

Role of NBA towards commercialization of genetically modified organisms (GMOs)

By:

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Vision



A World Class Biosafety Agency

Mission

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

THE BIOSAFETTY (ENVIRONMENTAL RELEASE REGULATIONS, 2012

- **Environmental release:** Introduction into the environment of an approved GMO
- Implies that No specific containment measures are used to limit contact , human or environmental safety
- Includes making GMO available to the public for purposes other than sale
- **Placing on the market:** Making GMO available for sale

THE BIOSAFETTY (ENVIRONMENTAL RELEASE REGULATIONS, 2012

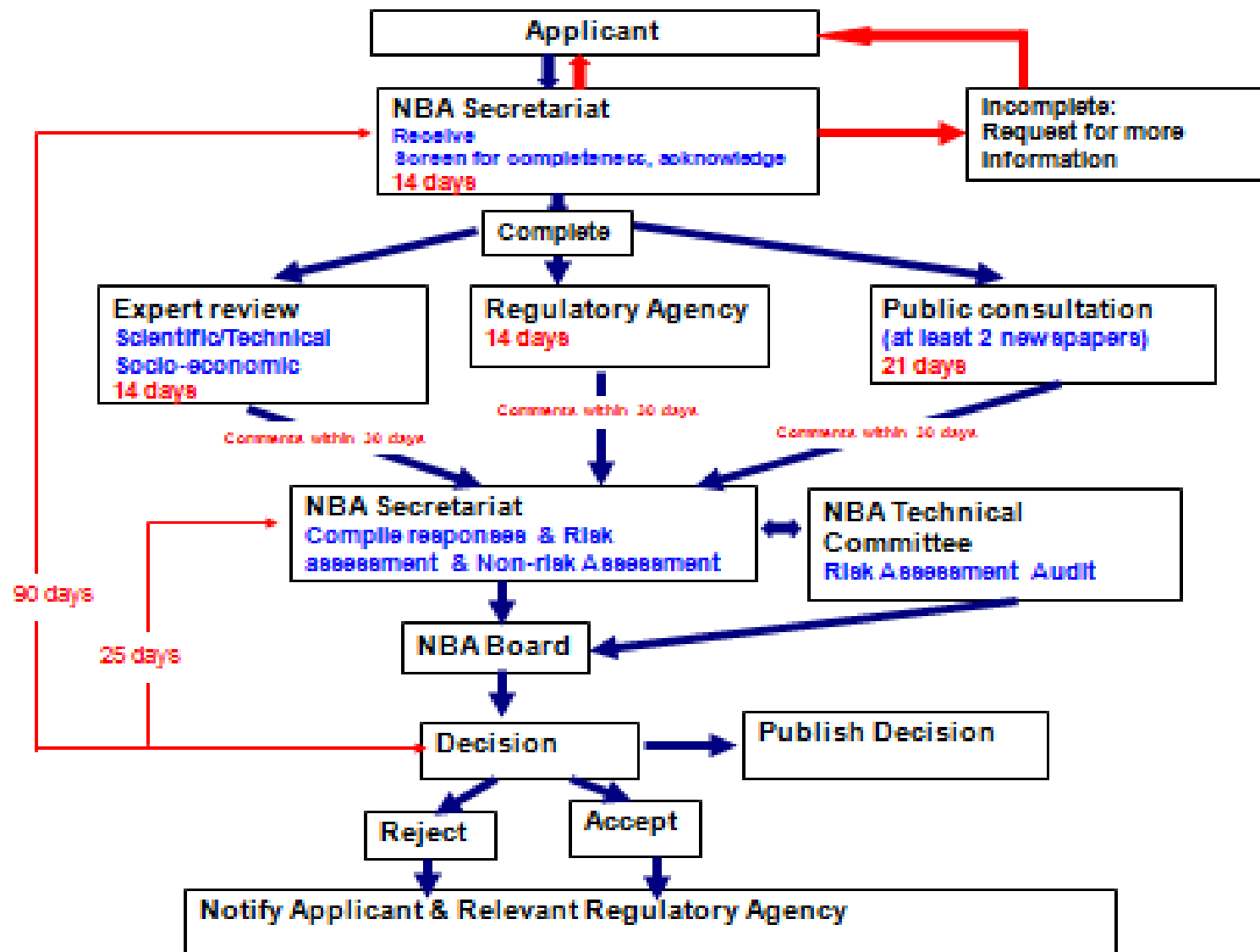
- **OBJECTIVE:**
- To ensure that potential adverse effects of GMO are addressed to protect human health and environment

APPLICATION PROCESS

- Applications shall be made using Schedule 1 forms
- Application fee; **KSh. 850,000**
- Additional risk assessment report may be included
- Any other relevant document may be also be submitted by the applicant
- Single application may include release at multiple sites

FLOW CHART-ENVIRONMENTAL RELEASE

FLOW CHART – ENVIRONMENTAL RELEASE/PLACING ON THE MARKET



Processing Application for Environmental Release

Screening

Technical Review

Decision Making

Public Consultation

Decision:
90-150 days
**Approve /
Reject**

NBA Board

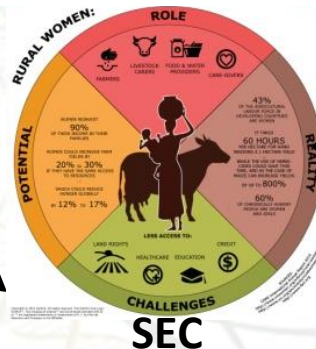
Application

NBA Secretariat

PUBLIC NOTICE

REQUEST FOR COMMENTS ON AN APPLICATION FOR ENVIRONMENTAL RELEASE
(OPEN FIELD CULTIVATION) OF GENETICALLY ENGINEERED MAIZE IN KENYA

Deadline for submitting comments: 23 Aug 2015



NBA Secretariat

Completeness & Accuracy
Fees: (850K)
Acknowledge: 30 days



RAs



Expert Reviewer

- Consolidated Risk Assessment (food & environment) (RAs, Experts & Applicant)
- Submissions by Public
- Socio-Economic Considerations

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Pillars for review of GMO application – Environmental release

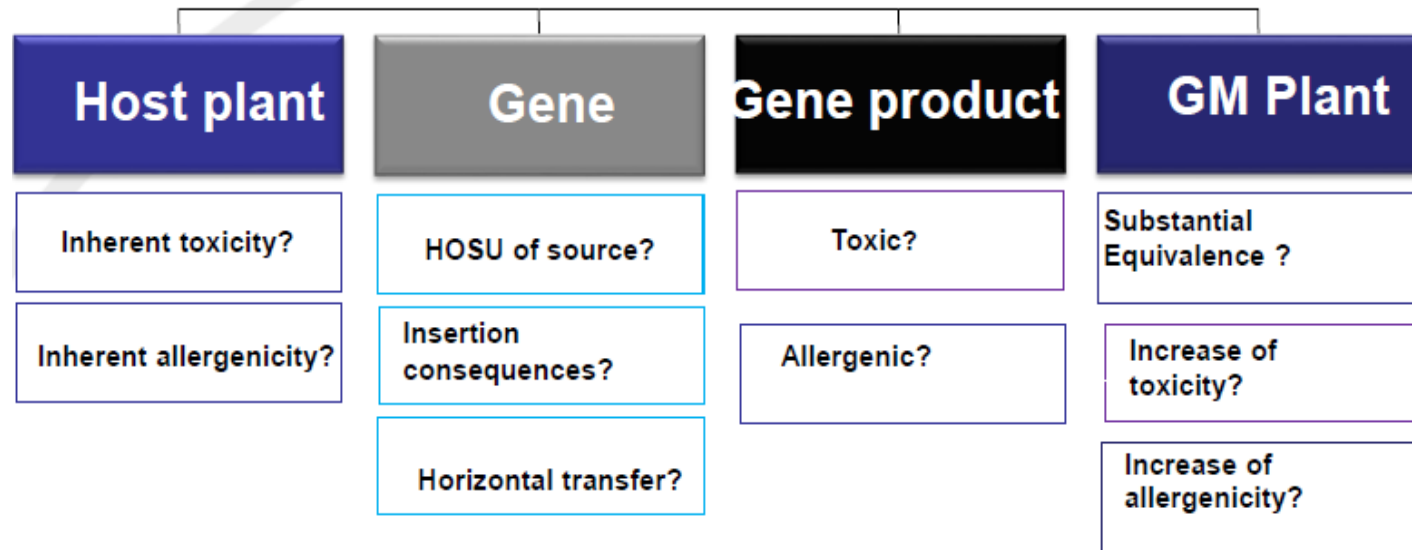
1. Technical and scientific assessment

- (a) Molecular data characterization
- (b) Food and Feed safety assessment
- (c) Environmental Risk Assessment

2. Socioeconomic considerations

3. Public awareness and Participation

Holistic approach



-Comparison of the GM crop to a conventional equivalent with a History of Safe Use (HOSU) guides the safety assessment

Elements of toxicity studies

- History of safe use
- Bioinformatics analysis
- Mode of action and Specificity
- In vitro digestibility and Lability
- Expression level and dietary intake
- Acute Toxicity assessment
- Repeated dose toxicity assessment
- Chronic toxicity assessment
- Animal feeding trials

Environmental Risk Assessment

- Environmental safety and fate
- Agronomic Performance (morphology, yield)
- Outcrossing (Gene flow)
- Weediness Assessment
- Susceptibility to disease
- Interaction with target and NTOs
- Interaction with abiotic environment & soil stability
- Ecotoxicological Studies (Fish, Earthworms)
- Insect Resistance Management (Refugia)

Public Awareness & Participation

- Regulation 12(1): Authority shall promote public awareness & participation on proposed release
- Regulation 12(3): Authority shall make available to the public non-confidential information on application for environmental release of GMO:
 - (a) by notice in the Gazette;
 - (b) in at least two newspapers of wide circulation;
 - (c) on its website

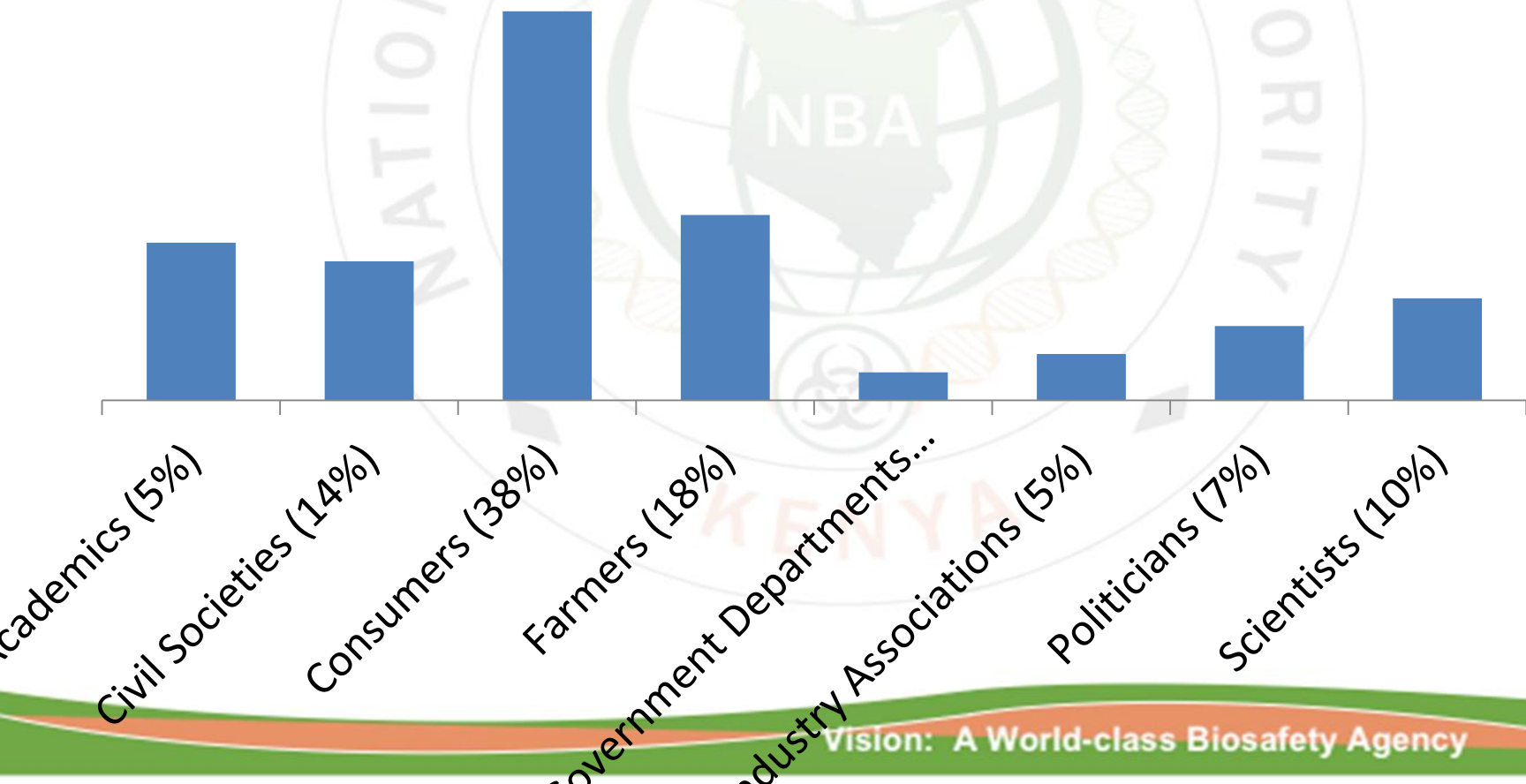
Process of Participation Contd'

- Authority to ensure decision made considers views of public participation. This includes analysis of comments and description of reasons for taking or not taking them into account in the decision
- When Authority has taken a decision, public to be informed;
 - (a) by notice in the Gazette;
 - (b) on its website
 - (c) Biosafety Clearing House (BCH)

Opinion on environmental release of MON810

YES	BLANK	NEUTRAL	NO	TOTAL
14,956	21	82	37	15,096
99.1%	0.1%	0.5%	0.2%	100%

Categories of submissions



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Decision Making

Authority shall take into account:

- Information submitted by applicant
- Reports from Expert Reviewers
- Information & conditions submitted by relevant RAs
- Risk Assessment Report
- Relevant submissions by members of public
- Socioeconomic considerations arising from impact of GMOs to the environment

- Authority communicate decisions (90-150)days:

Non- assessment of risk

- This may be considered due to the following conditions;
 - Sufficient experience or information exists to show environmental release poses no significant risk
 - **After approval**, subsequent release of same sps, or the same sps modified with the same gene or combination of genes

Validity and renewal of approval

- Approval given shall be valid for 10 years
- Renewal of approval shall be given for a further 10 years
- No further approval is required if product has been released for 20 years without any adverse reports on monitoring
- Approval once given, may be revoked or amended should new information on risk to human/environment be availed.

Handling of new information

- If environmental release results in adverse effects to human and to environment;
- The applicant shall;
 - Take necessary action to protect human health and environment
 - Inform the Authority of the change
 - Reverse measures specified in the approval

Handling of new information

- **The Authority;**
 - The shall evaluate the information and may inform the public and ;
 - May require applicant to “modify conditions, suspend or terminate environmental release

Monitoring

- The applicant shall submit a monitoring report to NBA
- NBA shall develop and issue an inspection manual and guidelines and other other control measures
- NBA together with the regulatory shall monitor and inspect all approved releases/placing in the market

Environmental release applications

1. Bt maize project (MON 810) – KALRO/AATF

- The application was approved for limited environmental release in January 2016 - to allow NEMA to conduct EIA and KEPHIS to conduct NPT.

2. Bt cotton project – Monsanto K Ltd

- The application was approved for limited environmental release in September 2016 - to allow NEMA to conduct EIA and KEPHIS to conduct NPT.

3. Gypsophila cut flowers— Application received from Imaginature Ltd. Application is under review

The logo of the National Biosafety Authority (NBA) is a circular emblem. It features a central map of Kenya, with a DNA double helix structure winding around it. The words "NATIONAL BIOSAFETY AUTHORITY" are written in a circle around the central image, and "NBA" is written below the map.

Thank You

For more information:

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