Biosafety Regulation in Zimbabwe

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Presentation

- Background
- Role of NBA
- National biosafety framework
- Regulatory guidelines
- Global regulatory arrangements
- Conclusion
WHO IS NBA?

- It is a strategic arm of the Government of Zimbabwe, established through the National Biotechnology Authority Act [Chap. 14:31] of 2006.
- National Competent Authority for all biotechnology, biosafety and biosecurity matters including GMOs.
- National focal point of Cartegena protocol on biosafety.
BACKGROUND

- 1998 - Research Act amended to provide for the management of potentially harmful technologies and undertakings.

- The Biosafety Board was formed.

- 2005 - Zimbabwe ratifies the Cartagena Protocol on Biosafety (CPB) and the National Biotechnology Policy was developed with support from UNEP-GEF.
Cartagena Protocol on Biosafety

- Influential in the improvement of the National Biosafety Framework
- Zimbabwe has been a party to the Convention of biological diversity (CBD) and to the Cartagena Protocol on Biosafety since 2005
- NBA is the Competent Authority for the Protocol and the National Focal Point and National Competent Authority for the BCH
• 2006 - the NBA Act [Chap.14:31] of 2006 was gazetted.

• This gave rise to the National Biotechnology Authority.

• NBA’s mandate further emphasised in 2rd Science Technology and Innovation Policy of 2012.
Scope of biotechnology which we regulate

- Biotechnology from our point of view as NBA looks at
- Industrial biotech
- Pharmaceutical/medical biotech
- Agricultural/crop biotech
- Food biotech
• It also focuses on regulation of related technologies such
• nanotechnology,
• synthetic biology
• *metabolic engineering, proteomics, metabolomics, DNA-chip technology, bioinformatics*
What is Biosafety?

- **Biosafety** is concerned with the safeguarding of the public and ecosystem health against risks from products and processes of modern biotechnology.

- These prevention mechanisms include regular reviews of the *biosafety* in laboratory settings, as well as strict guidelines to follow.
Zimbabwe`s Biosafety Framework

It comprises of:

• National Biotechnology Policy;
• An Act of Parliament - the NBA Act;
• Institutional arrangements - NBA & Institutional Biosafety Committees (IBCs);
• Mechanisms for risk assessment (reviews); mechanisms for decision making (NBA); mechanisms for public consultation; mechanisms for monitoring and enforcement (Biosafety Inspectorate); supporting guidelines and standards.
NBA Act of 2006 applies to:

• All research activities involved in development, importation, exportation and use of biotechnological processes;

• Import, export, contained use, release of any product of biotech that is likely to have adverse effect on human health, environment, economy, national security or social norms and values;

• Any activity involving biological /molecular engineering technologies (metabolic engineering, proteomics, metabolomics, nanotechnology, cloning, DNA-chip technology, bioinformatics and other technologies declared by the Authority to constitute potentially harmful research or undertakings

• All measures aimed at minimising impact of biotechnological processes on national security, human health, animals, plants environment.
Corporate governance & management structure

Minister for the MHTESTD

NBA Board

National Biotechnology Authority

Chief Executive Officer & Registrar

Regulatory Affairs

Public Awareness

Research Support

Finance and Administration

National Biotechnology Authority
In accordance with the NBA Act, the functions of the Authority are:

• To advise the Minister on all aspects concerning the development, production, use, application and release of products of biotechnology.

• To regulate biotechnology research, development, production, use, application, movement and release of products thereof.

• To provide programmes on public awareness and understanding of biotech and biosafety.

• To provide infrastructural capacity and human capital development.

• To administer the Biotech Fund on behalf of the Minister.
NBA`s Services

1. Regulatory Services
2. Research Support Services
3. Public Awareness and Education
4. Advisory Services
Research Support Services

- Administering the Biotechnology Fund.
- Conducting operational research.
- National Biosafety Reference Lab with biosafety levels BSL1-BSL4
Conducting biotechnology awareness:

✓ Public exhibitions

✓ Outreach programmes for farmers, students etc.
Regulatory Function

- Issuance of permits and certificates.
- Pre and post shipment inspections of imports and exports.
- Monitoring imports and exports at ports.
- Registration of biotechnology facilities.
- Biosafety policy development.
- Assessment of potential release of GMOs into the environment (GMO surveillance and Testing).
- Supervision of contained use, trial and general release of biotechnology products.
Registration of facilities

- NBA registers and issues permits to operate facilities that are used for biotechnology work to contain health and safety risks.
- This is accordance to Part III (Control and Monitoring of Biotechnology) of the NBA Act of 2006 [Chap.14.31].
- Section 22: specifies that the Authority’s biosafety guidelines and standards of practice and procedure shall be binding to users of the products of biotechnology.
Registration contd

• *Section 23*: provides for the establishment of a register of biotechnology facilities by the Authority.

• *Section 24*: prohibits the ownership or use of unregistered facilities
Registration steps

1. Pay application fee for registration
2. Submit completed application form
3. Elect an Institutional Biosafety Committee
4. Elect an Institutional Biosafety Officer
5. Develop an Institutional Biosafety Manual using Biosafety Guidelines
6. Submit the draft IBM to the NBA
7. After approval implement the system
8. Invite the NBA Inspectorate for an inspection audit
9. Wait for a NBA Lab Auditing notification
After audit if Authority is satisfied, institution is issued with a registration certificate valid for one year.
Process of Commercialization of GM

- Applicant registers biotech facility with NBA.
- Submits proposal for contained work through the IBC.
- NBA inspectorate reviews the proposal (Independent reviewers with expertises).
- NBA Board approves or disapproves the application.
- If contained work is successful applicant may be issued with a permit to conduct CFTs after reviewing the proposal.
- Results from the CFTs will be used to sanction the granting of a commercialization certificate.

NB/ Before granting a commercialization certificate interested stakeholders may be consulted.
Public Awareness Training & Education

- Producing awareness and education material.
- Training legislature/stakeholders on biotech through workshops/meetings.
GMOs in Zimbabwe

- Zimbabwe has not yet approved the commercialization of GM crops or animals.
- Confined field trials for Bt maize and cotton conducted from 2001 – 2005.
- Importation of GM positive material is highly regulated.
- Research on GMOs is not ruled out.
Effective regulation

- SPS regulatory agents
- PQS
- EMA
- MCAZ
- RCZ
- MRC
- PORT HEALTH
Global Biotech Regulation
Biotech and Biosafety legislation in Africa

Different regulations governing the use and application of biotech exists in Africa.

• African Union acknowledges that the need for African countries to have a harmonized position on Biotech and Biosafety: Modern law on biosafety

• SADC has draft guidelines for addressing issues of GMOs and Biotech.

• COMESA has a regional policy on commercial planting, trade and emergency food assistance involving GMOs: Regional Approach to Biotechnology and Biosafety policy in Eastern and Southern Africa (RABESA).
Biotech and Biosafety legislation in Africa
Concerns Around Biotech in the midst of Scientific Optimism in Africa

- Biotech concerns have global, regional and national dimensions.
- Other countries have adopted biotech while others have adopted a precautionary approach.
Major concerns to GM

- Revolve around safety to humans and animals consuming GM products,
- Plants and insects in the environments where crops are grown.
- In Africa, there is wide belief that GM crops are intended for use in industrialized countries, and are hence inappropriate for agriculture Africa.
Biotech concerns

• Trade concern that GM crops replaces conventional varieties and make farmers dependent on private seed companies.
• Capacities to undertake research and monitor and evaluate GM products
• Loss of export markets for specific crops to trade-sensitive countries has also been expressed. These fears stem from uncertainty over those who gain or lose from the technology.
Major concern

Socio-economic considerations for the regulator

• Cultural
• Religious
• Reliefs
• spiritual
Elswhere

- Different countries have different legislations/policies or stances on GMOs.
- Some countries have imposed labelling of GMO products.
- Most countries (170) implement the Cartagena Protocol on Biosafety.
Up to ~18 million farmers, in 28 countries planted 179.7 million hectares (444 million acres) in 2015, a marginal decrease of 1% or 1.8 million hectares (4.4 million acres) from 2014.

Source: Clive James, 2015.
NBA Prospects

Prospects

• Lobby Government to release funds for the Biotech Fund.
• Ratification to the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety and the International Centre for Genetic Engineering and Biotechnology (ICGEB) treaty.
• Development of the National Biosafety Clearing House
• Increase public awareness.
• Encourage more biotechnology and biosafety research.
Thank you

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