



Policy Brief

Government of Rwanda Adopts Biosafety Bill governing GMOs

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A path towards food security and improved livelihoods in Rwanda:

The purpose of this policy brief is to enhance understanding of the objectives, scope, and provisions of the Biosafety Bill, that was recently approved by the Lower Chamber of Parliament on December 4 2023, after the Parliament of Rwanda approved the draft biosafety law following consent by the Cabinet on mid-July 2023.

The Bill lays down legal and institutional frameworks for governing genetically modified organisms in Rwanda. Authors hope that the brief will encourage objective and constructive debate of the Bill in Rwanda.

Biotechnology Policy is the cornerstones of Rwanda's national biotechnology regulatory system. The implementation and enforcement of the two instruments

is indispensable if Rwanda is to become a competitive participant and beneficiary in the global biotechnology revolution.

The absence of a biosafety law exposes the country to regulatory gaps and could be a major weakness undermining the legitimacy and credibility of the national biosafety system. In this respect, enactment of a biosafety law in Rwanda is fundamental to provide adequate legal authority and enforcement.

This would provide an enabling environment for modern biotechnology research and development to thrive and at the same time safeguard the country from potential risks posed by the technology.

Biotechnology and Biosafety Developments in Rwanda:

The Rwanda government's vision and commitment towards promotion and application of biotechnology is paramount. For instance, through BioNTech initiative, the health sector has made significant advances compared to other sectors.

The Government also underscores the need to institute adequate biosafety measures that will ensure maximization of benefits of the biotechnology in agriculture and environment, while minimizing the risks. Biotechnology is any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use. Biosafety refers to measures put in place to prevent or mitigate potential risks to human health and the environment resulting from use of modern biotechnology for research or commercial purposes.

Rwanda joined other countries globally by signing the Cartagena Protocol on Biosafety. Rwanda moved another step by ratifying the process in 2003. Ratification of the protocol implies that a state has agreed to be legally bound by provisions of the Protocol and must comply with obligations stipulated in the instrument.

The Protocol's objective is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, considering risks to human health, and specifically focusing on transboundary movements.



Fig 2: The Lower Chamber of Parliament on December 4 passed a bill governing biosafety, which aims to address the potential risks associated with genetically modified organisms (GMOs).

The Government of Rwanda recently demonstrated further support for biotechnology by signing agreement in August 2021, whereby BioNTech agreed to set up vaccine production capabilities in Rwanda and a few other African countries together with the kENUP Foundation. The signing of the agreement brought together President Paul Kagame of Rwanda, President Macky Sall of Senegal, and President Ursula von der Leyen of the European Commission.

The decision was guided by the African Union, the Africa Centres for Disease Control and Prevention (Africa CDC), and the African Medical Agency (under formation). This shows high-level commitment by the government of Rwanda to harness benefits accrued from modern biotechnology (in Medicine).

The Biosafety Regulatory System:

Rwanda Environment Management Authority (REMA) has been working tirelessly in collaboration with other national institutions, UN agencies and Partners to overcome regulatory challenges emanating from scientific developments. For instance, (Rwanda Agriculture and Animal Resources Development Board (RAB) has been involved in Research and Development in the field of modern biotechnology whose research have been on hold due to lack of a biosafety law. REMA is the designated competent authority that handles all matters pertaining to biosafety in Rwanda.

The general mission of REMA is to promote and ensure the protection of the environment and sustainable management of natural resources through decentralized structures of governance and seek a national position to emerging global issues with a view to enhancing the well-being of the Rwandan people.

In the absence of a primary biosafety law, REMA has applied the guidelines and regulations in reviewing and approving applications to introduce modern biotechnology products exclusively for research trials, under the ambit of existing legislation.

These guidelines have not themselves, been promulgated into law and as such, lack adequate and streamlined legal enforcement. To fill this gap, the process of drafting a Biosafety Bill took place under the leadership of the REMA in collaboration with other national entities, partners, and donors.

The objectives, scope, and provisions of the Biosafety Bill:

The Biosafety Bill is consistent with the provisions and requirements of the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety. The objectives of the Bill are to ensure an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms that may have an adverse effect on human health and environment, and to establish a transparent science-based and predictable process to review and make decisions on genetically modified organisms and related activities.

In terms of scope, the Bill covers contained use, deliberate release, placing on the market, import and export of GMOs and products containing GMOs. The legal requirements and procedures required for obtaining approval before introducing GMOs for research or commercial purposes are specified. The Bill elaborates on the information required from the applicants, the risk assessment process, and the role of different regulatory agencies in ensuring compliance.

The Bill makes provision for establishment of a national biosafety committee. The committee shall be under the Ministry of Environment (REMA) and Health and will be managed by a board comprising eminent scientists, experts, permanent secretaries from key ministries, directors of biosafety regulatory agencies and civil society representatives. Key functions of the committee embrace overall supervision and control of the development, transfer, handling, and use of genetically modified organisms for research or commercial purposes.

The proposed committee is also charged with the responsibility of promoting public awareness and education to enhance understanding of biosafety. The Bill outlines mechanisms for obtaining and incorporating public input into the decision-making process.

To ensure safe and responsible use, the Bill makes provision for assessment and management of risks that may be caused by genetically modified organisms. The Bill imposes heavy penalties to persons dealing with GMOs without approval of the authority or fail to furnish correct information to the authority. Cessation orders stipulate immediate directives for terminating activities that pose imminent danger to the conservation and sustainable use of biological diversity, considering risks to human health.

Environmental restoration orders set forth legal sanctions to be enforced to remedy or rehabilitate damage to the environment as a result of negligence or deviation from risk management measures.

Why Rwanda needs a Biosafety Law

The need for and importance of a biosafety legislation in Rwanda is justified by a number of fundamental

reasons. A comprehensive biosafety legal framework ensures the development of biotechnology, protection of the environment and safeguarding the interests of consumers. Potential risks associated with application of modern biotechnology are minimized while facilitating the beneficial application of the technology in areas of agriculture, health, environment, and industry.

The law is vital to deal with transboundary movement of GMOs. For instance, delays caused by judicial and political decisions resulted to an increase in illegal planting of GM soyabean seeds in southern Brazil smuggled across the border from Argentina. Appropriate legislation and strong regulatory frameworks are also important in developing public confidence in biotechnology as a technological option.

National laws and regulations are required in order to fulfil and comply with the objectives of the Cartagena Protocol on Biosafety. Parties are required to make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines affecting transboundary movement of GMOs.

Existing Acts and regulations being employed to some extent, to facilitate application of biotechnology were enacted at a time when the technology was not a major public policy concern. In the last decade, scientific and technological developments in the field of modern biotechnology have been significant in Rwanda. At the same time, debates on benefits and risks of this technology have gained currency.

Confined field trials of genetically modified insect-resistant cassava are going on in Rwanda although there is still lack of substantive regulatory provision.

Biosafety Global Trends by December 2023

Global trends depict that approximately 10.3 million farmers in developing countries (including South Africa, China, and India) grew biotech crops in 2006, up significantly from 5 million farmers in 2002. The number of countries that are growing biotech crops increased from 6 in 1996 to 22 in 2006. This includes six countries in the European Union (Spain, France, Czech Republic, Portugal, Germany and Slovakia) where the degree of sensitivity and controversy associated with GMOs is high. The global area under biotech crops also increased significantly from 4.2 million acres in 1996 to 252 million acres in 2006 (over a 50-fold increase).

Since 1996, biotech crops have increased farm incomes by USD 27 billion worldwide. An Economic analysis study on potential benefits of biotech crops commissioned by the Common Market for Eastern and Southern Africa (COMESA) revealed that farmers' incomes in Rwanda would increase by USD 5.9 million and food security situation enhanced substantially if they adopted insect resistant genetically modified varieties of cotton and maize compared to the conventional counter parts.



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