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Report Highlights:

The Government of Tanzania uses a conservative, precautionary approach to manage genetically engineered (GE) products in the country. Due to the strict liability clause in the Biosafety Regulations of 2009, there are no GE products imported or commercialized in Tanzania. The regulation creates a de facto ban on GE products and otherwise suffers from many shortcomings, such as the lack of a sound scientific foundation, an inherent potential to distort regulatory priorities, and the relative ease with which it might be used to justify protectionist measures. Meanwhile, Tanzania has applied biotechnology in medicine, public health, industry, and other areas.

EXECUTIVE SUMMARY

In 2017, the Tanzanian government nominally relaxed the “strict liability” biosafety regime that had de-facto prevented plant scientists from testing GE crops (known locally as “GMOs”) outside the lab. The Government of Tanzania states that they recognize that biotechnology provides a set of novel and powerful tools with the potential to foster sustainable development in various sectors of the economy including agriculture, health and industry, as well as to benefit the environment. The government’s claimed commitment towards the promotion and application of biotechnology is articulated in the National Biosafety Framework of 2004 (NBF), National Agricultural Policy of 2013, and National Biotechnology Policy of 2010. The Environment Division under the Vice-President’s Office is the National Biosafety Focal Point and the National Competent Authority (NCA); it provides the Biosafety Clearing House (BCH) with required data for the Cartagena Protocol. The NBF includes national policies related to biosafety and the regulatory regime; administrative, decision-making and monitoring; and mechanisms for public awareness, education, and participation. However, in practice, progress toward science-based decision-making in the regulation, trade, and commercialization of GE agricultural products is impossible due to a strict liability biosafety regime that requires all approvals for introduction of GE products and derivatives to be subjected to a condition that the applicant is strictly liable for any damage caused to any person or entity.

While the Government has put in place all the necessary policies and legal and institutional frameworks for safe and responsible use of modern biotechnology, progress in research and utilization of GE technologies has been hindered by the lack of facilitative biosafety regulations and inadequate knowledge and understanding of biotechnology and biosafety issues by various stakeholders. In light of the slow pace of adoption of biotechnology in the country and increasing activism, the science and technology stakeholders in Tanzania formed an independent association, the Biotechnology Society of Tanzania (BST), that assists the government of Tanzania in fostering socioeconomic development using biotechnology and other scientific advances. The Society is dedicated to promoting the advancement and use of biotechnology in the country. Membership in the Society is open to all scientists, academics, farmers, consumers, manufacturers, policy and decision makers, industry, media, non-government organizations (NGOs) and community-based organizations (CBOs) interested or involved in fostering, developing, and supporting the application of biotechnology tools and information in various sectors of the economy to enhance the living standards of the people of Tanzania.

The Tanzanian government claims to allow importation of GE products from the United States and other countries that meet national standards. However, there is no GE food in the Tanzanian market due to the strict liability clause in the Biosafety Regulations of 2009.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

The ongoing public debate on the biosafety legal regime in Tanzania has affected research on GE crops, despite the Parliamentary Committee for Agriculture, Livestock and Water's appreciation of GE research in Tanzania. In early 2020, the Government of Tanzania (GoT) stated that it will not promote the production of GE seeds, but will instead rely on the Tanzania Agricultural Research Institute (TARI) to produce Tanzania's own conventional seeds. Equally GoT directed the National Biotechnology Advisory Committee (NBAC) to ensure that it closely monitors all research on biotechnology so that it can advise the government on proper methods to ensure the health of the people is safe. Presently, the GE crops researched in the country are cassava and maize presented in Table 1.

Table 1: GE Crop Research Project in Tanzania:

GE Plant	Trait	Developer	Stage	Number of trials
White maize/corn	Drought tolerant	Bayer	CFT	4
White maize/corn	Drought tolerant and insect resistant	Bayer	CFT	3
Cassava	Virus resistant (CBSD/CMD)	TARI	Lab	

The following are some of the main biotechnology applications in Tanzania:

1. Tissue Culture and Micro Propagation

The application of tissue culture techniques to address constraints of disease-free planting materials and rapid improvement in crop production is now routinely applied in several institutions in Tanzania. Institutes conducting tissue culture in Tanzania are: Mikocheni Agricultural Research Institute (MARI) in Dar es Salaam; Agricultural Research Institute (ARI) Mlingano in Tanga; ARI Uyole, Mbeya; Horticulture Research Institute-Tengeru (Arusha); Kizimbani Agriculture Research Station (Zanzibar); Tropical Pesticides Research Institute (TPRI), Arusha; Sokoine University of Agriculture (SUA); and Tanzania Coffee Research Institute (TACRI) through Crop Bioscience Solutions Ltd (CBS). CBS is the commercial crop biotechnology company dedicated to modern agricultural technologies. Through innovative biotechnology, they deliver quality-planting materials that are affordable at a competitive price.

2. DNA Markers and Marker-Assisted Technologies

MARI, SUA- the Faculty of Veterinary Medicine, Central Veterinary Laboratory (CVL), Molecular Biology and Biotechnology Department (DMBB), University of Dar es Salaam (UDSM) and Ifakara Health Research Development Centre carry out the use of DNA marker technology that simplifies the genetic improvement and disease diagnostics.

3. Developing Genomics and Bioinformatics capacity in Tanzania

SUA has established a state-of-the-art Genome Science Centre, which supports research and postgraduate training in the area of functional genomics and bioinformatics.

The Genome center has facilities for cDNA works, printing microarrays using a high throughput GENETIX microarray and 4-colour scanning of arrays.

4. Genetic Engineering

The first GE research is being conducted at ARI, Mikocheni on cassava in a contained environment. Additionally, confined field trials (CFTs) are being conducted on GE corn as part of the TELA Maize Project at Makutupora in Dodoma.

b) COMMERCIAL PRODUCTION

There is no commercial production of GE crops or GE seeds.

c) EXPORTS

Tanzania does not export GE crops to the United States or any other country since there is no legal authorization for GE commercial production.

d) IMPORTS

Government of Tanzania (GOT) has never publicly banned the importation of GE food or products. However, the absence of GE food and products (imported or domestic) in Tanzania speak to a *de facto* ban of GE products in the country. Officially, a GE food importer must follow existing food importation law plus the sections in the Environment Act, which governs the importation of GE Food. For more information, please visit the Tanzania Ministry of Environment website.

e) FOOD AID

Tanzania is not a food aid recipient country; movement of GE food aid products is permitted under the environmental regulations governing handling of GE products in transit.

f) TRADE BARRIERS

The strict liability clause in the Biosafety Regulations of 2009 is a *de facto* barrier to the commercialization of GE products for cultivation or import. Regulation 56. -(1) “Any person or his agent who imports, transits, makes contained or confined use of, releases, carries out any activity in relation to GMOs or products thereof or places on the market a GMO shall be strictly liable for any harm, injury or loss caused directly or indirectly by such GMOs or their products or any activity in relation to GMOs.” (2) The harm, injury or loss includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity and takes into account socio-economic, cultural and ethical concerns. The regulation and the language used ignores science-based evidence in decision-making as it employs the “precautionary principle” of risk management, which puts a priority on anticipating and guarding against environmental damage—even if there is no evidence of said risk and with no consideration given to the costs and benefits to the public. Even in the absence of a scientific basis, this approach put the onus of proof on those who propose a change.

The liability clause in the Biosafety Regulations of 2009 imposes strict regulations on researchers and producers. The regulations suffer many shortcomings such as the lack of a sound, scientific foundation, the potential for it to distort regulatory priorities, and the relative ease with which it might be used to justify protectionist measures. Furthermore, regulations such as these create unnecessary bureaucratic delays and moratoria that, ultimately, stifle important research and subsequent benefits for producers, consumers, and others across the food and agricultural economy.

PART B: POLICY

a) REGULATORY FRAMEWORK

The Environment Division under the Vice-President's Office is the National Biosafety Focal Point and the National Competent Authority (NCA); it provides the Biosafety Clearing House (BCH) with required data for the Cartagena Protocol. The NBF includes national policies related to biosafety and the regulatory regime; administrative, decision-making, and monitoring; and mechanisms for public awareness, education, and participation. In 2010 the Ministry of Education Science and Technology established the National Biotechnology Policy (NBP) by the Environment Management Act of 2000. According to Tanzania Clearing House Mechanism, the regulatory regime for the application of Modern Biotechnology in the country is guided by the following principles:

- i. *Precautionary Principle*: This shall be implemented through the decision-making system, particularly in accordance with the procedure for risk assessment, risk management and evaluation of socio-economic risks.
- ii. *Preventive principle*: prevention of adverse effects of GE products on environment and human and animal health
- iii. *A balanced approach*: Such approach recognizes both the potential benefits and risks of modern biotechnology to human and animal health, agriculture, biological diversity, and the environment.
- iv. *Prior informed consent*: The exporting Party shall notify the National Biosafety Focal Point prior to the first intentional transboundary movement of GE products. A failure to acknowledge receipt of a notification should not imply consent to importation of GE products.
- v. *Strict liability*: A person who imports, arranges transit, makes contained use of, releases or places on the market a GE or product of a GE shall be strictly liable for any harm caused by such a GE or product of a GE. The harm shall be fully compensated.
- vi. *Socio-economic and ethical considerations*: the social, economic, and ethical considerations shall be taken into account in Biosafety decisions.
- vii. *Transparency and Public Participation*: decision taken under the NBF shall be arrived at in a transparent and participatory manner. All relevant stakeholders shall have appropriate access to information and opportunity to participate in Biosafety decision-making process.
- viii. *Duty to protect the environment*: Every person living in Tanzania shall have a stake and a duty to safeguard and enhance the environment and to inform the relevant authority of any activity and phenomenon that may affect the environment significantly.

A review of existing pieces of legislation has shown that there is yet no single legislative instrument that addresses biosafety concerns in the country. Rather, there are various pieces of sectoral legislation covering plant protection, animal, and human health, which would implicitly address issues of biosafety in their respective mandates. They address the issues of plant protection substances including pesticides

and herbicides; animal health; food quality; health control; environmental protection and natural resources management.

The following are some of the legislation that have been assessed in order to establish the extent to which they regulate the application of biotechnology in the country:

- Environmental Management Act (Cap. 191);
- The Plant Protection Act No. 3 of 1997;
- The Veterinary Act No. 16 of 2003;
- The Animal Diseases Act No. 17 of 2003;
- Fertilizers and Animal Feedstuffs Ordinance Cap. 467;
- The Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003;
- The Merchant Shipping Act No of 2003;
- The Tanzania Civil Aviation Authority Act No. 10 of 2003;
- The Fisheries Act No 22 of 2003;
- Forest Act No. 14 of 2002;
- Beekeeping Act No. 14 of 2002;
- Wildlife Conservation Act No. 12 of 1974;
- The Tanzania Commission for Science and Technology Act No. 7 of 1986;
- The Tanzania Bureau of Standards Act No. 33 of 1975; and
- The Industrial and Consumer Chemicals (Management and Control) Act No 3 of 2003.

The National Environmental Policy (1997) recognizes the importance of conservation and sustainable utilization of the national biological resources. Paragraph 32 stipulates the need for undertaking programs and actions for the conservation and sustainable utilization of biological resources to prevent and control the causes of significant reduction or loss of biological diversity. It further states, “Strategic measures shall be put in place for the development of biotechnology, especially to ensure fair and equitable sharing of the results and benefits arising out of utilization by foreign recipients, of genetic resources originating from Tanzania, and biosafety.”

In addition to the National Environmental Policy, there are sectoral policies relevant to biosafety. For example, the National Science and Technology Policy for Tanzania (1996) acknowledge the existing weakness in emphasis on basic and applied research. The Policy focuses on, inter alia, biotechnology, genetics and genetic engineering, and exploitation of medicinal, agrochemicals and industrial chemicals. National Biotechnology Policy (2010) seek to ensure that Tanzania has the capacity and capability to capture the proven benefits arising from health, agriculture, industry and environmental applications of biotechnology while protecting and sustaining the safety of the community and the environment.

The institutional framework consists of:

- National Biosafety Focal point (NBFP),
- National Biosafety Committee (NBC),
- National Biotechnology Advisory Committee (NBAC),
- Ministerial Competent Authorities,
- Plant Biosafety Centre of Excellency Tanzania Bureau of Standards (TBS) and
- Institutional Biosafety Committees (IBC)

Figure 1: The institutional structure as per NBF:

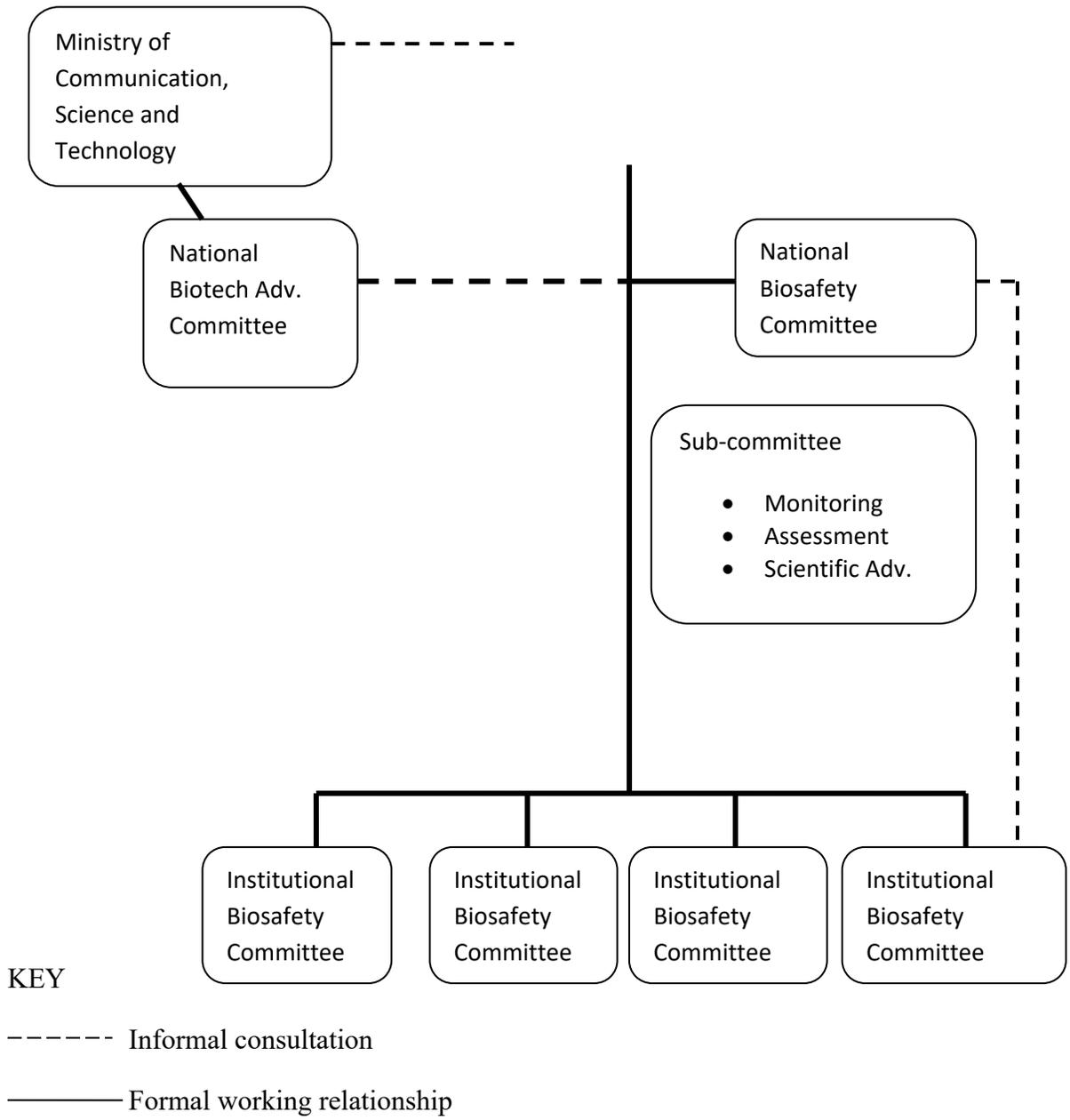
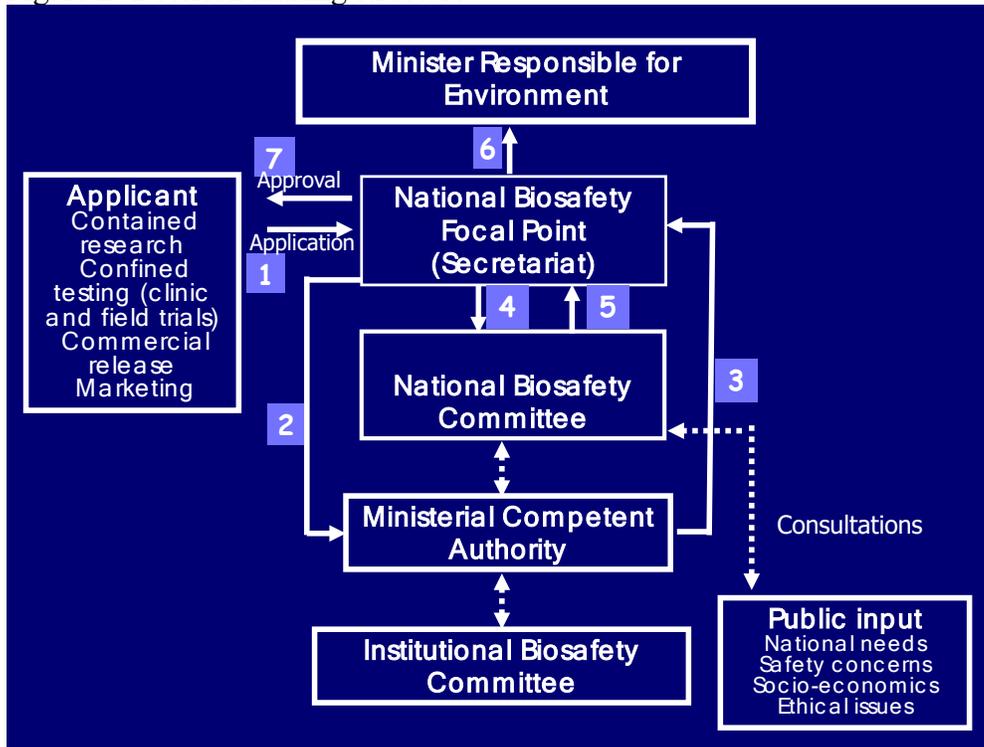


Figure 2: Decision making structure



a) APPROVALS

No plants are registered for cultivation, import or export in Tanzania.

b) STACKED EVENT APPROVALS

Biosafety regulations direct a case-by-case review. Depending on the character of the trait, the National Biosafety Committee may require extra information to make decision. TARI is preparing to submit a TELA maize with stacked traits for approval.

No plants are registered for cultivation, import or export in Tanzania.

c) FIELD TESTING

Tanzania has allowed CFTs for GE corn. The trial is on a two-hectare plot at Makutupora research station, Dodoma Tanzania. There are no GE crop trials in farmers' fields.

GE Plant	Trait	Developer	Stage	Number of trials
White maize/corn	Drought tolerant	Bayer	CFT	4
White maize/corn	Stack (Drought tolerant and insect resistant)	Bayer	CFT	3
Cassava	CBD/CMD resistant	TARI	Lab	

b) INNOVATIVE BIOTECHNOLOGIES

The application of biotechnology in Tanzania is considered in the context of the country's need for food for the nutrition and survival of its people. The regulatory approach for innovative biotechnologies in plants and plant products still underdeveloped.

c) COEXISTENCE

The country has GE handling manuals that provides the guidelines on coexistence between GE and conventional crops. Once GE crops are released for commercialization, more capacity building is needed for smallholder farmers and technology developers to comply with the guidelines on coexistence.

g) LABELING and TRACEABILITY

Biosafety regulations require labeling for bulk shipments, raw material, packaged food or feeds, or other products derived from and/or containing ingredients from GE plants. The required information is skewed towards the consumer's right to know. Currently, there are no legal GE products on the market. Tanzania borders are extremely porous, chances of illegal importation of GE products is very high due to informal cross border trade. Informal flows of commodity outside formal system are large. Meaning that activity is not typically recorded in government statistics or inspected and taxed through official channels. These flows vary from very small quantities moved by bicycle to large volumes trucked over long distances.

h) MONITORING AND TESTING

GE products are monitored in supermarkets and at points of entry. National Biosafety Focal Point (NBFP) is responsible for approving imports of GE products, while Tanzania Bureau of Standards (TBS) monitor and test agricultural commodity and food product imports at ports of entry. However, the Tanzanian government has limited personnel and testing facilities for evaluating agricultural products for GE content.

i) LOW LEVEL PRESENCE POLICY

Tanzania has no low-level presence policy.

j) ADDITIONAL REGULATORY REQUIREMENTS

GE crops or products, after securing approval from Vice Presidents Office, Division of Environment, are subjected to other national laws. In the case of crops, the variety will be subject to legislation and regulations guiding variety release, while food products are further subject to the Tanzania Food and Drug Act and other regulations.

k) INTELLECTUAL PROPERTY RIGHTS

Tanzania is a member of the Trade Related Intellectual Property (TRIPS) Agreement. Tanzania does not have a National Intellectual Policy (NIP). However, there are number of institutions that are currently dealing with and promoting IP issues. They include:

- a) Business Registrations and Licensing Agency (BRELA)
- b) Commission for Science and Technology (COSTECH)
- c) Copyright Society of Tanzania (COSOTA)
- d) Fair Competition Commission (FCC)
- e) Fair Competition Tribunal (FCT)
- f) Ministry of Agriculture (Plant Breeders Rights - PBR)
- g) Tanzania Bureau of Standards (TBS)
- h) Tanzania Food and Drugs Authority (TFDA)
- i) Tanzania Revenue Authority – Customs (TRA)
- j) Commercial Court (High court of Tanzania)
- k) University of Dar es Salaam (UDSM)
- l) Sokoine University of Agriculture, (SUA), and Nelson Mandela African Institution of Science and Technology (NM-AIST)
- m) National Institute of Medical Research (NIMR)
- n) Tropical Pests Research Institute (TPRI)

l) CARTAGENA PROTOCOL RATIFICATION

Tanzania acceded to the Cartagena Protocol on Biosafety (CBP) on March 16, 2003. It was adopted on January 29, 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on September 1, 2003. NBFP is Tanzania's focal point of the CBP and shares data with the Biosafety Clearing House, a mechanism set by CPB to facilitate information exchange on GE product development and to assist member countries in complying with their obligations under the protocol.

m) INTERNATIONAL TREATIES and FORUMS

Tanzania is a member of several international organizations that deal with plant protection and plant health, including the International Plant Protection Convention (IPPC), International Treaty on Plant Genetic Resources for Food and Agriculture, Codex Alimentarius, World Trade Organization (WTO), WIPO, and ARIPO and has ratified the International Convention on Biological Diversity (CBD), Plant genetic Resources for Food and Agriculture (IT-PGRFA) and the aforementioned CPB.

n) RELATED ISSUES

The Government of Tanzania (GOT) has not banned importation of GE food outright, though the absence of GE products on the market is indicative of a de facto import ban due to their strict liability clause. Any person who wishes to import, transit, or place on the market what is known locally as "a GMO" intended for direct use as food or feed, or for processing, shall submit an application in writing with a reference to the information on the item found in the CBP to the NBFP for approval.

Tanzania adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CBP. It gives Tanzania flexibility to implement legislative, administrative, or judicial rules and procedures relevant to liability and redress.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The debate on biotech crops and bioengineered foods remains contentious and political. Anti-GE and “anti-GMO” movements have exposed Tanzanian consumers to negative messaging, while the Commission for Science and Technology (COSTECH) and Vice President’s Office (VPO) and Biotech Society of Tanzania continue to provide balanced messaging.

b) MARKET ACCEPTANCE/STUDIES

Recent studies conducted by GoT VPO, United Nations Environment Programme (UNEP) and Global Environment Facility (GEF) revealed limited understanding of genetic engineering and products thereof, among Tanzanians except for a small section of elites with a tertiary level of education. Most Tanzanians disregard scientific evidence and opine that GE products (“GMOs”) and modern biotechnology are disadvantageous and erroneously consider the health and agricultural sectors to be the most affected. The study was carried out in three out of seven designated agro-ecological zones in the country. Selected study areas were Central zone (Dodoma - arid land/ drought prone), Eastern zone (Morogoro - high rainfall and fertile soil with many high learning institutions) and Northern zone (Same - semi arid with lots of farming communities). Respondents in the Eastern zone were relatively more informed than the Central and Northern zones. Higher learning institutions are believed to have played a major role into such awareness. The GE debate is raging in Tanzania with some adamantly for the technology and others demanding the government cease all GE research. There will be no progress without understanding public opinion and ensuring that science informs public understanding, policy, and practice.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Not applicable

b) COMMERCIAL PRODUCTION

Not applicable

c) EXPORTS

Not applicable

d) IMPORTS

Not applicable

e) TRADE BARRIERS

Same as for Plant Biotechnology

PART E: POLICY

a) REGULATORY FRAMEWORK

The National Biosafety Act covers both plants and livestock, but no regulations have been developed specifically for animal biotechnology.

b) INNOVATIVE BIOTECHNOLOGIES

Not applicable

c) LABELING and TRACEABILITY

Same as for Plant Biotechnology

d) INTELLECTUAL PROPERTY RIGHTS

Same as for Plant Biotechnology

e) INTERNATIONAL TREATIES and FORUMS

Tanzania is a member of the World Organization for Animal Health (OIE) since December 14, 1961. OIE is an inter-governmental organization whose 181 Members have mandated it to improve animal health and welfare worldwide.

f) RELATED ISSUES

Not applicable

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Same as Plant Biotechnology

b) MARKET ACCEPTANCE/ STUDIES

Not Applicable

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

- a) **COMMERCIAL PRODUCTION:**
There is no commercial production of microbial GE
- b) **EXPORTS:**
Tanzania does not export microbial GE to the United States or any other country since there is no legal authorization for GE commercial production.
- c) **IMPORTS:**
Tanzania does not import microbial GE from the United States or any other country since there is no legal authorization for GE trade.
- d) **TRADE BARRIERS:**
Same as for Plant Biotechnology since the Tanzania National Biosafety Framework includes GE microbes in the de-facto ban.

PART H: POLICY

- a) **REGULATORY FRAMEWORK:**
Same as for Plant Biotechnology
- b) **APPROVALS:**
Same as for Plant Biotechnology
- c) **LABELING and TRACEABILITY:**
Same as for Plant Biotechnology
- d) **ADDITIONAL REGULATORY REQUIREMENTS:**
Same as for Plant Biotechnology
- e) **INTELLECTUAL PROPERTY RIGHTS (IPR):**
Same as for Plant Biotechnology
- f) **RELATED ISSUES:**
Not applicable

PART I: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS**
Same as Plant Biotechnology
- b) **MARKET ACCEPTANCE/STUDIES:**
Not Applicable

Attachments:

No Attachments