in volume or 2500cm^2 in surface area as specified on Article 8 (a) of Directive 3.

3.2 GENERAL information

A. NAME AND ADDRESS OF APPLICANT

B. INFORMATION ON PERSONNEL AND TRAINING

Name, training and other qualifications of person(s) responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and safety, in particular the name and qualifications of the responsible scientists.

4. Information relating to the GMO(s) or products thereof

4.1 CHARACTERISTICS OF:

A) THE DONOR OF THE TRANSGENE(S)

B) THE RECIPIENT OF THE TRANSGENE(S)

C) PARENTAL ORGANISM(S) OF THE TRANSGENE(S), AND

d) modified RNA Or DNA.

1) Scientific name
2) Additional taxonomic information
3) Other names (usual name, strain name, cultivar name etc.).
4) Phenotypic and genetic markers
5) Degree of relatedness between donor and recipient or between parental organisms
6) Description of identification and detection techniques
7) Sensitivity, reliability (in quantitative terms) and specificity of detention and identification techniques
8) Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts
9) Potential for RNA and DNA transfer and exchange with other organisms
10) Verification of the RNA and DNA stability of the organisms and factors affecting it, taking into account the relevance of the laboratory experiments undertaken to the authentic ecological conditions under which the organisms live or are used
11) Pathological, ecological and physiological traits:
    a) Classification of hazard according to existing national rules concerning the protection of human health or animal health,

biological diversity, the environment, socio-econmic conditions, ethical values or cultural norms of local communities or the economic condition of the country.

b) Generation time in natural ecosystems, sexual and asexual reproductive cycles

c) Information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia

d) Pathogenicity: infectivity, toxigenicity, virulence, allergenicity, ability to be a carrier (vector) of pathogens, possible vectors, host range including non-target organisms, possible activation of latent viruses (proviruses), ability to colonize other organisms,ability of RNAor DNA molecules to be introduced in to the cells or tissues of other species.

e) Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy

f) Involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12) History of previous genetic modifications

4.2 Characteristics OF THE VECTOR

1) Nature and source of the vector

2) Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO(s) or the GMO (s) that gives rise to the products and to make the introduced vector and insert function in the GMO(s) or the GMO (s) that gives rise to the products

3) Frequency of mobilization when inserted into the rcepient organism and/or genetic transfer capabilities from the recipient organism and methods of determination ot these traits

4) Information on the degree to which the vector is limited to incorporating the DNA required to perform the intended function

5) Factors (chemical, biological, climatic, etc.) influencing the functional level of the promoter/enhancer, and how the functional level is changes

4.3 CHARACTERISTICS OF THE GMO(S) OR PRODUCTS THEREOF

1) Information relating to the genetic modification:

a) Methods used for the modification

b) Methods used to construct and introduce the insert(s) into the recipient or to any nuclic acid or protien sequence; or to change the chemical composition of any nucleic acid or protien sequence.

c) Description of the insert and/or vector construct.

d) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function

e) Number of intact and truncated vector inserts. Sequence, functional identity and location of the altered/inserted/deleted nucleic acid or protien segment(s) in question with particular reference to any known harmful sequence

f) Sequence and methylation pattern of the recipient nucleic acid as far as 100 kbp up and down stream from all nucleic acid inserts

2) Information on the final GMO:

a) Description of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed

b) Structure and amount of any vector and/or donor nucleic acid remaining in the GMO(s) or products thereof

c) Stability of the traits

d) Rate and level of expression of the new genetic material. Method and sensitivity of measurement

e) Activity of the expressed protein(s)

f) Expression levels for the recipient's genes situated as far as 100 kbp up and down stream from all nucleic acid inserts or chemical changes

g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques

h) History of previous releases or uses of the GMO(s) or products thereof

4.4 Considerations of impacts on health

a) Toxic, allergenic, tetratogenic or hormon mimicking effects of the GMO(s) or products thereof and/or their metabolic products on humans or any animals

b) Comparison of the GMO(s) or products thereof with the donor recipient or un modified parental or oroducts thereof regarding pathogenicity,allergencity, teratogencity or mimicking hormons

c) Capacity for colonization

d) If the organism is pathogenic, allergenic, teratogenic or hormon mimicking to a humans which is immunocompetent

- diseases or disability caused and mechanism of pathogenicity including invasiveness and virulence
- communicability
- infective dose
- host range and possibility of alteration of hosts
- possibility of survival outside of human or other organisms
- vector or means of dissemination
- biological stability
- antibiotic-resistance patterns

- availability of appropriate therapies

5. Information relating to the conditions of release and the receiving environment

5.1 INFORMATION ON THE RELEASE

1) Description of the proposed deliberate release, including the purpose(s) and foreseen products
2) planned dates and durations of the release
3) Preparation of the site previous to the release
4) Size of the site
5) Method(s) to be used for the release
6) Quantities of GMO(s) or products thereof to be released
7) Disturbance on the site (type and method of cultivation, mining, irrigation, or other activities)
8) Worker protection measures taken during the release
9) Post-release treatment of the site
10) Techniques foreseen for elimination or inactivation of the GMO(s) or products thereof at the end of the experiment or use
11) Information on, and results of, previous releases of the GMO(s) or products thereof, especially at different scales and in different ecosystems

5.2 INFORMATION ON THE ENVIRONMENT

Information should be given both on the site and the wider environment. Note that in the case of GMOs or their products thereof destined to be used as food or feed or for processing, the environment includes the transportation routes and the market places as well as all the catchments and downstream areas.

1) Geographical location and grid reference of the site(s) of release
2) Physical or biological proximity to humans and other significant biota
3) Proximity to significant biotopes or protected areas
4) Size of local population
5) Economic activities of local populations which are based on the natural resources of the area

6) Distance to closest areas protected for drinking water and/or environmental purpose
7) Climatic characteristics of the region(s) likely to be affected
8) Geographical, geological and pedological characteristics
9) Flora and fauna, including crops, livestock and migratory species
10) Description of target and non-target ecosystems likely to be affected
11) A comparison of the natural habitat of the recipient or transformed organism with the proposed site(s) of release
12) Any known planned developments or changes in land use in the region which could influence the environmental impact of the release

6. Information relating to the interactions between the GMO(s) or products thereof and the environment

6.1 CHARACTERISTICS AND FACTORS AFFECTING SURVIVAL, MULTIPLICATION, GENE EXPRESSION AND DISSEMINATION

1) Biological features which affect survival, multiplication and dispersal of the GMO or products thereof
2) Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals etc.)

6.2 INTERACTIONS WITH THE ENVIRONMENT

1) Predicted habitat of the GMO
2) Studies carried out on the behaviour and characteristics of the GMO or products thereof and its ecological impact carried out in simulated natural environments, such as growth rooms, greenhouses etc.
3) Genetic transfer capability:

a) post-release transfer of genetic material from GMO or products thereof of the GMO into organisms in ecosystem(s) of the release site and its cathment and downstream area

b) post-release transfer of genetic material from indigenous organisms to the GMO(s)

4) Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMO or products thereof

5) Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal or transfer of genetic material. Methods to verify stability

6) Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including dispersal by wind or water inhalation, ingestion by, surface contact with or burrowinginto animals, etc.

7) Description of ecosystems to which the GMO or products thereof could be disseminated.

6.3 POTENTIAL ENVIRONMENTAL IMPACT

1) Potential for excessive population increase in the environment

2) Competitive advantage of the GMO or products thereof in relation to the unmodified recipient or parental organism(s)

3) Identification and description of the target organisms that are likely to be affected by the GMOs

4) Anticipated mechanism and result of interaction between the released GMO(s) or products thereof and the target organism

5) Identification and description of non-target organisms which may be affected indirectly.

6) Likelihood of post-release shifts in biological, or in host range

7) Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens

8) Known or predicted involvement in biogeochemical processes
9) Other potentially significant interactions with the environment

7. Information on monitoring, control, waste treatment and emergency response plans

7.1 MONITORING TECHNIQUES

1) Methods for tracing the GMO or products thereof, and for monitoring its effects
2) Specificity (to identify the GMO or products thereof, and to distinguish it from the donor, recipient orothe related organisms), sensitivity and reliability of the monitoring techniques
3) Techniques for detecting transfer of the introduced or chemically changed genetic material or protien to other organisms
4) Methods to detect aberrant gene expression

7.2 CONTROL OF THE RELEASE

1) Methods and procedures to avoid and/or minimize the spread of the GMO or products thereof beyond the site of release or the designated area for use
2) Methods and procedures to protect the site from intrusion by unauthorized individuals
3) Methods and procedures to prevent other organisms from entering the site

7.3 WASTE TREATMENT

1) Type of waste generated
2) Expected amount of waste
3) Possible risks
4) Description of treatment envisaged

7.4 EMERGENCY RESPONSE PLAN

1) Methods and procedures for controlling the GMO or products thereof in case of unexpected spread
2) Methods for decontamination of the areas affected, e.g. eradication of the GMO or products thereof
3) Methods for disposal or sanitation of plants, animals, soils, etc. that were exposed during the unexpected spread
4) Methods for the isolation of the area affected by the unexpected spread
5) Plans for protecting human health and the environment in case of the occurrence of an undesirable effect

8. ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING A COMMODITY CONSISTING OF GMOS OR PRODUCTS THEREOF ON THE MARKET

8.1 THE FOLLOWING ADDITIONAL INFORMATION SHALL BE PROVIDED IN THE NOTIFICATION FOR PLACING A COMMODITY ON THE MARKET:

1) Name of the commodity and name(s) of GMO(s) contained therein
2) Name and address of the maker and distributor of the GMOs or products thereof
3) Specification for accessing information on the GMOs or products thereof in the Biosafety Clearing House of the Cartagena Protocol on Biosafety
4) Type of expected use: food, feed or processing
5) Measures to take in case of unintended release or misuse
6) Specific instructions or recommendations for storage and handling
7) Proposed packaging. This must be appropriate so as to avoid unintended release of the GMO(s) or products thereof during storage, or transportation at a later stage

8) Proposed labelling. This must include, at least in summarized form, the information referred to in points A.1, A.2, A.3, A.5 and A .6

8.2 The FOLLOWING INFORMATION SHALL BE SHOWN CLEARLY ON EACH PACKAGE CONTAINING THE COMMODITY:

1) The words "This product contains GMO(s) or products thereof' whenever there is evidence of the presence of GMO(s)or products thereof in the commodity
2) A specification of the including
   - The scientific name
   - The common name, where available
   - The unic identification
3) The words "This product contain no GMOs" where the product is known to be free from GMOs and products there of.
4) Where applicable, further or as a qualification to C.1 or C.2, the words "This product contains genetic material (nucleic acids) from GMO(s)" or "This product is based on raw materials from GMO(s)"

10. Effective Date

This directive shall enter into force as of the---- day of 200….

Done at Addis Ababa, this ---- day of ------- 200….

Chairperson of the Environmental Council

DIRECTIVE No. TWO

DIRECTIVE ON RISK ASSESSMENT PARAMETERS OF GENETICALLY MODIFIED ORGANISMS (GMOS) OR PRODUCTS THEREOF

WHEREAS every transaction in GMOs or products thereof should be preceded by an appropriate risk assessment,

WHEREAS, identifying the key parameters is essential to harmonize and standardize the application of a risk assessment procedure in the country;

THEREFORE, this directive is issued in accordance with Article of the Biosafety Proclamation No. ----------

1. Designation

   This directive may be cited as ‘’Directive No. 02/ 2007 issued to determine Risk Assessment Parameters of genetically modified organisms and their products.

2. Transactions subject to these Directives

A transaction subject to these directives shall include any research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism or products thereof.

3. Directive on risk assessment parameters of Genetically Modified Organisms (GMOs) or products thereof

The user shall carry out an assessment prior to the use or release of GMOs or products thereof as regards the risks to human or animal health, biological diversity, the environment ethical values or cultural wellbeing’s of local community or the country. This assessment shall take the following parameters into consideration including any other parameter deemed to be relevant:

3.1CHARACTERISTICS OF DONOR AND RECIPIENT ORGANISMS OR PARENTAL ORGANISMS**:**

1) Scientific name and taxonomy;
2) Strain, cultivar or other name;
3) Species it is related to and degree of relatedness;
4) The degree of relatedness between the donor and recipient organisms

5) All sites from where the donor and recipient organisms wwere collected, if known
6) Information on the type of reproduction (sexual/ asexual) and the length of reproductive cycle and generation time, as well as the formation of resting and survival stages;
7) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
8) Phenotypic and genetic markers of interest;
9) Description of identification and detection techniques for the organisms, and the sensitivities of these techniques;
10) Geographic distribution and natural habitats of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts;
11) Climatic characteristics of original habitats;
12) Ability of the organisms to survive and colonize the environment to which release is intended or may accedentally occure;
13) Genetic stability of the organisms, and factors affecting the stability;
14) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;
15) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;
16) Pathogenicity to humans or animals, if any;
17) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;
18) Known allergenicity,terratogenecity or the mimicking of hormones, toxicity of biochemical and metabolic products;
19) Availability of appropriate therapies for pathogenicity, allergenicity toxicity and mimicking of hormones.

3.2 CHARACTERISTICS OF THE CONSTRUCTS USED VECTOR(S), PROMOTER(S), TERMINATOR(S), MARKER GENE(S)

1) Nature and source of the vector(s);

2)Genetic map of the vector(s), position of the gene(s) inserted, other coding and non-coding sequences that may affecti the expression of the gene(s), marker gene(s); promotor(s) and termintator(s)

3)Ability of the vector(s) to mobilize and transfer genes by integration and methods for determining the presence of the vector(s);

4)History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

5)Potential for pathogenicity and virulence, allergenecity, terratogenecity and the mimicking of hormones in humans and animals;

6)Natural and host range of vectors;

7)Natural habitat and geographic distribution of natural and potential hosts;

8)Potential impacts on the environment;

9)Measures for counteracting adverse impacts;

10) Potential to survive and multiply in the environment, or to form genetic recombinants;

11) Genetic stability of vector(s), such as hypermutability.

3.3 CHARACTERISTICS OF GENETICALLY MODIFIED ORGANISM:

1)The description of the modifications;

2)The function of the genetic modifications including any new insert, marker gene(s);

3)Purpose of the modification and intended use in relation to need or benefit;

4) Method of modification, and in case of transgenic organisms, the methods for constructing inserts and for introducing them into the recipient organism;

5)Whether introduced gene(s)has (have)been integrated or is (are) extrachromosomal;

6) Number of insert(s), position(s) in the host genome, and its/their structure(s), for example, the copy number whether in tandem or other types of repeats;

7) Product(s) of the induced change(s), or trnsfered gene(s), levels of expression and methods for measuring experssion;

8) Stability of the introduced gene(s) or introduced gene(s) whether expressed or not , structure(s) and site(s) of modification or integration;

9) Biochemical and metabolic differences of genetically modified organism compared with its unmodified counter part;

10) Probability of vertical or horizontal gene transfer to other species;

11) Probability of modification(s), insert(s), to generate pathogenic recombinants with endogenous viruses, plasmids or bacteria;

12) Allergenicities, toxicities, pathogenicities, mimicking hormons and unintended effects;

13) Autecology of the genetically modified organism compared with that of its unmodified counter part;

14) Susceptibility of the genetically modified organism to diseases and pests compared with its unmodified counter part;

15) Detailed information on past uses including results on all experiments leading to previous releases.

3.4 CHARACTERISTICS OF RESUSCITATED ORGANISM(S) AND GENE(S) AND FOSSIL DNA SEQUENCES:

3.4.1. Resuscitated organism

1) Scientific name and taxonomy;
2) Identity of nearest living (i.e. non- extinct) species and their characteristics which are of relevance to the intended use;
3) Site at which it was found;
4) Method used for resuscitation;
5) Purpose of resuscitationand the organism and benefits, if any;
6) Impacts on human and animal health and the environment;
7) Measures for counteracting adverse impacts;
8) Length of time the organism has been in use;
9) Genetic stability;
10) Likelihood of gene transfer to other organisms;
11) Fossil nearest relative species;

12) Biological and biochemical differences from related living species;

13) Information on previous uses since resuscitation.

3.4.2. DNA sequences from fossils or from resuscitated organism

1) Scientific name and taxonomy of the species whether resuscitated or a fossil;
2) Site of origin of the fossil;
3) Site of the gene in the resuscitated genome, if known;
4) Base sequence of the extracted gene;
5) Method used in extracting the gene;
6) Function of the genes, if known;
7) Purpose of use and benefits, if any;
8) Environment in which it lived before fossilization;
9) Fossil species related to the species from which the gene was taken;
10) Living species related to the species from which the gene was taken.

3.5 SAFETY CONSIDERATIONS FOR HUMAN AND ANIMAL HEALTH:

Information on the genetically modified organism and when it is genetically engineered using recombinant DNA technology, information on the donor and recipient organisms as well as the vector including before it was disarmed or disabled, marker genes, promoter(s), and terminator(s) regarding:

1) Capacity for colonization;
2) If the genetically modified organism is pathogenic to humans or animals the following information is required:
    a) diseases caused and mechanism of pathogenicity, including invasiveness and virulence;
    b) communicability;
    c) infective dose;
    d) host range and possibilities of using new host;
    e) ability to survive outside of the human or animal host;

f) the existence of vectors or other means of transmission;

g) biological stability;

h) allergenicity, toxicity, phatogenecity, mimicking hormones and other impacts

i) availability of appropriate therapies.

3.6 ENVIRONMENTAL CONSIDERATIONS:

Information on the genetically modified organism, and when it is genetically engineered, using recombinant DNA technology, information on the donor and recipient organisms as well as the vector including before it was disarmed or disabled, marker gene(s), promoter(s), terminator(s) regarding:

1) Factors affecting the survival, reproduction and spread in the environment;
2) Available techniques for detection, identification and monitoring
3) Available techniques for detecting transmission of genes to and from;
4) Known and predicted habitats;
5) Description of the ecosystems which could be affected by accidental release;
6) Possible interactions other organisms which might be affected by accidental release into the environment;;
7) Known or predicted effects on plants or animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, colonization, other impacts;
8) Possible involvement in biogeochemical processes;
9) Availability of methods for decontamination of the area in case of accidental releases;
10) Effects on agricultural practices;

3.7 SOCIO-ECONOMIC CONSIDERATIONS:

Anticipated changes in the existing social and economic patterns resulting from the introduction of the genetically modified organism or product thereof marker gene(s), promotore(s), and terminator(s)

1) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;
2) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies with the GMO or products thereof;;

3) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected;

4) Possible countries and/or communities out side of Ethiopia to be affected in terms of disruptions to their social and economic welfare;

5) Possible effects within Ethiopia in the other neighboring countries which are contrary to the social, cultural, ethical and religious values of communities.

4. Effective Date

This directive shall enter into force as of the---- day of 200….

Done at Addis Ababa, this ---- day of ------- 200….

Chairperson of the Environmental Council

DIRECTIVE nO. THREE

A DIRECTIVE ISSUED TO DETERMINE THE PROCEDURES FOR RISK MANAGEMENT

WHEREAS it is important to design a risk assessment plan to deal with emergency situations in any transaction involving GMOs or products thereof,

WHEREAS it is essential to set the minimum requirements to be fulfilled when designing a risk management plan,

THEREFORE, this directive is issued in accordance with Article of the Biosafety Proclamation No. ----------

i. Designation

This directive may be cited as ‘’Directive No. 03/ 2007 issued to determine the Procedures for Risk Management.

2. Transactions subject to these Directives

A transaction subject to these directives shall include any research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism or products thereof.

3. Procedures for risk management

The user shall employ the following risk management schemes and procedures from the development, through all stages of testing of the genetically modified organism or the product thereof, to its intended use or commercialization.

3.1) Imported products of genetically modified organisms used for human or animal health (e.g. antibodies, drugs and hormones):

a) Observation to ensure that changes in food habits, nutrition and other factors that could conceivably modify the expected impacts are insignificant;

b) Such observation can be limited in scope when it is shown that adequate trials on the specific products have been made on humans or animals, as appropriate, in other countries.

3.2) Genetically modified microbial organisms imported for human and animal health:

Besides the limited observation specified in 1, experiments shall be carried out to evaluate viability and risks of reacquiring virulence or lending virulence to other micro-organisms when in the body and in the environment, since some spilling is inevitable.

3.3) Genetically modified organisms imported for contained use:

i) The products of genetically modified organisms will be treated as in paragraph 1;

ii) Experiments will be made in complete laboratory containment to determine:

a) longevity of the genetically modified organism in cases of unintended release in the premises and in the surrounding environment, and

b) genetic transfer into other micro-organisms or other organisms and implications thereof on human and animal health and the environment; and

c) Methods for counteracting adverse impacts resulting from unintended releases should be specified.

3.4 Products of genetically modified organism made locally:

a) Trials on experimental animals will be made when the product of the genetically modified organisms is intended to be used on humans; when these are all successful, trials on fully informed volunteers will be carried out.

b) In all other cases, trials will be made on the species for which the product of the genetically modified organism has been designed.

3.5) Genetically modified organisms made locally to be used as pharmaceuticals for human or animals:

a) Initials molecular, tissue culture, serological and other related studies shall be made in the laboratory in complete containment;

b) Trials with experimental animals under strict containment shall be made;

c) Experiments in complete containment to evaluate the extent of chemical change in nucleic acids or protiens or the transfer of genes of the vector introduced or of other genes through the agency of the vector to the GMOs or to other species which will be found in association;

d) Trials on animals completely contained isolated from other individuals within their species and within species which are known to be

susceptible to the chemical changes to the nucleic acids or protiens or to be recepients of the genes in the GMO;

e) Statistically valid trials in conditions in which the that has the pharmaceutical used on them live in their communities.

3.6) Genetically modified plant or microbial organisms imported for release:

a) The reports from releases in areas outside of Ethiopia shall be thoroughly evaluated by the Environmental Protection Authority. Particular emphasis shall be given as to whether the applicable regulations in the previous release have been adequate to ensure safety;

b) If the regulations mentioned in Subparagraph (a) of this paragraph have not been found adequate, the Environmental Protection Authority will decide at which step in Paragraph 8 the observations should begin;

c) If it is decided that the previous release mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;

d) The observations will include on the health of the GMO, the health of the target organism within the area of limited release, and the biological diversity and the ecology of the area;

e) Nationally approved limited field releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

3.7) Genetically modified animal organisms imported for release:

a) The reports from releases in areas outside of Ethiopia shall be thoroughly evaluated by the Environmental Protection Authority. Particular emphasis shall be given as to whether the applicable regulations in the previous releases have been adequate to ensure safety;

b) If the regulations mentioned in Sub paragraph (a) have not been found adequate, the Environmental Protection Authority shall decide at which step in item 9 the observations should begin;

c) If it is decided that the regulations used in the previous releases have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;

d) When the results have met the stated requirements, then a trial release may be authorized with adequate emergency plans put in place to deal with cases of escape.

3.8) Genetically modified plant or microbial organisms produced locally for eventual release:

a) The maximum volume of any solution which is a medium of any microorganisms that are physically and chemically isolated shall be 500 ml if it is to be considered as being under contained use. The maximum area of solid meduim on which any microorganisms to have been plated shall be 2500cm^2 if it is tb considered as being under contained use.

b) Laboratory biomolecular experiments on chemical changes to nucleic acids and associated protiens or, as the case may be, on transformation or resuscitation and other phenomena will be carried out in complete containment;

c) Tissue culture experiments to develop the genetically modified organism, when required, will be carried out in complete containment;

d) Observations aimed at understanding the nature of the GMO shall be carried out in complete containment;

e) Experiments with the soil, soil micro-organisms, plant and animal species, under the environmental conditions of the area of intended release, will be carried out in complete containment;

f) Complete observations of the interactions of the GMO with the environment (soil including micro-organisms and terrestrial communities) will be made in enclosed fields but not fully contained. At the end of the experiment, the products of the genetically modified organisms may be used on an experimental basis, otherwise they shall be destroyed;

g) The product from the genetically modified organism shall be subjected to the procedure in paragraph 4;

h) The monitoring of the spread and behaviour of any released genetically modified plant or micro-organism shall continue for at least 150 years in the case of trees, and for at least 30 years in the case of annuals and micro-organisms, the duration for perennials which live shorter than trees being in between. The user who was responsible for releasing the GMOs or his or her or its successor shall provide annual reports to the Federal Environmental Protection Authority.

3.9) Genetically modified animals produced locally for eventual release:

The maximum volume in which the animal is living physically and chemically isolatedshall not exceed 100 times its own volume when adult if it is considered to be under contained use. In the casees of mixtures of animal species, that maximum volume shall not exceed 500 times that of the largest adult.

a) Laboratory biomolecular experiments on chemical changes to nucleic acids and protiens or, as as the case may be, on transformation (or resuscitation) will be carried out in complete containment;

b) Methods of incubating the transformed generative cell or the resuscitated animal will be carried out in complete containment;

c) The rearing of and observations on the GMO will be carried out under complete containment;

d) The GMO shall be observed under complete containment in an experimental environment which simulates the intended area of release in climatic, microbial, animal and plant communities. The observations shall include the condition of the genetically modified animal and those of its micro-organisms, especially in the context of nucleic acid and protien chemical change or of gene transfer and those of the microbial, plant and animal communities in the experiment, again including nuceic acid and protein chemical change or of gene transfer;

e) A limited release will be carried out in an area with appropriate enclosure and emergency measures put in place to prevent escape. Observations will include the condition of the genetically modified animal, its micro-organisms focusing on chemical chenges to nucleic acids and proteins and on gene transfer, and the ecology of the microbial, plant and animal communities in the area, again including chemical changes to nucleic acids and proteins and on gene transfer;

f) If the animal is intended to yield a product, the regulation of the product will follow the procedure in paragraph 4;

g) The monitoring of the spread and behaviour of any released genetically modified animal will continue for at least 30 years.

3.10) General Requirements:

a) All trials, experiments or observations specified in all the above cases (1-9) have been written in their logical sequence and progress to the highst level shall be subjected to an approval by the Federal Environmental Protection Authority.

b) Experiments starting from changes to nucleic acids or proteins or from transformation of living organisms or resuscitation of fossil organisms carried out under completely contained laboratory conditions and continuing in the development of a GMOs or products thereof shall be subject to approval by the Federal Environmental Protection Authority.

c) Once approval from the the Federal Environmental Protection Authority is has been obtained at the completion of the final stage of the trials, experiments or observations, the GMO in question or the product thereof can be put to its intended use.

d) Whenever there is a need to dispose of the GMO or product thereof upon the completion of any trial or experiment, it shall be made through complete incineration or other means of complete destruction approved by the Federal Environmental Protection Authority.

e) The release of GMOs or products thereof shall be monitored appropriately and emergency plans to prevent escape and accident shall always be in place.

3. Effective Date

This directive shall enter into force as of the---- day of 200….

Done at Addis Ababa, this ---- day of ------- 200….

Chairperson of the Environmental Council

DIRECTIVE No. FOUR

A DIRECTIVE ISSUED TO DETERMINE THE PROCEDURES FOR THE APPLICATIONS OF THE TRANSPORT OF GENETICALLY MODIFIED ORGANISMS OR PRODUCTS THEREOF BY ROAD

WHEREAS it is deemed important to determine the essentials of an application for transporting Genetically Modified Organisms or products thereof by road to avert any possible risk that may occur.

THEREFORE, this directive is issued in accordance with Article of the Biosafety Proclamation No. ----------

1. Designation

This directive may be cited as ‘’Directive No. 04/ 2007 issued to determine the Procedures for the for the application of the transport genetically modified organisms or products thereof

2. Transactions subject to these Directives

A transaction subject to these directives shall include any research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism or products thereof.

3. A DIRECTIVE FOR THE APPLICATION OF TRANSPORT OF GENETICALLY MODIFIED ORGANISMS (GMOs) OR PRODUCTS THEREOF BY ROAD

In order to be engaged in transport action of GMOs, or products thereof, a driver shall be licensed and certified in accordance with the procedures and requirement to be established by the concerned licensing agency and the Federal Environmental Protection Authority

3.1 When licensing and registering drivers, the competent authority responsible for transport may limit the number of drivers that will be registered to transport GMOs or products thereof and shall require such drivers to carry adequate insurance to cover any harm to human health or the environment that may result from an accidental release of any GMOs or products thereof, that are being transported by road.

3.2 The competent authority responsible for transport will only issue a license once the driver has satisfactorily passed an established training programme on the handling and transportation of GMOs and products thereof, which shall undertaken every two years.

3.3 When it is satisfied that a GMO or products thereof cannot cause any risk to human or animal health or the environment, the Federal Environmental Protection Authority may exempt any GMO or products thereof, from these procedural

requirements on transportation. Such exemption shall, whoever, not override any requirements that any competent Regional Environmental Agency may impose within that Region.

4. **APPLICATION INFORMATION**

4.1 Any person who wishes to transport any genetically modified organisms shall apply in writing to the competent authority responsible for transport as well as to the Federal Environmental Protection Authority

4.2 Any application for a permit that is submitted under shall contain Sub Article 1 shall contain:

(a) a full and accurate description of the genetically modified organisms or products thereof, to be transported, including the technical and common names;

(b) A statement of the quantities to be transported;

(c) The name and location of the place from where the genetically modified organisms or products thereof are to be transported; and

(d) The name and location of the place to which the genetically modified organisms or products thereof are to be transported.

4.3 Upon receipt of any application to transport GMOs or products thereof in contained use, the Federal Environmental Protection Authority shall verify that the location to which the GMOs or products thereof, are to be transported is, as appropriate, an area for contained use, and thereafter may refuse permission for intended transportation or issue a permit which may or may not specify conditions.

4.4 Any route specified should, where practicable be planned to minimize risk to human health and the environment.

4.5 If any requirement or conditions contained in an authorization are not strictly compiled with, the competent authority responsible for transport may issue such directions as may be considered appropriate for immediate cessation of the transportation of the GMOs or products thereof

4.6 Within seven days of issuing any permit, the competent authority responsible for transport shall inform this to the authority, which shall lodge a copy of the permit with the National Biosafety Clearing House.

4.7 The competent authorities responsible for transport will carry out inspection of drivers and vehicles to ensure compliance with any permit, standard and procedures and for this purpose is empowered to execute spot checks to ensure compliance with any such requirement.

4.8 Any driver convicted, in addition to any other penalty imposed, may be prohibited from transporting genetically modified organisms or products thereof, for five years.

4.9 The driver who is to transport GMOs or products thereof, upon receiving the document specified above, inspects the load and documentation to ensure that the consignment complies with the description contained in the documentation.

4.10 All GMOs or products thereof in transit by road must be secured with load restraint to prevent movement of the load during normal operating conditions.

4.11 In the event of any spill or accident during the transportation of any GMOs or products thereof by road, it shall be the responsibility of the driver to:

(a) Secure the area around the vehicle or spill;

(b) Determine whether emergency services are to be called;

(c) Assess the situation and react in an appropriate manner; and

(d) Immediately notify the consigner the consignee and the competent authority responsible for the transport and the Federal Environmental Protection Authority of the nature of the spill or accident.

5. DOCUMENTS ACCOMPANYING THE TRANSPORT OF GMOS OR PRODUCTS THEREOF

5.1 All GMOs or products thereof that are transported, imported, or exported shall be accompanied by authorization issued by the Federal Environmental

Protection Authority, which shall, at all times, be available for inspection by any inspector.

5.2 The accompanying documentation shall, as a minimum, contain the following particulars:

(a) Name and address of the shipment;

(b) Name of the organism;

(c) The number and type of packages and the total quantity covered by the description;

(d) Additional Handling Information, including the control and emergency measures and any other information necessary to ensure that the substance will be segregated correctly and to indicate additional precautions that must be taken;

(e) The addresses of the consignor and consignee, and contact phone number;

(f) A Consolidated Package Certificate for Dangerous Goods, containing information about the package of GMOs or products thereof, for goods carried in bulk;

(g) A Load Plan, stating where the genetically modified organisms are located on the aircraft or vehicle, which must be singed by the person loading the goods; and

(h) An Emergency Procedure Guide, providing information concerning emergency procedures those are to be employed in the event of any accidental release or other emergency.

5.3 The information specified in Article 2 of this directive shall be presented in one of the following forms as appropriate.

6. Effective Date

This directive shall enter into force as of the---- day of 200….

Done at Addis Ababa, this ---- day of ------- 200….

Chairperson of the Environmental Council

DIRECTIVE NO. five

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

WHEREAS the storage of Genetically Modified Organisms and products thereof need to follow environmentally acceptable steps to avoid any harm to human or animal health or the environment occurring as a result of the use of poorly managed storage facilities,

THEREFORE, this directive is issued in accordance with Article of the Biosafety Proclamation No. ----------

a. Designation

This directive may be cited as ‘’Directive No. 05/ 2007 issued to determine the Procedures for the storage of genetically modified organisms”

2. Transactions subject to these Directives

A transaction subject to these directives shall include any research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism or products thereof.

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

3.1 Only licensed and registered facilities shall store or process any GMOs or products thereof.

3.2 The Federal Environmental Protection Authority, in consultation with the agency responsible for health and labour affairs, will undertake licensing and registration of premises for the storage of GMOs and products thereof and for this purpose may establish:

(a) Standards pertaining to the storage or processing of GMOs and products thereof

(b) Procedures and requirements for the licensing and registration of premises;

(c) Requirements for the training of employees in the safe handling of GMOs and products thereof

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

3.4 The person in charge of any premises that is to be used for the storage or processing of any GMO or products thereof shall apply in writing to the Federal Environmental Protection Authority for permission to use such premises for such a purpose.

3.5 Any application for a permit to store GMOs or products thereof shall contain:

(a) A full and accurate description of the GMOs or products thereof that is to be stored or processed, including technical and common name;

(b) A statement of the quantities of GMOs or products thereof to be stored or processed and the duration of such storage;

(c) The name and location of the place where the GMOs or products thereof to be stored or processed;

(d) A description of the processing that is to be undertaken on GMOs or products thereof;

(e) A copy of the risk management scheme and emergency measures that operate within the facility.

3.6 Upon receipt of any application to store or process GMOs or products thereof the Federal Environmental Protection Authority shall inspect the premises to determine if:

(a) Adequate facilities exist for the safe storage or processing of the specified GMOs or products thereof;

(b) Adequate security, segregation and safety measures exists at the premises; and

(c) Employee training in the management of GMOs and products thereof has been undertaken.

3.7 Up on completion of any inspection undertaken the Federal Environmental Protection Authority shall:

a) Issue a permit without conditions;

b) Issue a permit, which may specify conditions;

c) Refuse permission for the storage or processing of GMOs and products thereof.

3.8 Any permit issued shall contain information regarding:

(a) The name and location of the place where the GMOs or products thereof to be stored or processed;

(b) Full and accurate description of the GMOs or products thereof that are to stored or processed including technical and common names;

(c) A statement of the quantities to be stored or processed, and the duration of such storage or processing;

(d) Any special risk management measures pertaining to any GMOs or products thereof that is to be stored or processed.

3.9 The Environmental Protection Authority may for just cause, at any time, cancel the permit that has been issued under this article if any requirement conditioned contained in a permit is not strictly complied with, order the immediate cessation of the storage or processing of the GMOs or products thereof as may be considered appropriate.

3.10 Within seven days of issuing any permit under this article the Federal Environmental Protection Authority shall loge a copy of the permit with the National Biosafety Clearing -House

3.11 Any premises used for the storage or processing of GMOs or products thereof must ensure that all such GMOs or products thereof in the premises are packed, labeled and segregated.

3.12. The person in charge of any premises used for the storage or processing of GMOs or products thereof shall

a) Ensure that GMOs or products thereof in storage areas or processing areas are secured against unauthorised access;

b) Maintain data sheets on any GMOs or products thereof stored or processed on the premises and shall ensure that these sheets are readily accessible for inspection and in the event of an emergency;

c) Ensure that emergency procedures that are to be employed in the event of any accidental release or other emergency are realized;

d) Ensure that a daily inspection is undertaken by a responsible person of the GMOs or products thereof stored in the premise is under taken by a responsible person to assure no accidental release or leakage is occurring

3.13 Notwithstanding the provisions of this the Ministry of Labour and Health will carry-out inspections of premises to ensure compliance with any permit, standard and procedures established herein and for this purpose is empowered to execute spot checks to ensure compliance with any of such requirements.

4. Effective Date

This directive shall enter into force as of the---- day of 200….

Done at Addis Ababa, this ---- day of ------- 200….

Chairperson of the Environmental Council

DIRECTIVE No. SIX

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

WHEREAS it is important to give prompt and direct response to an accidental release of Genetically Modified Organisms products thereof,

THEREFORE, this directive is issued in accordance with Article of the Biosafety Proclamation No. ----------

1. Designation

This directive may be cited as ‘’Directive No. 08/ 2005 issued to determine responses to accidental release of Genetically Modified Organisms”

2. Transactions subject to these Directives

A transaction subject to these directives shall include any research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism or products thereof.

3. EMERGENCY MEASURES

3.1 The Federal Environmental Protection Authority shall, in order to be ready to give direct response to any accidental release of GMOs or products thereof establish an Accidental Release Response Group.

3.2 The Accidental Release Response Group shall comprise representatives from relevant institutions capable of undertaking risk management measures.

3.3 The Federal Environmental Protection Authority shall appoint a leader, who shall direct the activities of the Accidental Release Response Group and for this purpose shall have the powers and responsibilities provided under this Directive.

3.4 The duties and functions of the Accidental Release Response Group shall be to:

a) Develop appropriate systems for the detection and reporting of accidental releases of any GMOs or products thereof or of incidents related to the transport and use of GMOs or products thereof which could result in such accident;

b) Ensure that prompt response is made in the event of an accidental release of any GMOs or products thereof to prevent damage to biodiversity, the environment or human health.

c) Ensure that the correct response techniques and risk management measures are used in the event of an accidental release of any GMO or products thereof and that the disposal of recovered GMOs or products thereof is carried out in an environmentally sound manner;

d) Ensure that complete and accurate records are maintained regarding all the expenditures incurred in responding to the event of an accidental release of any GMOs or products thereof to facilitate cost recovery and the payment of compensation;

e) Provide adequate protection for public health and the protection of the environment in the event of an accidental release of any GMOs and products thereof;

f) Ensure the prompt and efficient mobilization of available manpower, resources, equipment which will be used in the event of an accidental release of any GMOs and products thereof; and

g) Develop, implement and keep under review a national risk management plan.

3.5 The Accidental Release Response group leader shall co-ordinate emergency preparedness and response measures, and for this purpose shall use available resources to develop and implement a National Accidental Release of GMOs Risk Management Plan, establish such communications with stakeholders as are necessary to ensure the efficient administration and control of all emergency preparedness when any accidental release of GMOs and products thereof has occurred.

3.6 The Accidental Release Response Group shall be the sole authority responsible for response to any accident, and shall direct the activities of agencies or parties that may offer assistance in the event of an accident.

3.7 The Accidental Release Response Group shall meet at such times and with such frequency as may be necessary to fulfill the duties and responsibilities required, which in any event shall not be less than every six months.

4. Effective Date

This directive shall enter into force as of the---- day of 200….

Done at Addis Ababa, this ---- day of ------- 200….

Chairperson of the Environmental Council