

The Biosafety framework in Kenya

Prof. Dorington O. Ogoyi

Director, Technical Services

National Biosafety Authority

Presented at the plant Biotechnology and Biosafety
Workshop, Brasilia, Brazil, April, 2013

Introduction to Biosafety in Kenya

- National Biotechnology Development Policy Published in 2006
- National Biosafety Committee (NBC) under (NCST: Science and Technology Act Cap 250)
- Kenya signed the **Cartagena Protocol** on Biosafety in 2000 and ratified it in 2003.
- Member countries are required to designate competent authorities and National Focal Points (Liaison officers) to deal with national GMO matters and liaise with the international secretariat of CBD

Biosafety Act, 2009

- Makes provision for the establishment of a legal framework for the safe handling, use and transfer of genetically modified organisms
- Sets up the National Biosafety Authority as the National focal point of all Biosafety matters in Kenya
- NBA to exercise general supervision and control over dealings in GMO with a view to ensuring safety to human and animal health and protection of the environment

Mandate of National Biosafety Authority

- Consider and determine applications for approval for the safe transfer, handling and use of GMOs;
- Co-ordinate research and monitor activities on all GMO work as per the Act;
- Strengthen national technical capacities and capabilities for biosafety;
- Develop regulations to operationalize the Biosafety Act;

Mandate of National Biosafety Authority

- Establish and maintain a Biosafety Clearing House (BCH) mechanism – web based information sharing of national database that is linked to the international BCH;
- Promote public awareness on biosafety and biotechnology;
- Enforce the provisions of the Biosafety Act;
- Provide advisory services on matters of biosafety;

Vision



A World Class Biosafety Agency

Mission

To ensure and assure safe development, transfer, handling and use of genetically modified organisms in Kenya

Regulatory Agencies

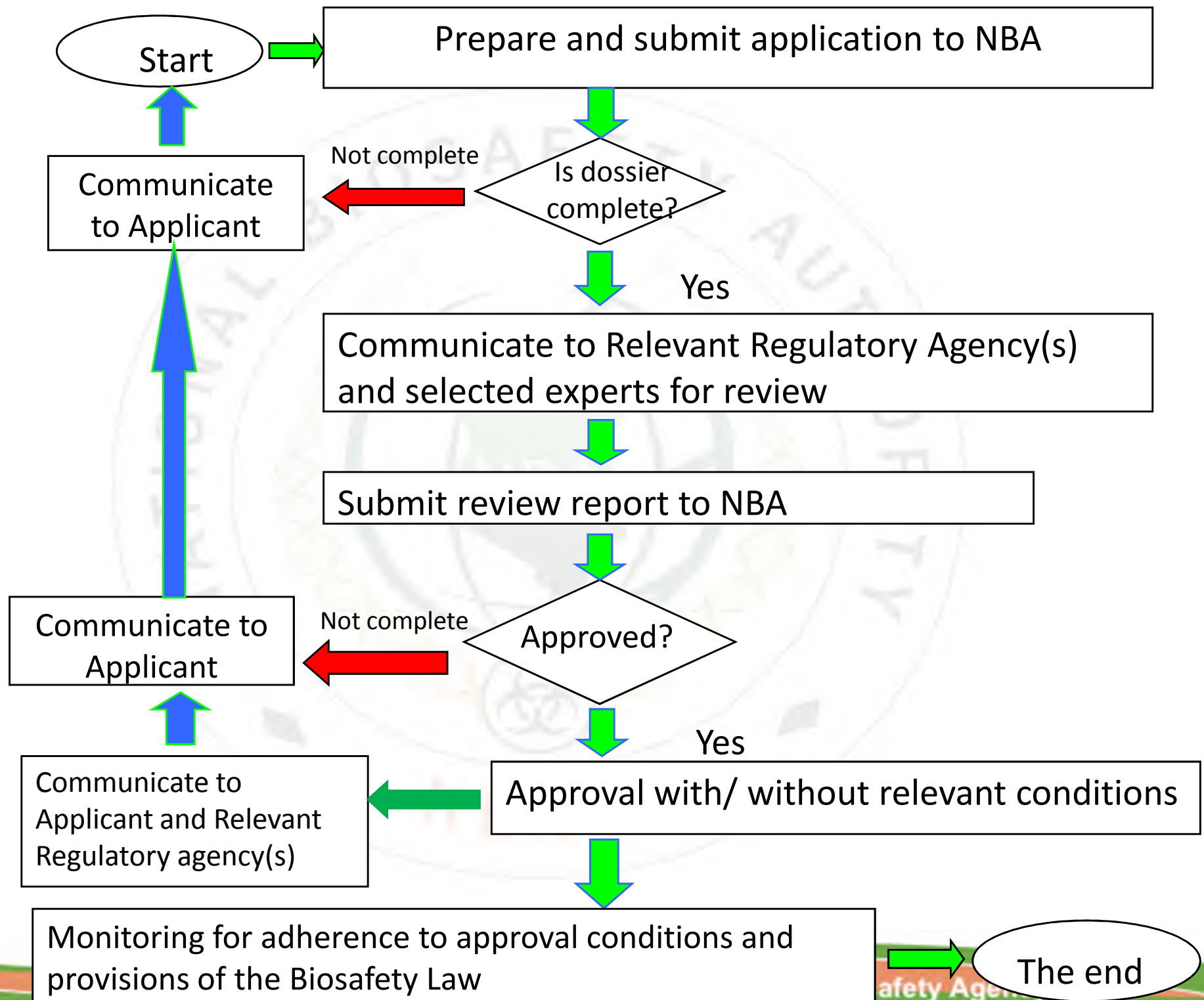
- The NBA implements mandate through various regulatory agencies namely:
 - Kenya Plant Health Inspectorate Service (KEPHIS)
 - Directorate of Veterinary Services (DVS)
 - Department of Public Health (DPH)
 - Kenya Bureau of Standards (KEBS)
 - National Environmental Management Authority (NEMA)
 - Kenya Wildlife Service (KWS)
 - Kenya Industrial Property Institute (KIPI)
 - Pesticide Control Products Board (PCPB)

Role of Regulatory Agencies

- Monitor approved GMO activity to ensure compliance with conditions of approval
- Inform Authority of any significant new scientific information indicating that an approved activity pose biosafety risks not previously known
- Inform Authority of unintentional or unapproved introduction of a GMO into the environment and propose mitigation measures

Handling Applications

- Any person wishing to undertake any activities using GMOs can only do so with the approval of the NBA
- Activities envisaged under the Act include-
 - Research- contained use, confined use
 - introduction into the environment/ Placing on the market
 - Import, transit, export



Risk Assessment

- **Risk assessment objective** “identify and evaluate the potential adverse effects of GMO to human health and environment”
- **General principles:**
 - i) Scientifically sound and transparent manner
 - ii) Lack of scientific knowledge or consensus does not imply a particular level of risk, absence of risk or an acceptable risk
 - iii) Risk of GMO must be considered in the context of non-GMO
 - iv) Risk assessment should be carried out on a case-by-case basis.

Decision Making

- Based on Risk assessment report from reviewers, submitted by applicant and available information
- The Authority then prepares a decision document
- The decision document will contain-
 - A summary of the application including the details of the applicant, the genes involved, the purposes of the intended use
 - The risk assessment
 - The decision

OTHER PROVISIONS OF THE ACT

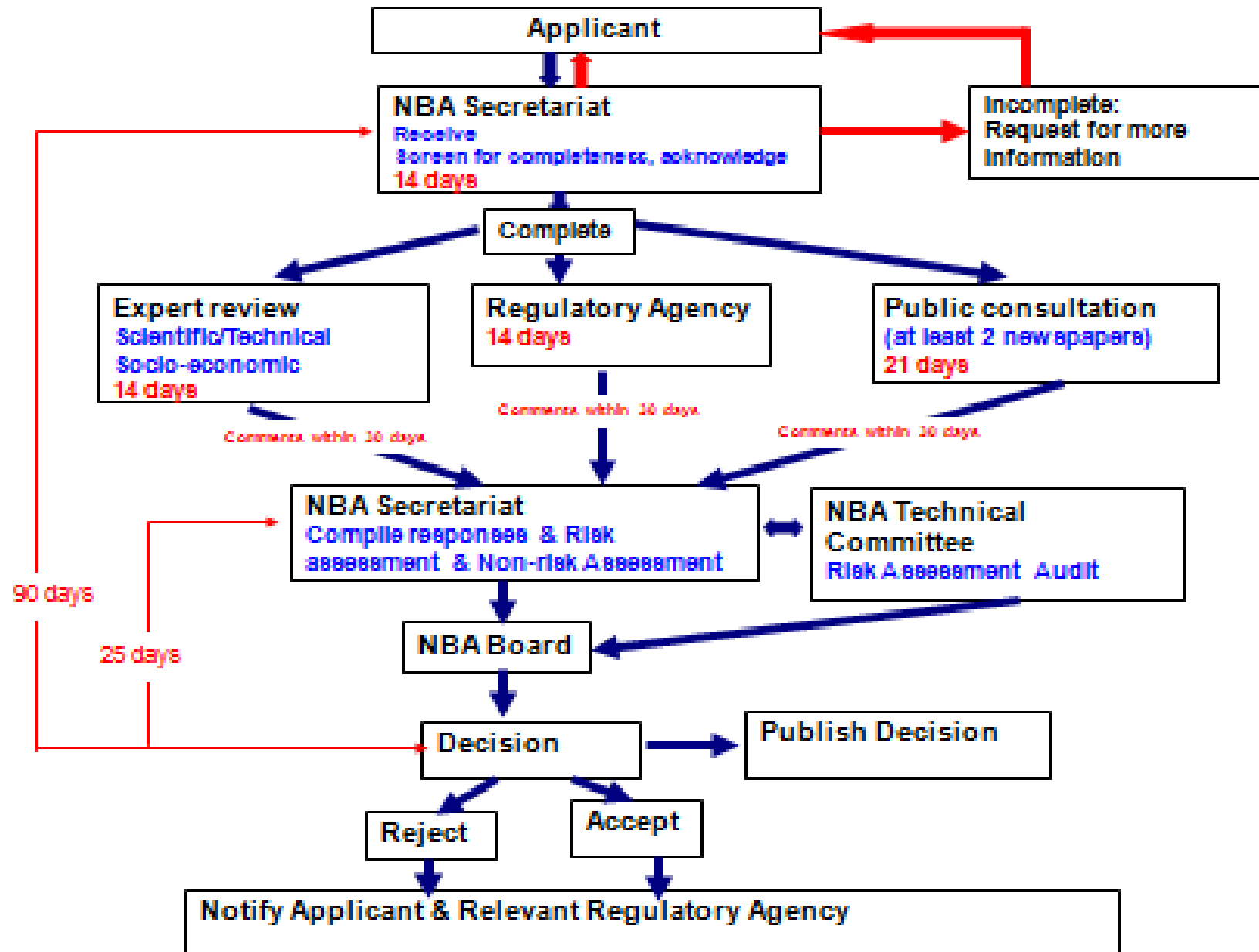
- Composition of the Board of Management
- Review and Appeal Mechanism
- Inspection and monitoring
- Restoration and Cessation orders
- Offences and Penalties

BIOSAFETY REGULATIONS

- The Law provided for gazzement of regulations that would be important for the implementation of the Biosafety Act 2009;
 - To date 4 regulations have been gazetted:
Regulations for;
 - Contained Use
 - Environmental Release
 - Import, Export and Transit
 - Regulations for Labeling (2012)

FLOW CHART-ENVIRONMENTAL RELEASE

FLOW CHART - ENVIRONMENTAL RELEASE/PLACING ON THE MARKET



LABELING REGULATIONS, 2012

- **Objective:**
- To ensure that consumers are aware that food/feed or product is GMO for informed choice
- To facilitate traceability of GMO products towards enforcement of appropriate management measures

Provisions of the labelling regulation

- **Application:** foods consisting of GMO or derived from GMO
- **Exemptions:** Where GMO is below 1% threshold level; **Highly refined foods** devoid of GMO, food additive, **food intended for consumption** and sold from food premises or vendors
- **Labelling requirement**
- **Monitoring inspection and compliance**

APPROVALS

- Import/export products
- Contained use:
(Laboratory, green house, CFT)-
- **Target crops in CFT:** cotton maize, sorghum, cassava
- **Animals:** Knock out mice, transgene cattle (trypanotolerant, Improved vaccine)
- Environmental release: Anticipated in 2014

APPLICATIONS SINCE AUGUST, 2010

	CFT	LAB/GREEN HOUSE	TRANSIT/IMPORT
APPROVALS	9	9	30
PENDING	0	0	0
TOTAL	9	9	30

Target crops in CFT: cotton maize, sorghum, cassava

Monitoring and Evaluation

- Quarterly reports expected from approved projects
- Monitoring In consultation with regulatory agencies
- Empowerment of Biosafety inspectors
 - Monitor compliance with the act
 - Undertake inspections

The logo of the National Biosafety Authority (NBA) is a circular emblem. It features a central map of Kenya with a green leaf and a white caduceus-like symbol. The text "NATIONAL BIOSAFETY AUTHORITY" is written around the top inner edge of the circle, and "NBA" is written in the center. Below the map, the words "BIOLOGICAL SAFETY" and "ENVIRONMENTAL PROTECTION" are written in a circular path.

Thank You

For more information:

Website: www.biosafetykenya.go.ke

E-mail: info@biosafetykenya.go.ke