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# **Report Name:** Agricultural Biotechnology Annual

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#### Prepared By: Jasmine Osinski and Fana Sylla

Approved By: Joshua Lagos

## **Report Highlights:**

The Government of Senegal is reviewing and revising its new biosafety law which may include language for an expedited approval process for certain genetically engineered (GE) products. A draft regional biosafety law is also still pending approval by the Economic Community of West African States members. Because reliable information is limited, many West Africans are not well informed about the issues involved with biotechnology. Gaining future market acceptance will depend on efforts to inform and educate the public about the safety and benefits of biotechnology products. This is a regional report on West Africa that primarily covers Senegal, Burkina Faso, and Mali, but also provides brief overviews in certain sections for Niger, The Gambia, Guinea-Bissau, and Mauritania.

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#### Section I. EXECUTIVE SUMMARY

This is a regional report on West Africa that primarily covers Senegal, Burkina Faso, and Mali, but also provides brief overviews in certain sections for Niger, The Gambia, Guinea-Bissau, and Mauritania.

The Government of Senegal is reviewing and revising its new biosafety law which may include language for an expedited approval process for certain genetically engineered (GE) products. The new draft law must be approved by the Council of Ministries before going to the National Assembly for final approval. However, the current process to review GE imports into Senegal prior to passage of the new biosafety law remains unclear and untested, preventing any GE products or derived products from being exported to Senegal.

Burkina Faso has the most experienced biosafety regulatory system in the West African region covered by FAS Dakar. In 2012, Burkina Faso adopted a new Biosafety Law to facilitate the research and commercialization of GE products. This facilitated the approval of GE cotton for cultivation, as well as the research and development for two GE products: pod borer resistant (Bt) cowpeas and GE mosquitos.

In March 2016, the Economic Community of West African States (ECOWAS) developed a draft regional biosafety law for all members; it is still undergoing evaluation and approval at the minister level for each member country. This draft law reportedly includes language that allows for regional approval of GE products.

Because reliable information is limited, many West Africans are not well informed about the issues involved with biotechnology. Gaining future market acceptance will depend on efforts to inform and educate the public about the safety and benefits of biotechnology products.

## Section II. PLANT AND ANIMAL BIOTECHNOLOGY

#### **Chapter 1: Plant Biotechnology**

#### Part A: Production and Trade

#### a) PRODUCT DEVELOPMENT

In Burkina Faso, since 2005, the Institut de l'Environnement et de Recherches Agricoles (INERA) has been developing Bacillus thuringiensis (Bt) cowpeas to control the legume pest *Maruca vitrata*; the institute is currently conducting field trials and testing the genetically engineered (GE) product's effect on non-target organisms. It is unclear when Bt Cowpea will be released for commercialization. Burkina Faso is the third largest producer of cowpeas after Nigeria and Niger. In 2011, INERA tried to develop a GE sorghum product (sorghum ABS188) with higher levels of vitamin A, zinc, and iron, but this effort has discontinued. In 2016, Burkina Faso conducted confined field trials for Bt maize and a stacked insect resistant and herbicide resistant maize (Bt X RRF). However, reportedly field trials have been suspended.

Sources noted that after local cotton ginning mills in Burkina Faso collectively agreed to stop the distribution of Bt cotton seeds during marketing year (MY) 2016/17 (please see the Commercial Production section below), all research collaboration on GE cotton with Monsanto in Burkina Faso was suspended. This included research on a Stacked Bollgard II x Roundup Ready Flex (insect resistant and herbicide tolerant) product.

In Mali, in 2011 the National Rural Economy Institute's Board of Directors authorized research on GE cotton in collaboration with Compagnie Malienne pour le Développement du Textile (CMDT); however, Post is not aware of any further developments.

Senegal, The Gambia, Niger, and Guinea are not conducting any GE plant research at this time.

#### b) COMMERCIAL PRODUCTION

Senegal, The Gambia, Mali, Niger, and Guinea have not approved any GE crops for cultivation. The only country that has approved a GE product for cultivation is Burkina Faso, which approved Bt cotton.

From MY 2009/10 to MY 2015/16 Burkina Faso farmers planted Bt cotton seed that was developed by Société Burkinabé des Fibres Textiles (SOFITEX) in partnership with Monsanto. Since MY 2016/17, according to Post contacts, local cotton ginning mills collectively agreed to stop the distribution of Bt cotton seeds due to its short fiber length, which apparently did not garner a high price on the international market. Sources believe that both farmers and local cotton ginning companies are supportive of agricultural biotechnology; however, they added that the introduction of a new Bt cotton variety would need to meet industry requirements.

Senegal, The Gambia, Mali, Niger, Guinea, and Burkina Faso are not currently planting any GE seeds for commercial production.

## c) EXPORTS

Senegal, The Gambia, Mali, Niger, Guinea, and Burkina Faso do not export GE commodities.

## d) IMPORTS

Current biosafety regulations in Senegal and Mali require biosafety approval to import GE commodities or derived products for food, feed, or processing. Burkina Faso requires biosafety approval for GE commodities; it does not require import authorization for derived products. Currently, Burkina Faso, Senegal, and Mali have not issued biosafety approvals for importation.

## e) FOOD AID

Previous or current food aid recipient countries include Burkina Faso, The Gambia, Guinea, Guinea-Bissau, Mauritania, Niger, Mali, and Senegal. GE commodities or food derived from a GE commodity should be notified to the recipient country's government for approval.

## f) TRADE BARRIERS

Many West African countries lack a clear or formal decision-making process, which can inhibit the trade of GE products or foods derived from GE products into the West African region. The current process to review GE imports into Senegal prior to passage of the new biosafety law remains unclear and untested, preventing any GE products or derived products from being exported to Senegal.

## **Part B: Policy**

## a) REGULATORY FRAMEWORK

## **Burkina Faso**

In 2012, Burkina Faso adopted a new Biosafety Law to facilitate the research and commercialization of GE products. The National Biosafety Authority (NBA), which is under the Ministry of Higher Education, Scientific Research and Innovation, is the country's biotech authority and has two main functions: 1) approving the use, importation, or exportation of GE commodities and 2) approving the research of GE products, including confined field trials. The NBA includes two advisory bodies: the National Biosafety Scientific Committee (NBSC) and the National Biosafety Observatory (NBO).

The NBSC has twenty members (thirteen permanent members and thirteen alternate members) from nine ministries (Ministries of Scientific Research, Secondary and Higher Education, Health, Defense, Environment, Agriculture, Animal Resources, Trade, and Justice) which specialize in various fields such as GE technology, environmental protection, and human and animal health, and three representatives from the NBA, the National Laboratory of Biosafety, and the Ethics Committee for Research. The NBSC evaluates dossiers for biotech products and provides a recommendation to the NBA for approval. The NBO has 33 members including 19 from different ministries and 13 from civil society; membership also includes the NBA and the Social and Economic Council. It monitors the use of GE products in accordance with Burkina Faso's laws and regulations, and also raises awareness on agricultural biotechnology to the general public. NBO members have a mandate of three years (up to a maximum of six years).

In order to initiate the approval process for a GE product (for importation or environmental release), an applicant must send a dossier to the NBA that, according to the Biosafety Law, will respond in 150 days. The NBA could request additional information during this process. If the NBA believes there is no significant risk for human and animal health, biodiversity, or the environment, it may utilize a simplified process that will expedite the time period for approval.

Burkina Faso's 2012 Biosafety Law requires import authorization for GE commodities, but not for derived products.

For more information on Burkina Faso's 2012 Biosafety Law, please see this GAIN Report.

## Mali

In December 2008, Mali adopted its Biosafety Law which regulates GE products and derived products. The main bodies include the National Competent Authority (NCA), the National Biosafety Committee (NBC), the National Focal Point / National Correspondent, and the Public Institutional Biosafety Committees (PIBC). The NCA is the Minister of the Environment, and manages the implementation of the Biosafety Law, including approving GE products. The NCA is also in charge of approving GE research activities. The NBC provides recommendations to the NCA on whether to approve GE products and issues directives on how to implement biosafety regulations. These directives are informed by Specialized Commissions such as the Commission for Management and Risk Assessment, the Commission for Public Participation, and the Commission for Legal and Regulatory activities. The NBC is composed of a president (the Minister of Environment or his/her representative), a vice president (the Minister of Agriculture or his/her representative), and 37 members from various ministries as well as researchers, scientists, members of the general public, farmers associations, and the media. The National Focal Point for the Cartagena Protocol helps facilitate exchange of information between the NCA and other government bodies and manages environmental issues. The PIBCs ostensibly include a variety of bodies that, according to the law, would focus on monitoring whether actors are following the Biosafety Law and regulations. However, their function is not clear since there has been no decree to define their exact role or to officially nominate members and form PIBCs.

In order to initiate the approval process for a GE product, an applicant must send a dossier to the NCA. The NCA will give the dossier to the NBC, which is in charge of reviewing proposals and providing a recommendation for approval to the NCA within a period not exceeding 270 days. According to the Biosafety Law, the NCA will provide final decision in 90 days. The NCA could request additional information during this process. If the NCA believes there is no significant risk for human and animal health, biodiversity, or the environment, it may utilize a simplified process that will expedite the time period for approval. Before commencing GE research in country, the biosafety law requires that this research be approved by the NCA, and after approval needs to be

monitored by a government body. At the present time, the NBC is assuming the role of monitoring all GE research in country.

A prior informed consent (PIC) or a written authorization from the NCA is required before importation, transit, confined use, release, and/or commercialization of a GE commodity or product derived from a GE commodity. This authorization is required for any GE product or derived product.

For more information on Mali's 2008 Biosafety Law, please see this GAIN report.

## Senegal

In July 2009, Senegal adopted its Biosafety Law and two decrees were issued in December 2009, describing the function, mission, and organization of the two main bodies: the National Biosafety Authority (NBA) and National Biosafety Committee (NBC), both of which are under the Ministry of Environment. On May 19, 2017, the Government of Senegal (GoS) issued a decree that modified the structure of the NBA by splitting it into two bodies: the Orientation Council (OC) and the Executive Bureau (EB), and in addition to the NBC added one new consultative committee: the Scientific and Technical Committee (STC).

The NBA is divided into two bodies: the OC and the EB. The OC advises and ensures that the EB's overall activities follow government policies and priorities. It also approves the organization of the NBA, the rules of procedures, and the draft budget. The OC has nine members: six representatives from the Ministries of Economy and Finance, Environment, Agriculture, Fisheries, Livestock, and Scientific Research, one representative from the General Secretary of the Office of the President, one representative from the General Secretary of the Office of the President, one OC Chairman nominated by the President. The OC members have a term of three years (maximum of two terms). The EB, which is the competent authority on biotechnology, coordinates dossiers for GE products for cultivation or food, feed, or processing, provides a recommendation to the Minister of Environment for approval, and distributes notifications on those decisions. The EB includes an executive director who specializes in biotechnology and a permanent secretary and includes 17 members from different ministries.

An additional ministerial decree is required to define the organization, composition, and function of the STC; this decree will also possibly redefine the organization and function of the NBC. In the meantime, the NBA will continue to be supported by the NBC, which is charged with scientifically evaluating dossiers (i.e., risk assessments for the importation, exportation, handling, transit, confined use, release or commercialization of GE commodities and/or foods derived from a GE product) and providing a GE product approval recommendation to the NBA. The NBC currently has 30 members that include scientists, the private sector, and members of the general public.

Regarding the approval process, which currently follows the 2009 Biosafety Law, the Minister of Environment will provide a decision on a dossier based on the recommendation of the NBA; the law notes the approval process could take 270 days. In addition, any person wishing to export a GE commodity or food derived from a GE product to Senegal must submit the request in writing to the NBA. The law notes that any person transporting GE products or foods derived from a GE product

through the national territory to other countries should inform the NBA within a specified period and comply with national and international requirements for containment and transport. The NBA will provide a Prior Informed Consent (PIC) before the transit is approved.

The GoS drafted a revised biosafety law, which could create a clear pathway to commercialization of GE products. The draft revision reportedly includes language for an expedited approval process for certain GE products that pose no significant risk to humans, animals, or the environment. The new draft law must be evaluated and approved by the Council of Ministries before going to the National Assembly for final approval. It is unclear how long it may take for the new draft law to go to the National Assembly.

For more information on Senegal's 2009 Biosafety Law, which will remain active until the new biosafety law is formally passed by the National Assembly, please see this <u>GAIN Report</u>.

#### The Gambia, Niger, Mauritania, Guinea-Bissau, and Guinea

The Gambia has developed a draft biosafety law, but the law has not been passed by its National Assembly. Until the biosafety law is passed, The Gambia noted that it will use the Cartagena Protocol as a guide to regulate GE products and derived products, including imports.

Niger's National Assembly passed Niger's Biosafety Law in October 2019. For more information, please see this <u>GAIN Report</u>.

Mauritania has no national biosafety law but may have other regulations or laws that regulate biotechnology.

Guinea-Bissau has a national biosafety law in effect.

No information is available on Guinea at the present time.

## **Regional Initiatives**

In 2007, West African Economic and Monetary Union (WAEMU) developed (but did not approve) a draft regional biosafety law for member countries (i.e., Benin, Guinea-Bissau, Cote d'Ivoire, Burkina Faso, Mali, Niger, Togo, and Senegal). In 2016, a technical working group in ECOWAS used the draft regional WAEMU biosafety law to develop a regional biosafety law for the ECOWAS community (i.e., Benin, Guinea-Bissau, Cote d'Ivoire, Burkina Faso, Mali, Niger, Togo, Senegal, Cape Verde, The Gambia, Ghana, Guinea, Liberia, Nigeria, and Sierra Leone). The regional law has undergone revisions and is now under evaluation by ministers of ECOWAS member states. This draft regional biosafety law reportedly includes language that allows for the free flow of GE products within the region if they have been approved by an accredited member's competent national authority, as well as regional accreditation criteria for national biosafety authorities. The law reportedly contains a provision for mutual recognition and equivalence, that is, ECOWAS members have the option to formally recognize the biosafety assessment procedures of other accredited ECOWAS members as equivalent. This could potentially allow ECOWAS members to recognize one another's GE safety assessments for food, feed, processing, or cultivation without

requiring additional approvals at the national level.

## b) APPROVALS

Burkina Faso approved Bt cotton seed for cultivation and has approved field testing of Bt cowpea and GE maize. Mali, Guinea, Niger, Senegal and The Gambia have not approved any GE products or derived products for importation or commercial production.

## c) STACKED EVENT APPROVALS

The maize varieties that was tested in Burkina Faso included a stacked insect resistant (Bt) and herbicide tolerant maize. However, Post is not aware whether a stacked trait will be treated differently from single trait events during the regulatory review.

## d) FIELD TESTING

Burkina Faso is conducting field tests on Bt cowpeas and (please see Production section) has also conducted confined field trials of insect resistant (Bt) maize and stacked insect resistant and herbicide tolerant maize.

## e) INNOVATIVE BIOTECHNOLOGIES

No information available.

f) COEXISTENCE

No information available.

g) LABELING

## Burkina Faso

The 2012 Biosafety Law notes that any GE product intended for commercialization in the national territory must be packaged and labeled. The label should contain, "Produced on the basis of genetically modified organisms" or "Containing genetically modified organisms."

#### Mali

The 2008 Biosafety Law notes that any GE product or food derived from a GE product must be clearly identified and labeled.

## Senegal

The 2009 Biosafety Law states that any "genetically modified organism (GMO)" or products derived from a GE commodity intended for direct human and animal consumption, processing, or introduction in the environment or national market must be packed and labeled. The label should contain, "Produced with Genetically Modified Organisms" or "Contains Genetically Modified

Organisms," in conformity with other additional standards defined by the competent national authority and other concerned bodies.

## h) MONITORING AND TESTING

The Senegalese laboratory of Plant Biology at the Faculty of Science and Technology of the University Cheikh Anta Diop (UCAD) has been designated as the national reference laboratory for biosafety, which includes testing samples for GE products to support monitoring and surveillance at the border. However, it is unclear if this lab is fully functional. In 2012 and 2017, the lab received new equipment, which was funded by WAEMU and the NBA.

In September 2019, Burkina Faso launched a National Biosafety Laboratory hosted at the Agricultural, Environmental and Training Research Station of INERA. It is unclear how the lab will be used, but it will be managed by the NBA. The Government of Burkina Faso acquired a loan from the World Bank of approximatively \$1 million to build the lab; the lab also received a \$1.4 million grant from WAEMU for equipment.

Mali has a national biosafety laboratory funded by WAEMU, which can be used to conduct research or test samples for GE products to support monitoring and surveillance at the border.

Monitoring may be occurring unofficially or ad hoc for certain countries; others may have an official protocol for monitoring, but if it exists it may not be publicly available.

## i) LOW LEVEL PRESENCE POLICY

Senegal, The Gambia, Mali, Niger, Guinea, and Burkina Faso do not have a policy on low level presence.

## j) ADDITIONNAL REQUIREMENTS

Senegal, The Gambia, Mali, Niger, Guinea, and Burkina Faso are signatories to an ECOWAS agreement (adopted in May 2008) called Regulation C/REG.4/05/2008 on the Harmonization of the Rules Governing Quality Control, Certification, and Marketing of Plant Seeds and Seedlings in the ECOWAS Region. This agreement harmonizes all member country seed regulations concerning variety release, quality control, certification, and production, as well as "reciprocal recognition of national certification standards and labeling." This regulation would also apply to GE seeds.

For additional information, please visit this website.

## k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Burkina Faso, Guinea, Mali, Niger, and Senegal are members of the African Intellectual Property Organization (OAPI), which includes 15 African French-speaking countries that are treated as one state in trademark law. There is no national trademark law for member states; therefore, it is not possible to obtain national registrations in these countries. Trademark protection is obtained via registration in OAPI. It is valid for 10 years from the date of application and renewable for the same period. Foreign applicants need a local agent. A non-legalized power of attorney is sufficient.

For additional information, please visit this website.

## 1) CARTAGENA PROTOCOL

Mali ratified the Cartagena Protocol in September 2003 Burkina Faso ratified the Cartagena protocol in November 2003 Senegal ratified the Cartagena Protocol in January 2004 Niger ratified the Cartagena Protocol in September 2004 Guinea ratified the Cartagena Protocol in December 2004 The Gambia ratified the Cartagena Protocol in June 2004

## m) INTERNATIONAL TREATIES/FORA

Mali, Burkina Faso, Guinea, The Gambia, Niger, and Senegal are members of ECOWAS, as well as the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex). Senegal, Burkina Faso, Niger, and Mali are members of WAEMU. All are members of the World Trade Organization.

## n) RELATED ISSUES

None.

## Part C: Marketing

## a) PUBLIC/PRIVATE OPINIONS

Post believes there is some government support for agricultural biotechnology in Senegal and Burkina Faso. In early 2017, the President of Senegal noted agricultural biotechnology as one tool for achieving food security solutions. The NBA in Burkina Faso believes there is a need to continue to educate the local populace on the benefits and safety of biotechnology.

Because reliable information is limited, many West Africans are not well informed about biotechnology. Anti-GE groups have a stronger presence in Mali and Burkina Faso, but also exist in other West African countries. Gaining future market acceptance will depend on efforts to inform and educate the public about the safety and benefits of biotechnology products.

## b) MARKET ACCEPTANCE/STUDIES

No information available.

## Chapter 2: Animal Biotechnology

Part D: Production and Trade

## a) PRODUCT DEVELOPMENT

Mali and Burkina Faso are part of the Target Malaria Project funded by the Bill and Melinda Gates Foundation and the Open Philanthropy Project Fund. Under the project, researchers are developing GE sterile male and gene drive mosquitos to prevent the spread of malaria. The Scientific Research Institute in Health in Burkina Faso and University of Sciences and Techniques in Mali are partners in this project.

In 2016, Burkina Faso issued a decree to authorize GE mosquito research to help address the spread of malaria. GE *Anopheles gambiae* eggs were imported from Italy; three genes (the homing endonuclease gene and two fluorescent marker genes) from these mosquitos were backcrossed into *Anopheles coluzzii*. In August 2018, the NBA provided a permit to release up to 10,000 sterile male GE mosquitoes within a defined area. Almost one year later, in July 2019, the permit was used to release 6,400 sterile male GE mosquitoes in a village called Bana located in the southwest of the country. The main objective of the research is to reduce the population of three mosquito species (*Anopheles gambiae*, *Anopheles coluzzii* and *Anopheles arabiensis*) that spread malaria.

In Mali, research on GE mosquitoes has been approved by the NBC. In September 2019, GE *Anopheles gambiae* eggs were imported into Mali; research on GE mosquitos was approved for laboratory confined trials for three years.

For more information, please visit http://targetmalaria.org/who-we-are/

- b) COMMERICAL PRODUCTION None.
- c) EXPORTS None.
- d) IMPORTS Burkina Faso and Mali have imported GE mosquito eggs for research purposes.
- e) TRADE BARRIERS Same as for plant biotechnology.

## **Part E: Policy**

- a) REGULATORY FRAMEWORK The biosafety laws for Senegal, Burkina Faso, and Mali apply to animal biotechnology, although there may not be decrees or guidance on how it is specifically regulated. The draft biosafety laws for Niger and The Gambia both reference animal biotechnology. Post is not aware of any regulatory framework on animal biotechnology for Guinea.
- b) INNOVATIVE BIOTECHNOLOGIES No information available.
- c) LABELING AND TRACEABILITY Same as plant biotechnology.
- d) INTELLECTUAL PROPERTY RIGHTS (IPR) Same as plant biotechnology.
- e) INTERNATIONAL TREATIES/ FORA Senegal, The Gambia, Mali, Niger, Guinea, and

Burkina Faso are members of the World Organization for Animal Health (OIE) and Codex.

## f) RELATED ISSUES - N/A

## **Part F: Marketing**

## a) PUBLIC/PRIVATE OPINIONS

Many West Africans likely have little to no knowledge of animal biotechnology. However, in Burkina Faso, the NBA has engaged the public and visited two villages and other locations in the country to increase awareness about animal biotechnology and disseminate information on GE mosquitos and the field trial process for GE mosquitos.

In 2018, anti-GE activists reportedly conducted street demonstrations, signed a petition, and tried to convince villagers to not agree to the field trials for GE mosquitos. They also asked the Burkinabe public to support a moratorium on all GE products. In response, the Open Forum on Agricultural Biotechnology (OFAB) met with Burkinabe National Assembly members to discuss GE technology (including GE mosquitos and applications in agriculture) as well as biosafety regulations. In addition, researchers and the NBA met with the President's office to discuss the technology. In 2019, according to sources, there have been no reported anti-GE demonstrators in Burkina Faso protesting against GE mosquito research.

## b) MARKET ACCEPTANCE/STUDIES

In 2018, an African Union (AU) High Level Panel on Emerging Technologies (APET) published a report on deploying gene drive mosquitos for malaria control and elimination in Africa. The APET acknowledged that while existing interventions have significantly reduced the burden of malaria across Africa, complementary new and innovative interventions are required to eventually achieve malaria elimination on the continent. The Panel recommended that Africa invest in the development and regulation of gene drive technology and urged regulators to consider the value proposition as well as potential risks. The report encourages the AU, regional economic communities, and AU member states to facilitate the development, coordination and harmonization of regulations and guidelines for regulating the development, approval and use of the final product. Researchers and partners should establish a network of Africa-based scientists and developers to register their studies, self-regulate, share information regarding their technology, and peer-review all ongoing developments and field testing of the technology on the continent.

## References

- Convention on Biological Diversity <u>http://www.cbd.int/biosafety</u>
- Interstate Committee for Reducing Desertification in the Sahel (Comité permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel) – <u>http://www.cilss.int/</u>
- African Intellectual Property Organization (OAPI) <u>http://www.oapi.int/index.php/en/</u>
- Economic Community of West African States (ECOWAS) <u>http://www.comm.ecowas.in</u>
- West African Economic and Monetary Union (WAEMU) <u>http://www.uemoa.int</u>

# Acronyms

CILSS	Permanent Interstate Committee for Drought Control in the Sahel
GE	Genetically Engineered
INERA	Institut de l'Environnement et de Recherches Agricoles
NBA	National Biosafety Authority
NBC	National Biosafety Committee
UEMOA/WAEMU	West African Economic and Monetary Union
CEDEAO/ECOWAS Economic Community of West African States	

Attachments:

No Attachments