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Report Highlights:

Although Burma (also called Myanmar) does not yet have a comprehensive biosafety legislation, the final version of the National Biosafety Framework is completed and pending approval, and Biosafety Guidelines are in the final stages of development. The Framework is expected to be approved and launched in late 2020 or early 2021. This report describes the current policy related to agricultural biotechnology and how it is expected to change under the new framework. To date, only genetically engineered (GE) cotton has been approved for cultivation under the National Seed Policy.

EXECUTIVE SUMMARY

Although Burma does not have a comprehensive biosafety legislation, the final version of the National Biosafety Framework is completed and pending approval, and the Biosafety Guidelines are in the final stages of development. This emerging policy is a result of several years of engagement by USDA's Foreign Agricultural Service (FAS) and, once approved and implemented, it is expected to facilitate a transparent, predictable, and science-based approach to agricultural biotechnology in Burma that will give the Government of Burma (GoB) the ability to regulate biotechnology in a safe and appropriate manner. The government seeks to launch the framework in late 2020 or early 2021.

While the government plans to ultimately pursue a biosafety law, there are currently no laws, implementing regulations, or comprehensive guidelines or regulations that regulate GE plants or animals. There are, however, several laws that have some relation to biosafety issues, including the [National Food Law](#) and [the Pesticide Law](#), [the Plant Pest Quarantine Law](#), [Plant Variety Protection Law](#), [Seed Law](#), the National Seed Policy, Animal Health and Livestock Development Law, [the Myanmar Marine Fisheries Law](#), Aquaculture Law, Conservation of Biodiversity and Protected Areas Law, and the Science, Technology and Innovation Law.

GE cotton has been approved for planting in Burma under the National Seed Policy. All imported seed, except cotton, for both trials and commercial distribution, are required to be accompanied by a non-GE certificate. Burma does not have clear legislation governing imports of GE food or agricultural products, nor any process for requesting approvals.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** Although research by several Burmese biotechnology experts is ongoing, Burma has not yet commercialized any GE products, except Bt cotton. Burma first developed a Bt cotton variety, Ngwe Chi-6, in 2001. In 2010, following years of field trials, the government recognized the Ngwe Chi-6 cotton variety for commercialization and extended the allowable planting area. In 2014/15, the Cotton Research and Technical Development farm developed other Bt cotton varieties, Ngwe Chi-9 and Shwe Daung-8, which produced higher yields and a moderate resistance to pests commonly found in Burma (i.e., bollworm).

Burma has many scientists with advanced degrees in biotechnology from both private and public Burmese universities, and institutions such as the Plant Biotechnology Center under the Department of Agriculture and the Department of Agricultural Research Institute (DARI) under the Ministry of Agriculture, Livestock and Irrigation (MOALI). Due to a lack of policy guidelines and regulations, Burma is not currently developing new GE plant varieties. Transparent and science-based biosafety laws and regulations will enable the Government of Burma to safely conduct biotechnology research and development and will encourage the private industry to invest into the development of plant varieties that are able to meet the pest and disease challenges commonly found in Burma.

- b) **COMMERCIAL PRODUCTION:** Despite a lack of biosafety legislation, Burma commercially cultivates the bollworm-resistant Bt cotton variety Ngwe Chi-6 (i.e., Silver-6), Ngwe Chi-9, and Shwe Daung-8. The average yield for Ngwe Chi-6 cotton is about two metric tons per hectare (MT/Ha). Burma produced more than 300,000 metric tons (MT) of Bt cotton in 2018-2019 (October-September).
- c) **EXPORTS:** Burma does not export a significant quantity of GE commodities. Almost all cotton grown in Burma is consumed domestically.
- d) **IMPORTS:** According to the Food and Agricultural Organization of the United Nations (FAO), Burma recognizes the Association of Southeast Asian Nations (ASEAN) Guidelines on Risk Assessment of Agriculture-Related GE Products. To harmonize with international regulatory requirements for the products of modern biotechnology, Burma became a signatory to the Cartagena Protocol on Biosafety (CPB) in 2001 and allows for the import of GE food and/or feed products. However, there is currently no authorization process for GE imports.

- e) **FOOD AID:** Burma receives food aid from the World Food Program (WFP), primarily for internally displaced persons (IDP) in the form of rice, pulses, oil, and salt. WFP also distributes high-energy biscuits for its school feeding programs and in remote and conflict areas. All rice, pulses, and salt are purchased domestically while oil, high-energy biscuits, and nutritional blended food products are imported. There are no issues related to biotechnology that impede the importation of these products. WFP maintains a policy in which all donated food meets the food safety standards of the donor and recipient countries and all applicable international standards, guidelines, and recommendations.
- f) **TRADE BARRIERS:** Importation of seed requires an import license and registration at the National Seed Committee (NSC). Distinctness, Uniformity and Stability (DUS) tests must be completed in three locations before commercial distribution of new seeds.

PART B: POLICY

- a) **REGULATORY FRAMEWORK:** Burma does not regulate agricultural biotechnology, except through the National Seed Policy, which restricts the import and planting of all GE seeds except for non-food crops such as Bt cotton. According to the 2016 National Seed Policy, only non-food GE seeds will be “partially accepted”.

Relevant stakeholders see the potential benefits of the use of agricultural biotechnology in Burma in both crop and animal sectors, and FAS has been collaboratively working with Burmese regulators to update Burma’s draft policy on biosafety. At present, Burma’s final draft National Biosafety Framework is completed and awaiting approval from the cabinet, while the Biosafety Guidelines are undergoing revisions from Burmese with the help of international experts. MOALI expects to approve and launch both the Biosafety Framework and Biosafety Guidelines in late 2020 or early 2021. A virtual public consultation meeting with parliament members, NGOs, Civil Society Organizations (CSOs), Union of Myanmar Federation of Chambers of Commerce and Industry (UMFCCI), and other stakeholders is planned prior to the launch.

The primary department responsible for the agricultural biosafety policy is the Department of Planning at MOALI. The Department of Agriculture will be responsible for the implementation of the policy. According to the current draft of the Biosafety Framework, MOALI would be responsible for plants and plant products, fungi, seafood, and animals. Meanwhile, the Ministry of Resources and Environmental Conservation will be responsible for biodiversity in the forest and the Ministry of Health and Sports will be responsible for food safety.

According to the current draft of the Biosafety Framework, The National Biosafety Committee (NBC) will be the highest decision-making authority on the topic of biosafety. The NBC will be comprised of various ministries such as:

1. the Ministry of Agriculture, Livestock and Irrigation;
2. the Ministry of Natural Resources and Environmental Conservation;
3. the Ministry of Education, the Ministry of Commerce;
4. the Ministry of Planning, Finance and Industry;
5. the Ministry of Health and Sports;
6. the Ministry of Home Affairs;
7. the Union Attorney General's Office;
8. and other related ministries.

The Department of Agriculture will be the secretariat of National Biosafety Committee Clearing House (NBCH).

- b) **APPROVALS:** Burma does not have an approved biosafety law, nor does it have approval mechanisms in place. According to the current draft of the Biosafety Framework, the decision-making process will be done on a case-by-case basis for importation, cultivation, breeding, and production of crops for commercial purposes. Please see APPENDIX I for more information.
- c) **STACKED EVENT APPROVALS:** Not applicable.
- d) **FIELD TESTING:** Burma does not have a biosafety law governing the field testing of GE plants; however, limited field trials for Bt cotton were conducted by Shwe Daung Cotton research farm.
- e) **INNOVATIVE BIOTECHNOLOGIES:** Burma does not have any policies regarding innovative technologies such as gene editing. However, there are numerous ongoing biotechnology activities such as DNA fingerprinting, variety identification, genetic purity testing, and plant breeding for climate-smart agriculture. Burma has joint biotechnology projects with other countries, including the United Kingdom, the People's Republic of China, and ASEAN countries. Research activities related to biotechnology conducted by the different departments are listed in APPENDIX II.
- f) **COEXISTENCE:** Not applicable.
- g) **LABELING AND TRACEABILITY:** There are no requirements for labeling GE products.

- h) **MONITORING AND TESTING:** There is no policy regarding testing imported or exported products for GE content.
- i) **LOW LEVEL PRESENCE (LLP) POLICY:** There is currently no LLP policy. However, Burma is planning to follow the LLP policy as outlined in Codex once the draft Biosafety Framework is adopted.
- j) **ADDITIONAL REGULATORY REQUIREMENTS:** Not applicable.
- k) **INTELLECTUAL PROPERTY RIGHTS (IPR):** A new Plant Varieties Protection Law was approved on September 17, 2019. The Myanmar Plant Varieties Protection Law was presented to the International Union for the Protection of New Varieties of Plants (UPOV) Council on October 28, 2019 in Switzerland. The UPOV council accepted the Plant Varieties Protection Law and Burma is now going through an internal process to become a member of UPOV. In 2019, Burma enacted four IP laws; Trademark, Industrial Design Law, Patent Law, and Copyright Law. None of the IP laws had specific legislation for GE plants.
- l) **CARTAGENA PROTOCOL RATIFICATION:** In May 2001, the Burmese Ambassador to the United Nations signed the CPB. Burma also recognizes the ASEAN Guidelines on Risk Assessment of Agriculture-Related GE Products.
- m) **INTERNATIONAL TREATIES and FORUMS:** Burma signed the United Nations Environment Program and the Global Environment Facility (UNEP-GEF) Agreement to facilitate the development of a national biosafety framework in July 2003. Burma has also participated as official observers at the Asia-Pacific Economic Cooperation (APEC) High Level Policy Dialogues on Agricultural Biotechnology. Burma is a member of ASEAN MGF-Net and Convention on Biological Diversity (CBD).
- n) **RELATED ISSUES:** None.

PART C: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Knowledge about GE technology in Burma is low; there is an opportunity to educate the general public about the benefits of biotechnology and innovative plant breeding techniques to farmers, the environment, and the impact on food security.

Lack of awareness and understanding hampers the adoption and use of biotechnology in Burma. Increased transparency and clear policy guidelines from GoB on the

regulation of biotechnology will likely provide consumers greater confidence and knowledge of the benefits of agricultural innovations and biotechnology.

- b) **MARKET ACCEPTANCE/STUDIES:** In late 2019, Michigan State University conducted a Bt maize (corn) cost-benefit analysis under a USAID food security project in the Southern Shan State (in the eastern part of country). The survey revealed that the Fall Army Worm (FAW) resistant Bt maize would benefit corn farmers and that the benefit is sensitive to the FAW incident level.

There are no known publicly available studies on the public acceptance of biotechnology in Burma.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** Burmese researchers are not producing or developing GE animals.
- b) **COMMERCIAL PRODUCTION:** Burma does not produce any livestock clones, GE animals, or products derived from animal biotechnologies, and there are no related regulations on this technology.
- c) **EXPORTS:** Not applicable. There are no GE animals or GE animal-derived products in the market.
- d) **IMPORTS:** Burma does not import GE animals.
- e) **TRADE BARRIERS:** There are currently no known trade barriers for the import of GE animals other than the lack of related policy.

PART E: POLICY

- a) **REGULATORY FRAMEWORK:** There is no regulatory framework or regulation governing the production of GE animals. However, the drafted Biosafety Framework does address the production and importation of GE animals.
- b) **APPROVALS:** Not applicable.
- c) **INNOVATIVE BIOTECHNOLOGIES:** Not applicable.

- d) LABELING AND TRACEABILITY: Not applicable.
- e) INTELLECTUAL PROPERTY RIGHTS (IPR): Burma follows the World Organization for Animal Health (OIE) guidelines in general.
- f) INTERNATIONAL TREATIES AND FORUMS: Burma has been a member of the OIE since August 1989 and usually participates in OIE regional and global conferences.
- g) RELATED ISSUES: None.

PART F: MARKETING

- a) PUBLIC/PRIVATE OPINIONS: Knowledge about GE products in Burma is low, thus, there is an opportunity to educate the general public about the benefits of biotechnology products.
- b) MARKET ACCEPTANCE/STUDIES: There are no known publicly available studies on public acceptance of animal biotechnology in Burma.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

- a) COMMERCIAL PRODUCTION: There is no commercial production of food ingredients derived from microbial biotechnology. A number of universities have collected non-harmful recombinant microbes for education purposes.
- b) EXPORT: Not applicable.
- c) IMPORT: Burma imports microbial biotech-derived food ingredients and food additives, including yeast, enzymes, and dietary supplements such as coenzyme and probiotics. A list of imported food additives products can be found on [Myanmar FDA's website](#), and [also here](#). The link lists all imported food additives including microbial biotech-derived food ingredients.
- d) TRADE BARRIERS: Not Applicable

PART H: POLICY

- a) REGULATORY FRAMEWORK: All imported microbial biotech-derived food additives or ingredients must be registered with FDA. FDA is responsible for providing Import Recommendations (IR) and Import Health Certificates (IHC) for the importation of food

and food additives and the Department of Trade within the Ministry of Commerce is responsible for issuing the import licenses. FDA released Standard Operation Procedures for the import and export of food in December 2019. Currently, there are no specific policies related to microbial biotechnology-derived food additives/ingredients, but the current draft of the Biosafety Framework does provide policies on the matter.

- b) **APPROVALS:** The importer must apply for an Import Recommendation, which is valid for three years, from the Myanmar Food and Drug Administration (FDA) and apply for an import license, which is required for each shipment, from the Ministry of Commerce. A Certificate of Analysis must also be submitted to FDA for each shipment in order to obtain the required Import Health Certificate. Required tests for different categories of products are available [at this link](#). According to FDA, there are lists of imported GE microbes and/or derived food ingredients that are registered and used in Burma. Please visit the [FDA website](#) and [here for more information](#) about all imported food additives (these same links are provided above). List of imported microbial biotech-derived food ingredients that are registered with FDA include:
- Liquid Enzyme Alpha Amylase
 - Elco P - 100 K (GE-L1-AAA) Enzyme protein + soy flour + calcium phosphate,
 - Alphamalt BK - 5020 (Baking Enzyme)
 - Liquid Enzyme Preparation - beta glucanase and hemicellulose,
 - Food Additive: Enzyme Preparation - Glucoamylase Solution,
 - Enzyme Preparation for biscuit and cracker production
 - Flour Improver - mixture of enzymes, ascorbic acid, wheat flour carrier)
 - Premix Powder (Yeast Donut Mix)
 - Instant yeast
 - Super Alcohol Active Dry Yeast
 - Fish Sauce Enhancer 1104 (Powder).
- c) **LABELING AND TRACEABILITY:** Burma does not apply specific labeling and traceability requirements for microbial biotechnology-derived food additives and ingredients. Burma currently follows Codex guidelines and ASEAN Common Principles and Requirements for all food and food ingredients. The Consumer Protection Law was released in March 2019 and includes the following labeling requirements for all food, food ingredients, and drugs:
- 1) Product Logo, name of the products, size, quantity, net weight storage instruction, and direction for use;
 - 2) Date of manufacturing, expiry, and product serial number;
 - 3) If the product is imported, name and address of importers, name of manufacturer and address;
 - 4) The address of repacking;
 - 5) List of raw materials, quantity, and ratio;

- 6) Allergy alerts, warning, and side effects; and
- 7) Information specified by relevant government.

In September 2019, FDA released a notification requiring the labels of ready-to-eat food products to include the name of the company, address, ingredients list, the date of manufacturing, and the date of expiry. In addition, the date marking must not be easily removable, easily erased, or reusable. If the packaging is more than one layer, the date of manufacturing and expiry must be described on all packaging layers.

- d) MONITORING AND TESTING: Not applicable.
- e) ADDITIONAL REGULATION REQUIREMENT: Not applicable.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): In 2019, Burma enacted four IP laws; Trademark, Industrial Design Law, Patent Law, and Copyright Law. None of the IP laws have specific legislation for microbial biotech-derived food additives or ingredients.
- g) RELATED ISSUE: Not applicable.

PART I: MARKETING

- a) PUBLIC/PRIVATE OPINIONS: While imported microbial biotechnology-derived food ingredients are widely used and accepted in wine, beer, alcohol, yogurt, soy sauce, fish sauce, fermented food production, and in the bakery sector, the public is generally not aware that they are produced via microbial biotechnology.
- b) MARKET ACCEPTANCE/STUDIES: There are no known publicly available studies on public acceptance of microbial biotechnology-derived food ingredients in Burma.

APPENDIX I:

Decision making process on a case-by-case basis for importation, cultivation, breeding, and production of GE products for commercial purpose.

1. Application to NBC; they will reply to the applicants on its receipt within 10 days from the completion of documents; NBC will relay relevant documents to the Biosafety Technical Team (BTT) for risk assessment.
2. BTT will evaluate the proposal for commercial release using the policies formulated by NBC and Organisation for Economic Co-operation and Development (OECD) guidelines on risk assessment, coordinate with the respective departments within 30 days, and prepare the submission of reports from the applicants within 180 days.
3. BTT may request the additional tests if required in consideration to avoid impacts on biodiversity and health of human and animals and submit the report to NBC together with comments (recommendation/conclusion/scrutiny).
4. NBC will inform the applicant whether the application is accepted or rejected within 30 days based on the comments submitted by BTT.
5. The permission for importation, cultivation, breeding, and production of GE organisms for commercial purposes may be granted for up to 10 years and it can be extended three times for consecutive periods of 5 years. Extension may be obtained with the approval of NBC.

Decision making process for GE Food, Feed and/or Processing (FFP)

1. Submission of the application to NBC.
2. NBC will review the application and reply to the applicant within 10 days then NBC will relay relevant documents to BTT for risk assessment.
3. BTT will carry out risk evaluations within 60 days in accordance with Codex guidelines as well as conduct risk assessment through coordination with other departments within 30 days under mutual recognition for GE products if permission has been granted for commercial purposes in at least five OECD member countries;
4. BTT will submit the report to the NBC together with comments, such as recommendation/conclusion/scrutiny, and NBC will decide whether it is accepted or rejected within 30 days.
5. The decision-making process for GE food, feeds and/or processing must be informed to the applicant at the earliest in accordance with the guidelines of NBC and it must be published to the public.

Decision Making Process on a case-by-case basis for research and development

1. Submission of the application to NBC.
2. NBC will review the application and reply to the applicant within 10 days then NBC will relay relevant documents to BTT for risk assessment. NBC will complete the risk assessment within 30 days for low risk and 90 days for high risk products.
3. BTT will submit the report to NBC together with comments and BTT will submit the report to NBC (recommendation/conclusion/scrutiny).
4. NBC will decide whether it is accepted or rejected within 20 days based on the comments submitted by BTT.
5. The approval for research and development must be informed by the secretariat to the applicant at the earliest in accordance within the guideline of NBC.
6. The applicant may conduct the research at the prescribed locations for 2 years and applicant may apply for an extension to NBC if the research work is not completed within 2 years.

APPENDIX II:

Biotechnology Activities Undertaken by the Ministry of Agriculture, Livestock and Irrigation in 2019/20

	Departments	Biotechnology Activities
1.	Department of Agricultural Research, MOALI	<p data-bbox="854 443 1040 474"><i>Tissue culture</i></p> <ul data-bbox="808 516 1385 1350" style="list-style-type: none"> • Double Haploid Breeding in rice for early maturity, lodging resistance • Double Haploid breeding program for submergence tolerant rice • Study on Gametoclinal variation in rice • Identification of the anther culture response of <i>Indica</i> rice genotypes • Mutation breeding in banana, groundnut, and rice • Identification of inland salinity tolerant rice varieties by mutation techniques • Development of Yellow Mosaic Virus resistant green-gram variety by mutation techniques • Development of drought tolerant Groundnut variety by Mutation technique • Study on Burma germplasm for submergence tolerant rice • Identification of media response for sesame anther culture • Mass propagation of banana, sugarcane, medicinal orchid, turmeric, coffee, and avocado <p data-bbox="813 1392 1057 1423"><i>Molecular Biology</i></p> <ul data-bbox="808 1465 1360 1896" style="list-style-type: none"> • Gene identification and genetic purification of hybrid rice • Genetic diversification of maize, black gram, and rice germplasm • Marker Assisted Breeding Programs for Folia disease resistance in groundnuts • Marker Assisted Pseudo Backcross breeding for early maturity and lodging resistant in rice • Development of Banana mutant for <i>Fusarium</i> wilt resistance by Marker

		<p>Assisted Selection</p> <ul style="list-style-type: none"> • Study on Heterotic grouping and association analysis of promising maize inbred to development of potential hybrid • Investigation on Opaque-2 gene of promising maize varieties by using SSR markers • Identification of drought tolerant maize inbred lines by SSR markers <p><i>Microbial Biotechnology</i></p> <ul style="list-style-type: none"> • Production of Rhizobium inoculants • Evaluation and maintenance of different Rizobium strains • Quality assurance of rhizobium inoculants
2.	Plant Biotechnology Centre, Department of Agriculture, MOALI	<p><i>Tissue culture</i></p> <ul style="list-style-type: none"> • Micropropagation of banana, orchids, lily, elephant foot yam and eucalyptus • In vitro conservation of banana, medicinal orchids, potato, elephant foot yam • Identifying new media composition for micropropagation of crops • Rice Anther Culture <p><i>Molecular Biology</i></p> <ul style="list-style-type: none"> • Assessment of genetic diversity and population structure (DNA finger printing of mango, and determining genetic diversity and specific grain qualities of Pawsan rice) • Crop improvement to a climate resilient agriculture through molecular breeding (stress tolerance) (submergence and BB resistant gene pyramiding, Salinity and Heat tolerance rice variety, short duration rice variety for post flooded) • Varietal improvement for the quality and nutritious crop (high aromatic rice by pyramid on aromatic genes, high amylose

		<p>rice, Pawsan mutant backcross lines, brown color HYV rice, brown color HYV glutinous/sticky rice)</p> <ul style="list-style-type: none"> • DNA fingerprinting of Orchid Species <p>Service</p> <ul style="list-style-type: none"> • Providing non-GMO certificate • Certification on Nutrition and Grain Quality Analysis (Rice) <p>Biosafety</p> <ul style="list-style-type: none"> • Implementing Biosafety Framework and Guidelines
3.	Perennial Crops Research and Development Center, MOALI	<ul style="list-style-type: none"> • Embryo culture and Leaflet culture on oil palm
4.	Cotton and Allied Fiber Crop Division (Shwe Daung Cotton Research and Technology Development Farm), MOALI	<ul style="list-style-type: none"> • Developing cotton bollworm resistant varieties by using Marker Assisted Selection • Detection of bollworm resistant gene from Bt cotton (Ngwechi-6) by PCR based detection and developing bollworm resistant cotton variety by backcrossing
5	Department of Research and Innovation, Ministry of Education	<ul style="list-style-type: none"> • Public service for Medical plants for disease control • Genetic modification mosquito to control Dengue • Developing Submergence and Salinity and Heat tolerance rice variety <p>Microbial Biotechnology</p> <ul style="list-style-type: none"> • Commercial Production of Bio- fertilizers, Bio-fungicides • Inspection of food safety from food poison bacteria such as, Ecoli,

Source: Department of Agriculture, Department of Agriculture Research, Department of Research and Innovation, Cotton and Allied Fiber Crop Division, Perennial Crops Research and Development Center

Attachments:

No Attachments