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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Module structure

- 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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4.4 Unit 4 The Practice of dealing with risks by biotechnology (3 hours)

For details see the corresponding course notes

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Outline of Unit 4

- Objectives
- Contained use of GMOs
  - Introduction to contained use
  - Need for control and legislation
  - Classification of GMO containment
  - Application procedures
  - Working with bio-agents and modified organisms
- Confined Field Trials (CFTs)
  - Regulatory authorities involved in CFTs
  - Regulation of CFTs at the level of application
  - General requirements for CFTs
- Commercialization of GM Plants
- Case studies

Objectives of Unit 4

- To learn about the actual processes of genetic modification including; contained use in laboratory, green house and confined field trials.
- To learn about risks and safety to human health and environment emanating from the processes and products of modern plant biotechnology.
- To learn about the available control measures, legislations and regulatory authorities involved in the processing, use of GMOs and commercialization of its products.

Contained Use of GMO

The definition of contained use

- It is any activity in which organisms are genetically modified or in which such organisms are cultured/cultivated, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.

Introduction to contained use

- Covers any activity involving genetically modified micro-organisms carried out under containment.
- It relates to the actual process of genetic modification, including the use, storage, transport and destruction of GMOs.
- Contained use facilities can be microbiology laboratories, animal houses, green houses or industrial production facilities.
- Most of contained use activities involve organisms which do not cause disease and are very unlikely to survive in the environment outside containment facility

Introduction to contained use

- However, some contained use activities are carried out with more hazardous organisms whose escape from containment could be dangerous to human and environment.
- Risk assessment is hence important for all activities and control measures put to protect people and environment.

Need for control and legislation

- In EU there is legislation for control and formulation of measures for contained use activities. The contained use of Genetically Modified Micro-organisms regulation, 2008 (Legal Notice 127 of 2008).
- Similarly in Kenya, there are regulations that govern contained use activities - http://faolex.fao.org/docs/pdf/ken104833.pdf
- For example the Malta Environment and Planning Authority (MEPA) is tasked with the implementation of these regulations in Malta.
- The legislation requires the applicant to carry out a thorough risk assessment, which is then reviewed by MEPA in conjunction with the Biosafety Coordinating Committee.

Obligation under legal notice 127 of 2008

- Anyone carrying out contained activities must comply with the legal notice particularly:

1. Notify MEPA of their intension to use their premises for contained use activities for the first time
2. Carry out an assessment of the risks to human health and the environment of every contained use activity before it begins, reviewing and revising the assessment as necessary
3. Establish a genetic modification safety committee to advise on risk assessment;
4. Apply the necessary containment and control measures indicated by the risk assessment.

Classification of GMO containment

EU legislation classify GMO containment into four classes:

1. Class 1- activities of no or negligible risk
2. Class 2- activities of low risk
3. Class 3- activities of moderate risk
4. Class 4- activities of high risk.

Most genetically modified plants are considered to be class 1 because they are not usually modified to contain DNA sequences from human disease causing organisms

Class 4 is reserved for highly dangerous human and animal pathogens.

Public register and confidentiality claim

- Legal notice 127 of 2008 has provisions for public access to notifications of both premises and activities.
- All information is accessible to the public, except where a specific confidentiality is made by the applicant and deemed valid by MEPA.

Application procedures

- When undertaking genetic modification procedures for the first time, premises must be registered with MEPA specifying their first activity by submitting an application for first time use.
- Activities for class 1 and above need to notify MEPA of each new activity through an application for individual contained use activities.
- There are different notification processes required for different classes of micro-organisms.

1. Application form for notification for first time use
2. Application form for individual contained use activities.

Working with Bio-agents and Modified organisms

- Biological agents are microorganisms (fungi, bacteria, excretory products, viruses, cell cultures and endo-parasites) which could be harmful.
- If any changes has been made to their DNA they become GMOs
- Biological agents are classified into 4 categories. Category 1 the least harmful and 4 the most harmful.
- Cells also fall under the definition of biological agents. Cell lines suppliers therefore use the same classification, depending on the micro-organism that could be present in the cell.

Working with Bio-agents and Modified organisms

GMOs are classified based on:

1. The activity with the modified organism (small scale for research, educational and development purposes or non-small scale) and;
2. The origin of the modified organism (microorganism, plant, animals, etc.)
   - The classification determines the administrative procedures to be followed
   - The possible harmful effects of the GMO to the environment or health when released determine the containment level
   - Based on EU directive 98/81 four containment levels are distinguished

Confined Field Trial (CFT)

1. A CFT is an experiment of growing a regulated GM plant in the environment under specified terms and conditions that are intended to mitigate the establishment and spread of the plant.
2. A single CFT may comprise; reproductive isolation, site monitoring and post harvest land use restriction.
3. Experimental plants could be species/varieties/hybrids grown in a confined trial prior to approval for their environmental release.
4. CFT is restricted to a particular research field. Three considerations are taken into account:
    - CFTs are usually done on a small acreage - one hectare maximum
    - It is an experimental activity for data collection
    - The trials are conducted under conditions known to mitigate

Regulatory Authorities Involved in CFTs

- The activities involving the use of GMOs and products are regulated by many organizations, e.g. in Kenya the are regulated, for example, by the National Biosafety Authority (NBA), the National Environmental Management Authority (NEMA) etc while in the USA, they are regulated under rules of the manufacture, use/import/export and storage of hazardous microorganisms/GMOs or cells under the Environment Protection Act 1986.
- In the US, six competent bodies have been mandated to handle various aspects. These include:
  - Recombinant DNA advisory committee (RDAC)
  - Review committee on genetic manipulation (RCGM)
  - Genetic Engineering Approval Committee (GEAC)

Regulatory Authorities Involved in CFTs

- Institutional Biosafety Committee (IBSC)
- District Level Committee (DLC)

RDAC is advisory in function.

IBSC, RCGM and GEAC have regulatory functions

IBSC and DLC are for monitoring purposes.

In addition MEC has been set up by the RCGM to monitor the field performance of GM crops.

Regulation of CFTs at the level of Application

- A lot of information is required for submitting an application to conduct CFTs
- The application forms are completed on ready made format for various biosafety Research Trials.
- The application procedure is a long one including; when to apply, involvement of other institutions, authorization/approval process, etc.

General Requirements for CFTs

1. **Restriction on the size and number of CFT sites to maintain the integrity of the system as follows:**
   - Biosafety Research Level 1 are limited to 1 acre
   - Biosafety Research Level 2 trials are limited to 2.5 acres
2. **Monitoring of CFTs**
   - Members of the MEC, SBCC, DLC and SAU have the authority to inspect CFTs at planting/growing/harvesting and post harvest land restriction. As well as inspection of storage facilities.
3. **Records and Reporting:**
   - Keeping of records such as; compliance records, field trials reports, planting information, harvest information, etc.

General Requirements for CFTs

4. **Reproductive Isolation of CFTs:**
   - These include spatial isolation (minimum spatial isolation distance depends on reproductive biology of the plant)
   - Removal of floral parts before pollen maturity.
   - Bagging of flowers
   - Termination of trials prior to flowering.
   - Temporal isolation of pollination (planting earlier or later than any nearby sexual compatible plants)
5. **Deposition of material from CFTs:**
   - No harvested material or by product from CFT may be used as human food or livestock feeds
   - All plants materials from CFTs must be disposed off by methods approved by RCGM/GEAC (e.g. dry heat, steam heat, incineration, deep burial, chemical treatment, crushing or burying on the trial site

General Requirements for CFTs

6. Post harvest land use restriction and post harvest monitoring:

- In addition to reproductive isolation of the trial site during growing season of the CFTs, establishment of progeny plants on field trial site should be prevented during subsequent growing seasons
- RCGM/GEAC would establish a post harvest period for various plant species on a case by case basis

Commercialization of GM plants

- Products of Biotechnology have been available in the market for some time now
- However from the first generation GM crops (e.g. maize) two main areas of concern have emerged namely; risk to the environment and risk to human health, which have influenced commercialization of GM products

Concerns about risk to human health

- GM foods have been consumed by millions of people world wide for more than 15 years now with no reported ill effects
- In Europe GM crops are tightly regulated by several government bodies. The European Food Safety Authority (EFSA) and each individual member detail risk assessment of GM crops and derived food and feeds

Commercialization of GM plants

- In the USA, the FDA, the EPA and USDA, Animal and Plant Health Inspectorate all are involved in the regulatory process for GM crop approval
- Consequently, GM plants and products undergo extensive safety testing prior to commercialization
- GM products used in food and feed including seeds of GM crops must obtain authorization before they enter the market
- The product must be safe to both human and animals
- Thus there are regulations that must be adhered to before environmental release of a GM product is allowed
- E.g. regulations for Kenya can be found at http://www.biosafetykenya.go.ke/Docs/The%20Biosafety%20(Environmental%20Release)%20Regulations,%202011(2).pdf

Case Studies

1. Analysis of how provisions within Cartagena Protocol on Biosafety provides the legal frame work for regulating the cross boundary transfers of GMOs and their products.

2. A group exercise on formulation of a GMO regulatory system for a specific African countries