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#### **Report Highlights:**

This report describes the status of Burma's production and regulations for genetically engineered products and recent activities focused on agricultural biotechnology. Burma's (also called Myanmar) National Biosafety Framework and Biosafety Guidelines have been pending approval by the Minister of Agriculture since before the 2021 coup. To date, the Burmese government has only approved genetically engineered cotton for cultivation under the National Seed Policy.

# **EXECUTIVE SUMMARY**

Burma does not have a comprehensive biosafety law, implementing regulations, or comprehensive guidelines to regulate genetically engineered (GE) products. Burma's Department of Agriculture, however, has completed the National Biosafety Framework and Biosafety Guidelines and submitted them to the Agriculture Minister for approval. The guidelines will facilitate a transparent, predictable, and science-based approach to agricultural biotechnology in Burma that will give the Government of Burma the ability to regulate biotechnology in a safe and appropriate manner.

The only GE plant approved for cultivation under the National Seed Policy in Burma is cotton. Seed importers must present a non-GE certificate with all imported seeds, except cotton, for both research and commercial distribution. The Burmese government has not approved any GE animals or microbial products for domestic production. The Burma Food and Drug Administration has approved some microbial food additives for importation. The Burmese government, however, does not have the infrastructure or regulations in place to effectively inspect imports. <u>Burma's Food and Agricultural Import Regulations and Standards (FAIRS)</u> report mentioned the GE labelling.

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# CHAPTER 1: PLANT BIOTECHNOLOGY

#### PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: To date, the only approved and commercialized genetically engineered (GE) product in Burma is Bt cotton. Burma first developed a long staple Bt cotton variety, Ngwe Chi-6, in 2006/07. In 2014/15, the Cotton Research and Technical Development farm developed two more Bt cotton varieties, Ngwe Chi-9 and Shwe Daung-8, which produced higher yields and provided a moderate resistance to cotton sucking pests and bollworm commonly found in Burma. In the absence of policy guidelines and regulations, Burma is not currently pursuing new GE plant varieties.

Please see APPENDIX II for a list of research activities carried out by the Ministry of Agriculture, Livestock, and Irrigation (MOALI).

- b) COMMERCIAL PRODUCTION: The National Seed Committee (NSC) has registered 14 Bt cotton varieties despite a lack of biosafety legislation. Of these varieties, five locally produced Bt cotton varieties (i.e., Ngwe Chi-6, Ngwe Chi-9, Ngwe Chi-11, Shwe Daung-8, and Shwe Daung 10) are high-yielding and moderately resistant to bollworm. The remaining nine (Indian) varieties are not grown in Burma. Burma's average yield for cotton is about two metric tons per hectare (MT/Ha). Burma produced about 280,000 metric tons (MT) of Bt cotton in marketing year (MY) 2020/21 (October-September). The regime aims to expand cotton production to more than 500,000 MT in MY 2023/24.
- c) EXPORTS: Burma does not export a significant quantity of GE commodities. Burma utilizes almost all GE cotton grown domestically.
- d) IMPORTS: Burma imports soybean meal from the United States, Brazil, Paraguay, India, Bolivia, and Malaysia, and DDGS from the United States. Burma does not allow imports of DNA or non-DNA containing products derived from GE plants, except cotton, but generally lacks inspection capacity. The National Seed Policy states that only nonfood "GMO" crops will be considered for approval. Burma requires submission of a "non-GMO" certificate to import seeds for planting.
- e) FOOD AID: Burma receives food aid from the World Food Program (WFP), primarily for internally displaced persons 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. WFP purchases all rice, pulses, and salt domestically, and imports oil, high-energy biscuits, and nutritionally blended food products. WFP maintains a policy by 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: Seed importers must have a valid import license and register at the NSC. Seeds importers must also perform distinctness, uniformity, and stability (DUS)

tests on new seeds at three locations before commercial distribution. Seeds destined for commercial use must have a "non-GMO" certificate.

#### **PART B: POLICY**

a) REGULATORY FRAMEWORK: The only regulation that mentions biotechnology is the National Seed Policy that restricts the import and planting of all GE seeds except for non-food crops, such as Bt cotton.

MOALI intended to approve and launch both the new Biosafety Framework and Biosafety Guidelines in the early 2021. However, the COVID-19 pandemic and the military coup postponed the launch. MOALI still has not published the final Biosafety Framework and Biosafety Guidelines.

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

The current draft of the Biosafety Framework designates the National Biosafety Committee (NBC) as the highest decision-making authority on biosafety. The NBC members would come from:

- the Ministry of Agriculture, Livestock and Irrigation;
- the Ministry of Natural Resources and Environmental Conservation;
- the Ministry of Education, the Ministry of Commerce;
- the Ministry of Planning, Finance and Industry;
- the Ministry of Health and Sports;
- the Ministry of Home Affairs;
- the Union Attorney General's Office; and
- other related ministries.

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

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
သက်ရှိဇီဝရုပ်	Living organism	Draft National Biosafety Framework	Biological entity capable of
			transferring or replicating genetic

#### Table. Legal terms and definition

			material, including viruses, viroids and sterile organisms.
သက်ရှိပြုပြင်ဇီဝရုပ်	Living Modified Organism (LMO)	Draft National Biosafety Framework	Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology <sup>1</sup> . It has the same meaning as Genetically Modified Organisms (GMO). However, GMOs could contain both living and non-living modified organisms.
ဗီဇပြုပြင်ဇီဝရုပ် အနည်းဆုံးပါဝင်မှု	Low Level Presence (LLP)	Draft National Biosafety Framework	The detection of low levels of GM crops that have been approved in at least one country. Approval is on the basis of a food safety assessment according to the relevant Codex guidelines.

- b) APPROVALS: Burma does not have an approved biosafety law, nor does it have approval mechanisms in place. The final draft of the Biosafety Framework utilizes a case-by-case decision-making process 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 field testing of GE plants; still, Shwe Daung Cotton Research Farm and Plant Biotech Center conducted limited field trials for Bt cotton.
- e) INNOVATIVE BIOTECHNOLOGIES: Burma does not have any policies regarding innovative technologies, such as genome editing. However, there are numerous ongoing biotechnology activities such as DNA fingerprinting, variety identification, genetic purity

<sup>&</sup>lt;sup>1</sup> It is unclear how Burma classifies gene editing in this context.

testing, and plant breeding for climate-smart agriculture. APPENDIX II provides a list of research activities related to biotechnology.

- f) COEXISTENCE: Not applicable.
- g) LABELING AND TRACEABILITY: Burma does not have specific labelling and traceability requirements for bulk shipments, raw material and feed derived from GE plants. The Burma FDA released the Labelling Order for Pre-packaged Foods in January 2022, that requires a declaration on prepackaged food and food additives if the use of biotechnology transferred an allergen to any food or food ingredients.
- h) MONITORING AND TESTING: There is no policy regarding the testing of imported or exported products for GE content.
- i) LOW LEVEL PRESENCE (LLP) POLICY: There is currently no LLP policy. However, the draft Biosafety Framework follows the LLP policy outlined by Codex.
- j) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
- k) INTELLECTUAL PROPERTY RIGHTS (IPR): Burma's Parliament passed the Plant Varieties Protection Law on September 17, 2019. The International Union for the Protection of New Varieties of Plants (UPOV) Council accepted the Plant Varieties Protection Law on October 28, 2019. Prior to the coup under another Prime Minister, Burma initiated an internal process to become a UPOV member. In 2019, Burma enacted the following four IP laws: trademark law, industrial design law, patent law, and copyright law. None of the IP laws had specific legislation for GE plants.
- CARTAGENA PROTOCOL RATIFICATION: The Burmese Ambassador to the United Nations signed the Cartagena Protocol on Biosafety in May 2001. Burma also recognizes the Association of Southeast Asian Nations (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 an official observer at the Asia-Pacific Economic Cooperation (APEC) High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB). Burma is a member of the ASEAN Genetically Modified Food Network 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. However, there are no active institutions that are against the use of GE products or production in the country. Some people believe that there are negative side effects to "GMO" technology. Increased transparency and clear policy guidelines from the Government of Burma on biotechnology will likely provide consumers greater confidence and acceptance of agricultural innovations and biotechnology.

b) MARKET ACCEPTANCE/STUDIES: 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) in late 2019. The survey revealed that the Fall Army Worm (FAW) resistant Bt maize would benefit corn farmers.

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) RESEARCH AND PRODUCT DEVELOPMENT: There is no ongoing research on animal biotechnology.
- 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: There are no GE animals or GE animal-derived products in the market.
- d) IMPORTS: Burma does not import GE animals.
- e) TRADE BARIERS: There are currently no known trade barriers for the import of GE animals other than a 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 TRACEBILITY: Burma does not have specific labelling and traceability requirements for bulk shipments, raw material, and feed derived from GE plants or animals. The Burma FDA released the Labelling Order for Pre-packaged Foods in January 2022, that requires a declaration on prepackaged food and food additives if the use of biotechnology transferred an allergen to any food or food ingredients.
- e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): Burma follows the World Organization for Animal Health (WOAH) guidelines in general. In 2019, Burma enacted the following four IPR laws: trademark law, industrial design law, patent law, and copyright law. None of the IPR laws had specific legislation for GE animals.
- g) INTERNATIONAL TREATIES AND FORUMS: Burma has been a member of the WOAH since August 1989 and usually participates in WOAH regional and global conferences.
- h) RELATED ISSUES: None.

#### **PART F: MARKETING**

- a) PUBLIC/PRIVATE OPINIONS: Knowledge about GE products in Burma is low.
- 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 educational purposes.
- b) EXPORT: Not applicable.

- c) IMPORT: Burma imports microbial biotech-derived food ingredients and food additives, including yeast, enzymes, and dietary supplements (e.g., coenzyme and probiotics). The Burma Food and Drug Administration (FDA) lists imported food additives products on its <u>website</u>, and also <u>here</u>. 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 the Burma FDA. The Burma FDA is responsible for providing import recommendations (IR) and <u>import health certificates</u> (IHC) for the importation of food and food additives. The Department of Trade within the Ministry of Commerce is responsible for issuing import licenses. The Burma FDA released standard operating 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: Burma follows the General Standards of For Food Additives according to Codex guidelines. The importer must apply for an IR, which is valid for three years, from the Burma FDA and apply for an import license, which is required for each shipment, from the Ministry of Commerce. Importers must also submit a certificate of analysis to the Burma FDA for each shipment in order to obtain the required IHC. Required tests for different categories of products are available at this <u>link</u>. The Burma FDA has lists of imported GE microbes and/or derived food ingredients that are registered and used in Burma. Please visit the <u>FDA website</u> and <u>here</u> for more information about all imported food additives (these same links are provided above). Registered microbial biotech-derived food ingredients include the following:
  - 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; and
  - Fish Sauce Enhancer 1104 (Powder).
- c) LABELING AND TRACEBILITY: Burma does not apply specific 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 Burma FDA released the Labelling Order for Pre-

packaged Foods in January 2022, that requires a declaration on prepackaged food and food additives if the use of biotechnology transferred an allergen to any food or food ingredients.

- d) MONITORING AND TESTING: Not applicable.
- e) ADDITIONAL REGUALTION REQUIREMENT: Not applicable.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): In 2019, Burma enacted the following four IP laws: trademark law, industrial design law, patent law, and copyright law. None of the IP laws had specific legislation for microbial biotech-derived food additives or ingredients.
- g) RELATAED ISSUE: Not applicable.

#### **PART I: MARKETING**

- a) PUBLIC/PRIVATE OPINIONS: 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. However, 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 purposes

- 1. Application goes to the NBC. They will reply to the applicant upon 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 Organization 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 period of 5 years. An 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. Under mutual recognition for GE products, if permission has been granted for commercial purposes in at least five OECD member countries, BTT will conduct risk evaluations within 60 days in accordance with Codex guidelines and conduct risk assessment through coordination with other departments within 30 days.
- 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, it must be published, and made available 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 with the guidelines of NBC.
- 6. The applicant may conduct the research at the prescribed locations for 2 years and the 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 2022/23

#### I. Research on Rice Anther Culture

- 1. Identification of *Indica* Rice Varieties with Good Response Culturability by Using Anther Culture
- 2. Identification of Gametoclonal Variations for Buku-3 Variety Derived from Anther Culture
- 3. Study on Yield and Yield component traits of Ta Yoke Mhwe Variety Derived from Anther Culture
- 4. Evaluation of Sin Thukha Double Haploid Lines for Short-Duration Variety Derived from Anther Culture
- 5. Selection of Anther Culture Lines of RGB-72 And Htun Pu Rice Varieties

#### II. Research on Tissue Culture Technology

- 6. Study on Effective Protocol for In Vitro Multiplication of Avocado
- 7. In Vitro Propagation of Curcuma longa (Turmeric)
- 8. Somatic Embryogenesis in Coffee (Coffea canephora)
- 9. Development of Early Fusarium Wilt Resistant Mutant Banana Through Tissue Culture and Mutation Technology
- 10. Mass Propagation of Sugarcane
- 11. In Vitro Multiplication of King of Bitter (Andrographis paniculata (Burm. F.)
- 12. Basic media combination finding for Yam, lily and potato

#### **III.** Research on Molecular Breeding

- 13. Introgression of a Weak Allele of Fasciated Ear 2 (Fea 2) to
- 14. Increase Kernel Row Number (Krn) and Yield in Elite Maize Hybrids through Marker Assisted Selection
- 15. Improvement Aye Yar Min Rice Variety for Heading Date and Lodging Traits through Marker Assisted Pseudo Backcrossing
- 16. Development of Brown Plant Hopper Resistant Rice Variety through Marker Assisted Back Crossing
- 17. Identification of Male Fertility and Cytoplasmic Male Sterility Traits in Backcross Population of Hybrid Rice by using Molecular Markers
- 18. Characterization of Male Fertility and Fertility Restorer Gene (*Rfs*) in Source Nursery of Hybrid Rice by using Molecular Markers
- 19. Identification of Promising Japonica Rice Germplasm by using Molecular Markers
- 20. Marker Assisted Breeding for Salt-Tolerant Sin Thu Kha Rice Variety
- 21. Marker Assisted Breeding for Submergence Tolerant Paw San Yin Rice Variety
- 22. Development of Green Super Rice (Phase 2)
- 23. Study on Genetic Variation of the Maize Varieties for Heterotic Grouping
- 24. Genetic Improvement of Soybean Rust Resistance for Soybean(Glycine max)
- 25. Evaluation on grain Zinc content from pigmented rice accession (Oryza sativa)

- 26. Improvement of Submergence and Drought Tolerant Yadanartoe Rice variety through Marker Assistant Selection
- 27. Selection of Quality Protein Maize
- 28. Molecular breeding approaches for
  - Black rice for antioxidant
  - Black sticky rice (High yield, antioxidant and day natural)
  - Improvement on Root Crops
- 29. Crop improvement to a climate resilience agriculture through molecular breeding (stress tolerance for
  - Gene pyramiding program on rice and sesame
  - Improvement on premium rice (pawsan)
- 30. Assessment of genetic diversity and population structure (DNA finger printing) for
  - Paw san rice, Mango (Sein-ta-lone), Orchid, Royal Thazin

#### **Attachments:**

No Attachments