

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 2/8/2019

GAIN Report Number:

Senegal

Agricultural Biotechnology Annual

2018 West Africa Biotechnology Report

Approved By:

Joshua Emmanuel Lagos

Prepared By:

Jasmine Osinski and Fana Sylla

Report Highlights:

The Government of Senegal is in the process of approving a revised biosafety law which currently includes language for an expedited approval process for certain genetically engineered (GE) products. A draft regional biosafety law is pending approval by the Economic Community of West African States members that reportedly 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. This is a regional report on West Africa that covers Senegal, Burkina Faso, Mali, Guinea, Niger, and The Gambia.

TABLE OF CONTENTS

Section I: EXECUTIVE SUMMARY

Section II: PLANT AND ANIMAL BIOTECHNOLOGIES

CHAPTER 1: Plant Biotechnology

Part A: Production and Trade

Part B: Policy
Part C: Marketing

CHAPTER 2: Animal Biotechnology

Part D: Production and Trade

Part E: Policy
Part F: Marketing

Section I. EXECUTIVE SUMMARY

This is a regional report on West Africa that covers Senegal, Burkina Faso, Mali, Guinea, Niger, and The Gambia.

The Government of Senegal (GoS) is in the process of approving a new biosafety law, which currently includes 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. The GoS also issued a decree that modified the structure of the National Biosafety Authority which now includes two bodies: the Orientation Council and Executive Body.

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: Bacillus thuringiensis (Bt) cowpeas and GE mosquitos.

In March 2016, Economic Community of West African States (ECOWAS) developed a draft regional biosafety law for all members; it is still undergoing various evaluation and approval processes. 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, for the last five years, 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. The National Biosafety Agency believes that Bt cowpeas may be commercialized within two years, although other contacts believe the time frame is uncertain. In 2011, INERA tried to develop a GE sorghum product (sorghum ABS188) with higher levels of vitamin A, zinc, and iron, but it is not known if this effort has continued. Burkina Faso is the third largest producer of cowpeas after Nigeria and Niger.

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 and herbicide tolerance) product.

In Mali, in 2011 the National Rural Economy Institute's Board of Directors authorized research on GE cotton in collaboration with Compagnie Malienne des Fibres Textiles; 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 commodities for cultivation. The only country that has approved a GE product for cultivation is Burkina Faso, which approved Bt cotton seeds.

From MY 2009/10 to MY 2015/16 Burkina Faso farmers planted Bt cotton seed that was developed by Societe Burkinabe 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 commodities for commercial production.

c) EXPORTS

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

d) IMPORTS

Senegal, The Gambia, Mali, Niger, Guinea, and Burkina Faso have not approved any GE products for importation for food, feed, or processing.

e) FOOD AID

Previous or current food aid recipient countries include Burkina Faso, The Gambia, Guinea, Guinea-Bissau, Mauritania, Niger, Mali, and Senegal. Any GE commodity 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 functional approval process or a law or framework that regulates GE products. This inhibits the trade of GE products or foods derived from GE products into the West African region.

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.

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

Mali

In December 2008, Mali adopted its Biosafety Law; 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). Under the Ministry of the Environment, the NCA monitors and controls 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 oversees the Cartagena Protocol, facilitates the exchange of information between the NCA and other government bodies, and manages environmental issues. The PIBCs ostensibly include a variety of bodies that support the regulation of agricultural biotechnology; however, their function is not clear since there has been no decree to define their exact role.

In order to initiate the approval process for a GE product, an applicant must send a dossier to the NCA, which according to the Biosafety Law will respond 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.

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.

Sources noted that the Government of Mali has not officially nominated members to form an NCA, or possibly other regulatory bodies such as the PIBCs. It is unclear if the biosafety framework is functional at this time. However, sources reported that in response to the decision to import GE products for human or animal nutrition and in the absence of a regulatory authority, the NCA's decision may be based on a risk assessment according to available information within a period not exceeding 270 days.

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 Prime Minister, and 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 is in the process of drafting 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 since the draft law is allegedly undergoing some revisions.

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>.

Guinea, Niger, and The Gambia

The Gambia and Niger each developed a draft biosafety law, but the laws have not been passed by their respective National Assemblies.

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 expanded the draft regional WAEMU biosafety law so that it would apply to all ECOWAS member countries (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). Sources noted that funding is still needed to translate the draft biosafety law for ECOWAS into English and Portuguese, which is delaying the evaluation and approval process at the technical level. If approved at the technical level, the draft law will be evaluated by ministers of member states represented in ECOWAS for final approval. This draft regional biosafety law allegedly includes language that allows for the regional approval of GE products, as well as regional accreditation criteria for national biosafety authorities. Sources believe that the law currently states that if one accredited ECOWAS member approves a GE product, other ECOWAS members have the option to formally recognize that decision. This would allow an approved GE product to be commercialized for food, feed, processing, or cultivation in another ECOWAS member economy without undergoing additional approval processes.

b) APPROVALS

Burkina Faso approved Bt cotton seed for cultivation. Burkina Faso, Mali, Guinea, Niger, Senegal and The Gambia have not approved any other GE products for import or commercial production.

c) STACKED EVENT APPROVALS

No information available.

d) FIELD TESTING

Burkina Faso is conducting field tests on Bt cowpeas (please see Production section).

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" 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, according to contacts, the lab is not fully functional at the present time, and currently is not testing samples for GE products. In 2012 and 2017, the lab received new equipment, which was funded by WAEMU and the NBA.

Burkina Faso has a national biosafety laboratory funded by the Government of Burkina Faso, but it is unclear if this lab is fully functional or is being used to test samples collected at the border.

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.

Sources believe there are no official protocols for monitoring GE products in Senegal, The Gambia, Mali, Niger, Guinea, and Burkina Faso.

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. The agreement is available here.

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 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. Its communication strategy currently includes distributing a booklet and other documentation in various local languages.

Because reliable information is limited, many West Africans are not well informed about biotechnology. 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 Bill and Melinda Gates Foundation. 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 laboratory testing of GE mosquitos in confined conditions. GE *Anopheles gambiae* eggs were imported from Italy; two genes (homing endonuclease gene and two fluorescent marker genes) from these mosquitos were backcrossed into *Anopheles coluzzii*. Under the 2016 permit, *Anopheles coluzzii* colonies have been tested for transgene stability, mating, survival rate, and susceptibility to insecticides. In August 2018, the NBA granted permission for a limited release of up to 10,000 male sterile GE mosquitoes. It will be a controlled dissemination within a limited area. The main objectives are to assess the survival rate of GE mosquitos in the environment and its dispersal from the point of release. Contacts stated they do not have a release date to conduct the limited release.

For more information, please visit http://targetmalaria.org/who-we-are/ and https://www.statnews.com/2018/09/05/release-genetically-engineered-mosquitoes-africa/

b. COMMERICAL PRODUCTION - None.

- c. EXPORTS None.
- d. IMPORTS Burkina Faso has 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.

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 mosquitoes 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 August 2018, the NBA granted authorization for a limited release of GE mosquitos for field trials, but no activities have been conducted to date.

b. MARKET ACCEPTANCE/STUDIES

In 2018, an African Union (AU) High Level Panel under the development agency NEPAD published a report on deploying gene drive mosquitos for malaria control and elimination in Africa: http://www.nepad.org/publication/gene-drives-malaria-control-and-elimination-africa-0. The AU High Level Panel 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 http://www.cbd.int/biosafety
- Interstate Committee for Reducing Desertification in the Sahel (Comité permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel) http://www.cilss.bf
- African Intellectual Property Organization (OAPI) http://www.oapi.wipo.net
- Economic Community of West African States (ECOWAS) www.ecowas.int/member-states/
- West African Economic and Monetary Union (WAEMU) http://www.uemoa.int

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