

NATIONAL BIOSAFETY FRAMEWORK IN KENYA

NATIONAL COUNCIL FOR
SCIENCE AND TECHNOLOGY

Introduction

- Current situation after the development of national biosafety framework.
- Implementation of the National biosafety framework.
- Regulatory regime .
- Handling requests
- Monitoring and inspections
- Public awareness

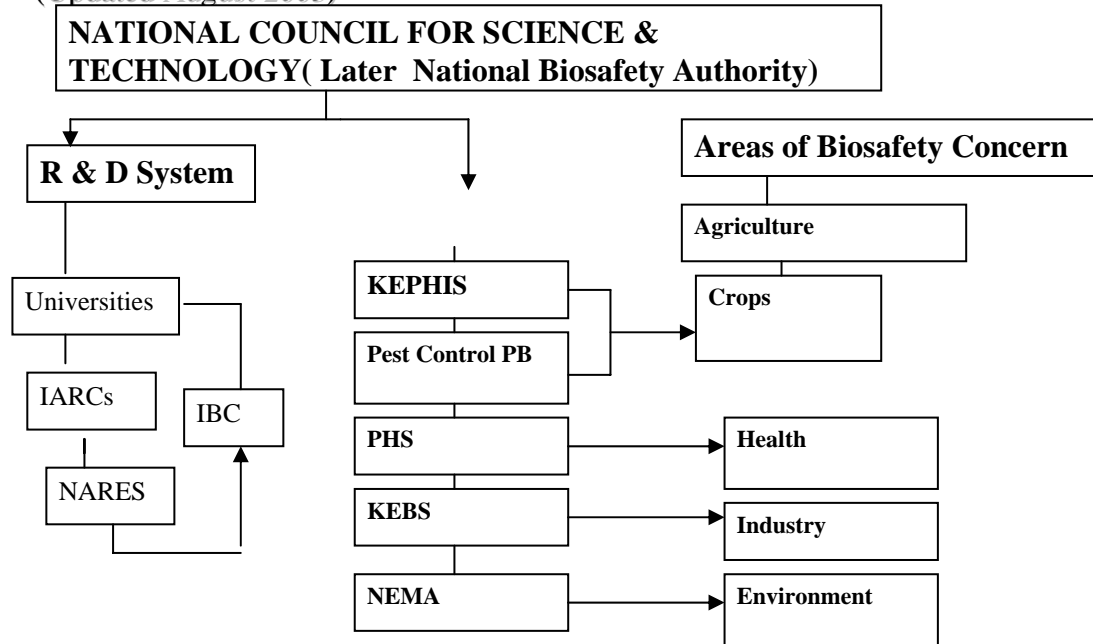
Topic One

- ❖ Through the UNEP-GEF funding the NCST has developed Draft Biosafety Policy; Draft biosafety bill; draft monitoring and inspection protocol.
- ❖ Has reviewed the existing regulations and guidelines for biosafety applications in Kenya.
- ❖ Implementation of the biosafety legal framework and policies will require serious collaboration of several government ministries that already carry out similar functions on conventional products.
- ❖ In September 2002, the NCST, received UNEP-GEF funding for the second phase (II) of the establishment of National Biosafety Framework.
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The National Council for Science and Technology (NCST) currently houses the office of the National Biosafety Committee (NBC).
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Figure 1. Framework for Effective Institutional linkages

(Updated August 2003)



- The Kenyan Government has assigned the NCST to prepare a draft for policy document on biotechnology and biosafety.

The NCST aims to prepare by the end of 2003 a policy document that addresses the following topics:

- Make Kenya a participant in National & International biotechnology enterprise (development).
- To realize this mission, Kenya needs infrastructure, conducive legal policy in environment and investment implementation.

- Advocates establishment of national authority to coordinate biotechnology and biosafety provisions.
 - The policy aims to highlight benefits from ethical uses of traditional and modern biotechnology.
 - Emphasizes need for legal framework and public awareness creation.
 - Advocates standards for biotechnology process and activities within a safe healthy environment.
 - Provides framework for sectoral and institutional policies.
 - Identifies risk assessment and management as cornerstone for biosafety regulatory framework.
 - Emphasizes flexibility to allow periodic review of policy

- b. The regulatory regime for biosafety.

National Biosafety Committee (NBC) provided guidelines for establishment of institutional Biosafety Committee (IBC).

Guidelines for handling GMO applications.

The interim regulations and guidelines have been applied in GM trial approvals of

- (i) Sweet potato
- (ii) IRMA Project
- (iii) Rinderpest vaccine
- (iv) Bt. Cotton

- *Draft Bill on Biosafety*

The future regulatory regime for biosafety in Kenya is intended to have the following structure:

- A law on Biosafety
- Implementing Regulations

The draft Bill on Biosafety has been under development since January 2003

- The objective of the draft Bill is to establish and ensure protection of the environment, including humans, in the development and use of GMOs.
The draft Bill aims to provide a legal basis for the eventual implementation of a national biosafety system consistent with the provisions of national policy, the Convention of Biological Diversity and the Cartagena Protocol on Biosafety.
- The scope of the draft Bill covers contained use, deliberate release, placing on the market, import and export of GMOs and products containing or consisting GMOs.

- The Bill establishes a competent authority to be known as National Biosafety Authority, which shall be under the Minister responsible for Science and Technology. The Bill lays out the requirements for applicant to obtain approval from the competent authority in order to handle GMO's. After obtaining the approval from the competent authority, the applicant shall be given a licence/permit by the appropriate regulatory agency.

The Bill therefore, outlines the procedure and requirements for applications.

The Bill also requires the competent authority to promote awareness and education of the public. The competent authority shall also publish notices concerning proposals and decisions on applications. The Bill (Act) spells out the role of regulatory agencies.

- The draft Bill has provisions on how to makes use of Public information, public consultation as well as the protection of confidential information.

Currently the following is being done to the draft bill.

- Expert review of the documents
- Sensitisation of Parliamentarians.
- Submission to Parliament in the late 2003 or early 2004.

It is anticipated that the Bill comes into force in 2004.

- © Systems for handling requests.

In the course of 2003 - 2004, the following will be developed:

- existing formats for notifications and requests for permission for the contained use, deliberate release, placing on the market and import of GMOs, differentiated for plants, animals and micro-organisms will be adjusted to the new regulatory regime.

- A system for efficient administrative handling of notifications and requests for permits, including:
 - A manual for the administrative handling of requests
 - a database
 - a system for the protection of confidential information,
 - a system to track dossiers and guard procedural

- A mechanism for reviewing risk assessments by the NBA, including:
 - internal rules of procedure for the National Biosafety Authority (NBA),
 - manuals for risk assessment to be used by the NBA,
 - access to relevant databases such as the Biosafety Clearing House, Gene Files and Botanical Files, GenBank, SwissProt,
 - training on risk assessment and risk management for members of the NBC, its secretariat and regulatory agencies.

- d. Monitoring and inspections.

In the draft Bill, plans for monitoring are part of notification or requests for permits.

Monitoring can consist of general surveillance and – depending on the results of the risk assessment.

The Competent Authority will appoint a monitoring task force on specific cases.

Monitoring and inspection task force has been formed to evaluate gaps and needs for implementation process.

- Inspections.

The draft Bill makes use of existing regulatory agencies for the enforcement of the provisions of the Bill.

Monitoring shall be compiled and included in the manual for risk assessment to be used by the Competent Authority on GMO as stipulated in draft bill.

This compilation will include methodologies for monitoring and inspections, equipment for laboratory, basic equipment for collecting samples,

- A program and manual for inspections of activities involving GMOs is drawn up, based on expert review of the existing infrastructure for inspections and the results of the survey which we are intending to carry-

- **At least one existing laboratory in Kenya shall be selected, certified and assigned with detection and identification of GMOs in the context of inspections.**

If necessary, the equipment of that laboratory shall be brought up to the required level.

A program ensuring the continuity of the use of those detection and identification shall be drawn up

- e. Public wareness and participation.

The draft national biosafety framework is developed in open consultation with all stakeholders and the different versions of the draft Bill have been made available to the public in two major conferences at Safari park hotel in Nairobi.. The Kenyan Government wishes to develop strategies to continue this level of public information and public participation in the Implementation of the national biosafety framework.

- -More workshops/conferences will be held to raise public awareness for the developments in biotechnology and biosafety. -
 - A web site will be published which provides general information about the national biosafety framework of Kenya. Already the Unep-Gef website in Geneva has put the Kenya progress on the their website.
 - A brochure will be prepared which will provide information for the general public in Kenya about modern biotechnology, the potential benefits and risks, and the national biosafety framework of Kenya.

These activities will as much as possible be carried in close consultation with relevant stakeholders.

THANK YOU VERY MUCH.