



# Biosafety Regulation in Zimbabwe

Dr. J.Mufandaedza – Chief Executive Officer &  
Registrar , National Biotechnology Authority



ZIMBABWE

# 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 Cartagena protocol on biosafety



ZIMBABWE

# 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





# BACKGROUND cont...



- 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 2nd 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





# contd



- 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.



ZIMBABWE

# 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



ZIMBABWE



# NBA Mandate

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





# Public Awareness Training & Education



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



- Step 1: Pay application fee for registration
- Step 2: Submit completed application form
- Step 3: Elect an Institutional Biosafety Committee
- Step 4: Elect an Institutional Biosafety Officer
- Step 5: Develop an Institutional Biosafety Manual using Biosafety Guidelines
- Step 6: Submit the draft IBM to the NBA
- Step 7: After approval implement the system
- Step 8: Invite the NBA Inspectorate for an inspection audit
- Step 9: Wait for a NBA Lab Auditing notification

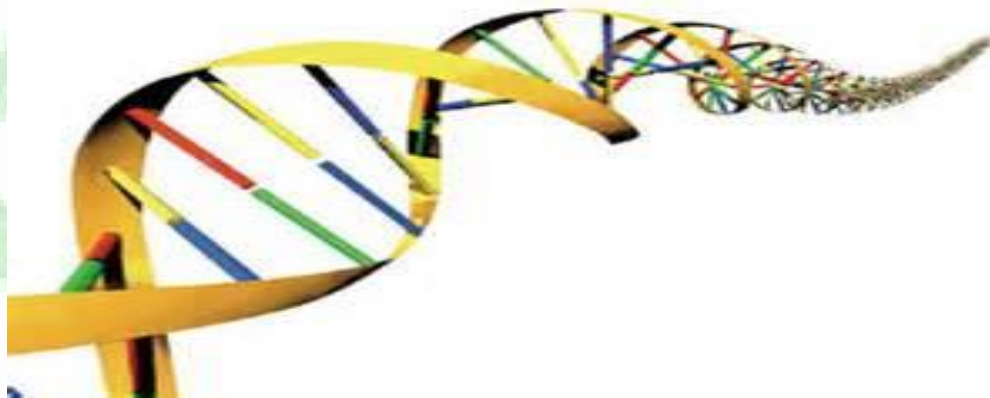




# Registration contd



- 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.

National Biotechnology Authority

*NB// Before granting a commercialization certificate interested*





# 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

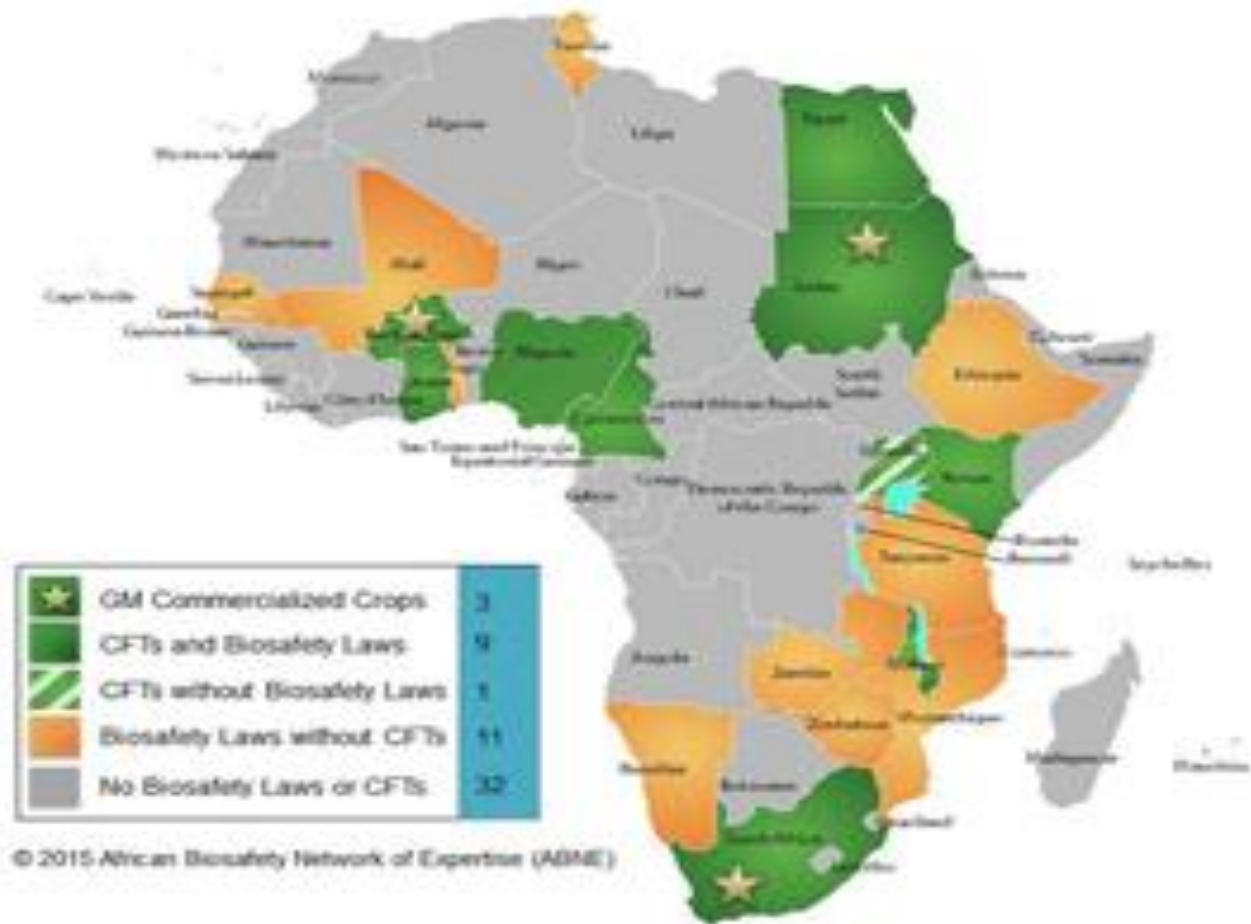


Different regulations governing the use and application of biotech exists in Africa.

- 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

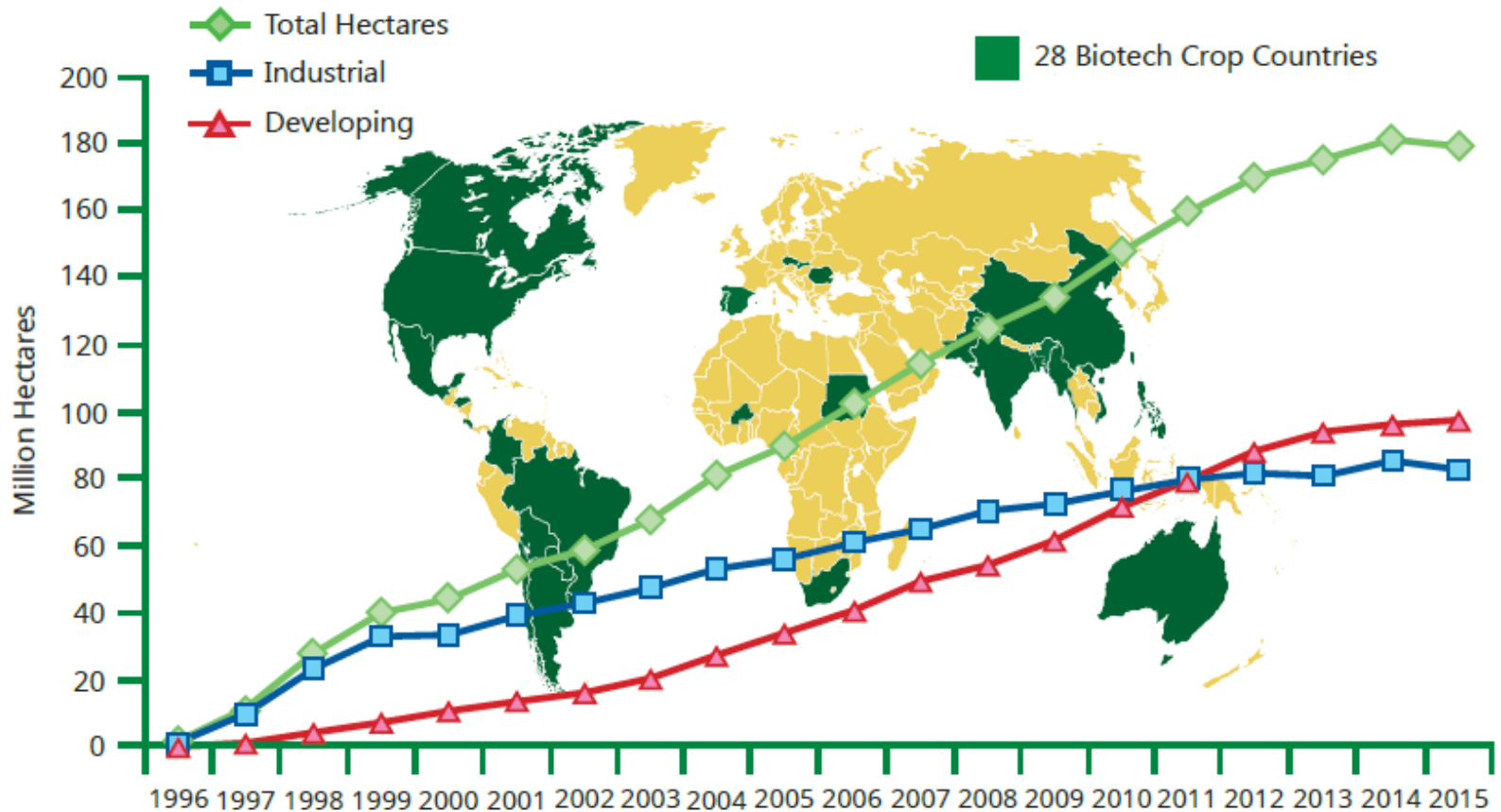


# Elswhere



- 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.

## GLOBAL AREA OF BIOTECH CROPS Million Hectares (1996-2015)



***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.



ZIMBABWE

# 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.



ZIMBABWE

# Thank you



For More Information Contact:

21 Princess Drive

Newlands

P. O. Box CY379

Harare

Tel: +263 4 782856/9

Email: [nba@nba.ac.zw](mailto:nba@nba.ac.zw)

Website: [www.nba.ac.zw](http://www.nba.ac.zw)