Food Security and Biotechnology in Africa

This project is financed by the European Union and implemented by the ACP Secretariat

Module 4
REGULATION AND POLICY APPROACHES TO BIOTECHNOLOGY

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1. Module contents

- **Unit 1: Cartagena protocol and regulation frameworks for biotechnology**
- Unit 2: Some relevant International regulation regimes for biotechnology
- Unit 3: Risk and Safety approaches toward biotechnology
- Unit 4: The practice of dealing with risks by biotechnology
- Unit 5: Consumer rights and labeling
- Unit 6: Politicization, scientization, and democratization in the debate on biotechnology

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Objective of module 4

To provide students with a broad understanding of international policy and regulation regimes including other agreements that govern the use of biotechnology and how these offer the framework for the development of national biosafety systems and to also expose students to various issues underlying the use and management of biotechnology

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4.1 Unit 1 Cartagena Protocol and Regulation Frameworks for Biotechnology (5 Hours)

For details see the correponding course notes

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flame of knowledge and innovation

Outline of Unit 1

- Objectives
- Cartagena Protocol
- The US Regulations
- The EU Regulations
- The African Regulations

Objectives of Unit 1

- Provide insight into similarities and differences in international regulatory regimes
- Provide understanding of how the regulatory regimes inform and shape formulation of biosafety laws
- Determine the effectiveness of the laws in regulating Biotechnology

History

1992 (May)- Convention on Biological Diversity was finalized in Nairobi

1992 (June)- Convention on Biological Diversity signed at Rio de Janeiro

1993 (December)- Convention on Biological Diversity convention entered into force

CBD Convention

- The main international instrument for addressing biodiversity issues.
- Provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of genetic resources

CBD Convention

- Biosafety addressed
- Biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology

CBD Convention

- **November 1995 - the Conference of the Parties (COP) to the Convention:**
  - Established an open-ended Ad-Hoc Working Group on Biosafety to develop a draft protocol on biosafety which would focus specifically on transboundary movement of any LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.
  - 29 January 2000 - Cartagena Protocol on Biosafety to the CBD signed in Montreal

Purpose of the Cartagena Protocol

- Provides international regulatory framework
- Reconciles the respective needs of trade and environmental protection with respect to the biotechnology industry
- Enables environmentally sound application of biotechnology
- Helps to maximize benefits from biotechnology;
- Helps to minimize risk to environment and to human health

The Cartagena Approach

- **Precautionary**
  - Ensures an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation
  - Takes into account risks to human health
  - Focuses on transboundary movements

Cartagena Issues

- **Pharmaceuticals**
  - Exception of LMO”s which are drugs
- **Transit and contained use**
  - With respect to Advanced informed agreement (AIA) the protocol does not apply to LMOs
  - LMO’s must be subject to risk assessment before import

Cartagena Issues

- **Advanced Informed Agreement Procedure**
  - Applies prior to 1st international transboundary movement of LMO”S
  - Exception LMO’s directly used for food and feed
  - Does not apply if LMO does not cause adverse environmental or human health effects

Cartagena Issues

- **Bilateral, Regional and Multilateral agreements and arrangements:**
  - Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of LMO's

Cartagena Issues

- **Biosafety Clearing-House (BCH)**
  - BCH is an information exchange mechanism established under the aegis of Cartagena Protocol on Biosafety
  - It facilitates sharing of information on, and experience with LMOs
  - It serves as a "one-stop shop" where users can readily access or contribute relevant biosafety-related information

Cartagena Issues

- **Risk assessment**
  - Following standard procedures

Cartagena Issues

- **Handling, Transport, Packaging and identification**
  - LMO's should be handled, packaged and transported under conditions of safety in accordance with relevant international rules and standards

Cartagena Issues

- **Competent National Authorities and National Focal Points**
  - Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat

The US Regulations

- Biotechnology derived (BD) products are regulated under same frameworks that govern health, safety, efficacy, and environmental impacts of similar products derived by more traditional methods
- Federal policy - no new laws were needed to regulate BD products (adopted 1986)

The US Regulations

- **Main basis for policy**
  - process of production posed no unique or special risk.
  - commercial product, regardless of its manner of production, regulated based on the product's composition and its intended use.

The US Regulations

- **Further**
  - microbial pesticides developed from biotechnology would be regulated in the same manner as other microbial pesticides.
- **Note**
  - no single statute and no single federal agency govern the regulation of biotechnology products.

The US Regulations

- **Span of BD products covered by the regulations include:**
  - wide range of foods,
  - animal feeds
  - human and animal drugs
  - Chemicals
  - biologics
  - pesticides
  - plant pests, and
  - toxic substances

The US Regulations

- **Federal agencies responsible for regulation include:**
  - the Food and Drug Administration, (FDA)
  - the Department of Agriculture, (USDA)
  - the Environmental Protection Agency (EPA)

The US Regulations

- **FDA**
  - safety of food and animal feed, and
  - safety and efficacy of human drugs and biologics, and animal drugs

The US Regulations

- **Four (4) centers within the FDA**
  - the Center for Food Safety and Applied Nutrition (CFSAN)
  - the Center for Veterinary Medicine (CVM)
  - the Center for Drug Evaluation and Research (CDER), and
  - the Center for Biologics Evaluation and Research (CBER)

The US Regulations

- **EPA responsibility**
  - use of pesticides and
  - setting allowable levels (tolerances) of pesticide residues in food, and for the regulation of non-pesticidal toxic substances, including microorganisms

The US Regulations

- **USDA responsible:**
  - for the safety of meat, poultry and egg products
  - for regulating potential agricultural plant pests and noxious weeds
  - for the safety and efficacy of animal biologics
  - Within USDA
    - the Animal and Plant Health Inspection Service (APHIS) is responsible for biotechnology regulation and for the Food Safety and Inspection Service (FSIS)

The US Regulations

- **At least ten different laws and numerous agency regulations and guidelines cover BD products**
  - The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) - (EPA)
  - The Toxic Substances Control Act (TSCA) - (EPA)
  - The Food, Drug and Cosmetics Act (FFDCA) - (FDA) and EPA)
  - The Plant Protection Act (PPA) - (USDA)
  - The Virus Serum Toxin Act (VSTA) - (USDA)
  - The Public Health Service Act (PHSA) - (FDA)

The US Regulations

- The Dietary Supplement Health and Education Act (DSHEA) - (FDA)
- The Meat Inspection Act (MIA) - (USDA);
- The Poultry Products Inspection Act (PPIA) - (USDA)
- The Egg Products Inspection Act (EPIA) - (USDA) and
- The National Environmental Protection Act (NEPA)

The US Regulations

- **Challenges**
  - fitting biotechnology products into precise product categories
    - E.g. crop plants that were genetically modified to make their own pesticide
      - This may simultaneously be a plant pest, a food, and a pesticide.
- E.g. animal could be genetically engineered to make a protein in its milk that can be extracted to create a medical drug or diagnostic
- E.g. a food plant could be altered to make proteins that could be extracted to make industrial chemicals.

The US Regulations

- As a result EPA has develop new regulations specifically applicable to “plant-incorporated protectants”
- In general, agencies have developed a number of regulations and guidelines that address the application of existing laws to BD products

The EU Regulations

Background

- EU is food secure and is net exporter of food commodities
- Globally, by 2009 134 MHa of arable land grew transgenic crop while in Europe only 0.1 MHa was covered (Total Arable land in Europe 101 Mha)
- EU has achieved strong performance in farming sector as a result of Common Agricultural Policy (CAP). Factors of production esp. labor have been optimized

The EU Regulations

- Implemented by European Food Safety Authority (EFSA)
- EFSA severely limits the cultivation and import of GMO crops , food, and feeds
- By 2011, the EU regulations had only allowed three events of approval for cultivation GM crops i.e. Maize MON810, maize HT T25 and potato EH92-527-1 (BASF Amflora)

The EU Regulations

- Products derived from or containing GMOs are strictly controlled with a zero tolerance for unauthorized GMOs.
- Authorization is given after a thorough risk assessment processe and availability of a validated method for detecting, identifying, and quantifying the GMO in food or feed
- Method for detection is validated by Joint Research Center (JRC) based in Institute for Health and Consumer Protection in Ispra, Italy

The EU Regulations

- EU policy on GMO respects the consumer's right-to-know by ensuring clear labeling and traceability of GMOs
- Critical threshold for labeling is 0.9%
- GMO analysis is based on the detection of known DNA sequences (targets) that are characteristic for GMOs in raw materials (seed, plant tissue) or in food or feed products
- JRC develops, produces and distributes certified reference materials (CRMs) for use in the analyses

The African Regulations

Regulation of GMO in Africa

- Modern biotechnology is associated with potential for resolving constraints ranging from
  - inherently low crop yield to
  - stress related issues ranging from pests, diseases and drought
- Major concern about GM technology in Africa
  - safety,
  - ethical and
  - trade-related issues
- Concern to the consumers and the environment

The African Regulations

- Most countries in Africa have ratified the CBD and the Cartagena Protocol on Biosafety
- Thus obligations of such countries include:
  - Having appropriate legal, administrative and other measures to ensure safe handling of LMO's
  - Reduction of risks to biological diversity and human health through the National Biosafety Frameworks (NBFs)

The African Regulations

National Biosafety Frameworks

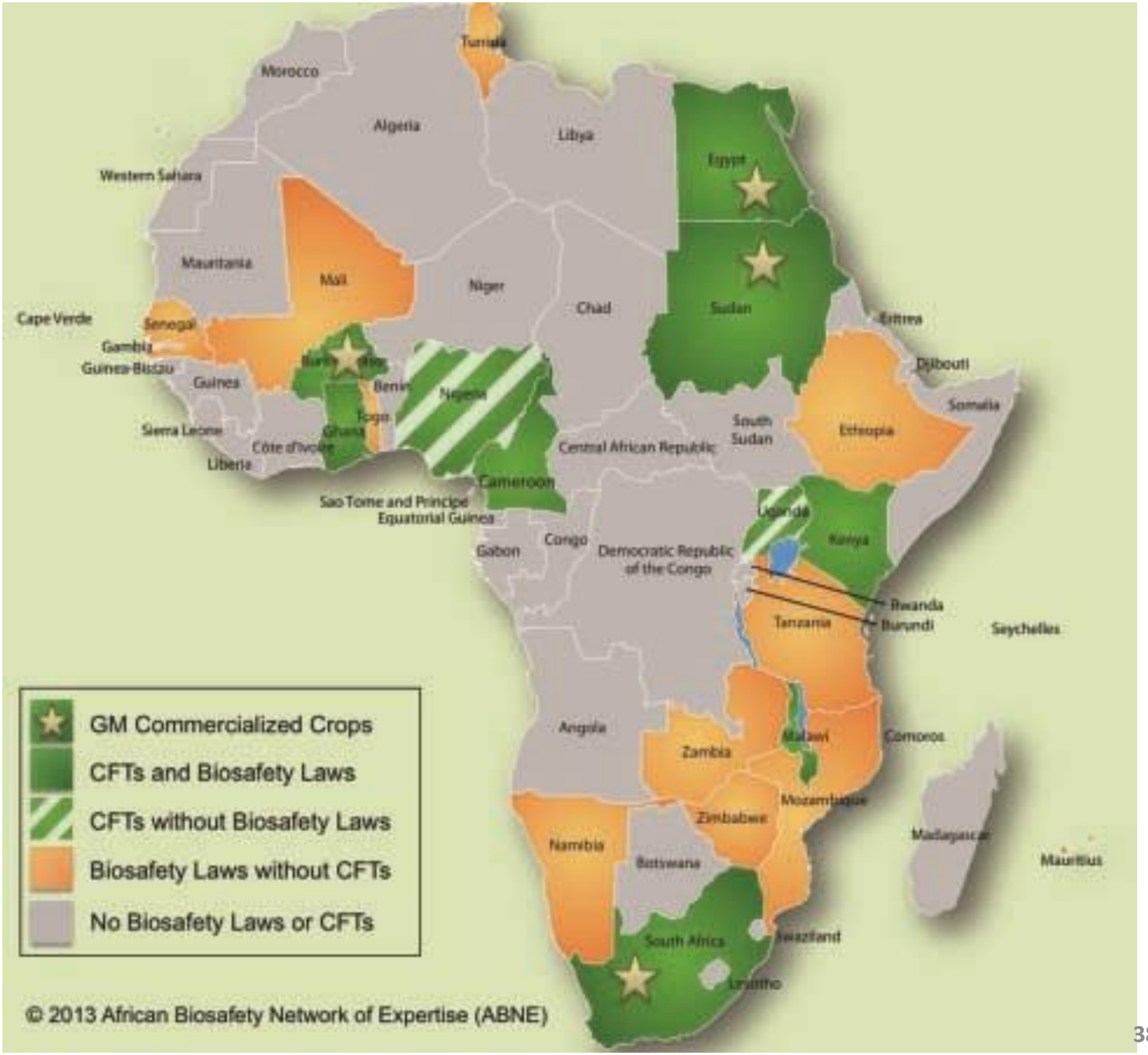
What is required?

- A policy on biotechnology
- Laws and regulations on biosafety constituting a regulatory regime for biotechnology,
- An administrative system for handling applications and issuance of permits and
- A mechanism for public participation in the biosafety decision-making process

The African Regulations

National Biosafety Frameworks

- All countries in Sub-Saharan African except Somalia are Parties to the CBD
- However only a few countries have embraced the Cartagena Protocol and set up fully functional NBFs (South Africa, Burkina Faso, Sudan and Egypt, Kenya, Malawi, Nigeria, Ghana, Cameroon)
- Four countries that have permitted commercialization are South Africa Burkina Faso **(though suspended for now)**, Sudan and Egypt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Equatorial Guinea
Uganda
Kenya
Gabon
Congo
Democratic Republic of the Congo
Rwanda
Burundi
Tanzania
Seychelles
Angola
Zambia
Malawi
Comoros
Mozambique
Zimbabwe
Namibia
Botswana
Madagascar
Mauritius
South Africa
Swaziland
Lesotho
GM Commercialized Crops
CFTs and Biosafety Laws
CFTs without Biosafety Laws
Biosafety Laws without CFTs
No Biosafety Laws or CFTs
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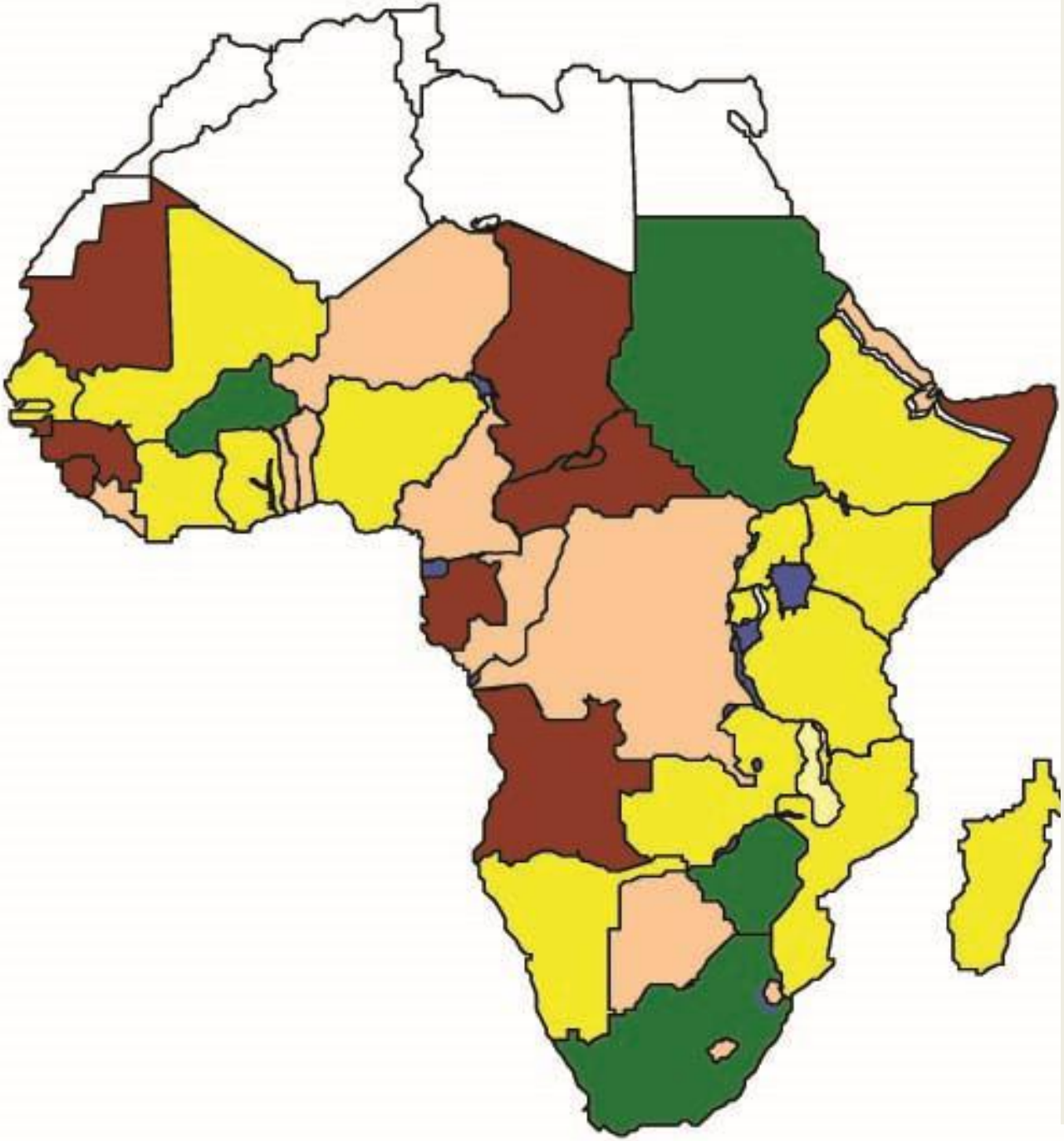

Four categories of countries:

1: *Fully-functional biosafety frameworks, (Dark Green)*

2: Interim biosafety frameworks, (yellow)

3: 'work-in-progress' (Brown)

4:Without NBFs.(Light Brown)

The African Regulations

South Africa leads

- Has permitted commercialization of GMO'S
- Has set up suitable public and private laboratories
- >160 biotechnology projects ongoing e.g. glyphosate tolerant Eucalyptus, genetically inserted bromoxynil, Bt cotton, maize, and soya

The African Regulations

The other six African Countries with fully functional NBFs include:

- Burkina Faso
- Mauritius
- Sudan
- Zimbabwe
- Nigeria (most recent in 2015)
- Kenya

The African Regulations

Role of ABNE (African Biotechnology Network of Expertise)

- Formed from the Partnership between NEPAD (New Partnership for Africa's Development) and Michigan State University
- Supported by Bill and Melinda Gates Foundation
- Supports building of Functional Biosafety Systems in Africa

The African Regulations

Role of ABNE

- Works with national governments
- Provides:
  - up-to-date training
  - information,
  - technical assistance, and
  - networking opportunities in biosafety to regulators and their support systems

Discussion Questions

- Discuss the benefits and challenges of the Cartagena Protocol agreement to African Nations
- Discuss the steps required and challenges faced by different African countries in setting up and implementing provisions for fully functional National Biosafety Frameworks.

Discussion Questions

- Using appropriate examples outline the benefits that would accrue to an Africa Nation upon full implementation of the Cartagena Protocol under the following subtitles
    a. Human health
    b. Biodiversity
    c. Economic well being
    d. Benefit sharing