



**Required Report:** Required - Public Distribution **Date:** November 04, 2024

**Report Number:** BM2024-0015

Report Name: Agricultural Biotechnology Annual

**Country:** Burma - Union of

Post: Rangoon

Report Category: Biotechnology and Other New Production Technologies

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#### **Report Highlights:**

This report described Burma's current production, regulations and trade for genetically engineered products, as well as recent activities focused on agricultural biotechnology. Burma's (also called Myanmar) National Biosafety Framework and Biosafety Guidelines have been pending approval by the Ministry of Agriculture since before the 2021 coup. Given the lack of regulatory developments since the coup, this report is similar to the 2023 Agricultural Biotechnology Annual for Burma.

#### **EXECUTIVE SUMMARY**

Burma does not have a comprehensive biosafety law, implementing regulations, or comprehensive guidelines to regulate genetically engineered (GE) products. Although Burma completed the National Biosafety Framework and Biosafety Guidelines, they have been pending approval by the Department of Planning since before the 2021 coup.

The only GE plant approved for cultivation under the National Seed Policy in Burma is Bt cotton. Burma imports hybrid Bt cotton seeds mainly from India. 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. Burma's 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.

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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 (also known as Myanmar) 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. Burma does not used GE plants to produce antibiotics or pharmaceuticals for human or animal diseases. Please see APPENDIX II for a list of research activities carried out by the Ministry of Agriculture, Livestock, and Irrigation (MOALI).
- b) COMMERCIAL PRODUCTION: Burma's sole commercially cultivated GE product is Bt cotton, including seeds. 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 380,000 metric tons (MT) of Bt cotton between April 2023 and March 2024. In 2022, the regime added cotton to the list of important crops and aims to expand cotton production area.
- c) EXPORTS: Burma does not export a significant quantity of GE commodities. Nearly all GE cotton grown domestically is used domestically, with a small volume exported to China.
- d) IMPORTS: Burma imports hybrid Bt. cotton seeds from India. 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 non-food "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 Programme (WFP), primarily for internally displaced persons in the form of rice, pulses, oil, and salt. WFP purchases all rice, beans and 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. Burma's proposed Biosafety Framework and Biosafety Guidelines have not advanced through MOALI since the 2021 coup.

#### i. Legal terms and definition

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
သက်ရှိဧီဝရုပ်	Living organism	Draft National Biosafety Framework	Biological entity capable of transferring or replicating genetic material, including viruses, viroids and sterile organisms.
ဗီဇပြုပြင်ဇီဝရုပ်	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. 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.

The primary department responsible for drafting the agricultural biosafety policy is MOALI's Department of Planning. When it finalizes the Framework and Guidelines, MOALI's Department of Agriculture would be responsible for policy implementation. According to the draft Biosafety Framework, MOALI would have oversight over plants and plant products, fungi, seafood, and animals. The Ministry of Resources and Environmental Conservation would be responsible for forest biodiversity, and the Ministry of Health would be responsible for food safety.

The draft 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;
- the Ministry of Health;
- the Ministry of Home Affairs;
- the Union Attorney General's Office; and
- other related ministries.

The Department of Agriculture would host the secretariat of the National Biosafety Committee Clearing House (NBCH).

- b) APPROVALS: Burma does not have an approved biosafety law, nor does it have approval mechanisms in place but has approved Bt cotton as an exceptional case. The 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 OR PYRAMIDED EVENTAPPROVAL/AUTHORIZATION: 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. The Department of Agriculture is looking for assistance to conduct field testing for GE crops.
- 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 testing, and plant breeding for climate-smart agriculture at Plant Biotechnology Center, DOA and Department of Agriculture Research (DAR). 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): not applicable 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. Burma drafted Biosafety Framework according to the Cartagena protocol on Biosafety.
- 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). Burma joined Codex in 1997. The Department of Food and Drug Administration (FDA) and MOALI are the competent authorities. However, national operations have been underdeveloped due to the absence of a national Codex structure through the Codex Contact Point (CCP). In June 2019, a new CCP was appointed, and the Myanmar Codex Committee was established. Burma is currently developing its national Codex structure.
- 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 for farmers, the environment, and 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 with greater confidence and acceptance of agricultural innovations and biotechnology. There is interest in initiating research activities on genetically engineered (GE) plants on the part of technical staff.
- 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 is no associated regulation.
- 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, if implemented, the draft Biosafety Framework would address the production and importation of GE animals.
- b) APPROVALS/AUTHORIZATION: Not applicable.
- c) INNOVATIVE BIOTECHNOLOGIES: Not applicable.
- d) LABELING AND TRACEBILITY: Burma does not have specific labelling and traceability requirements for bulk shipments, raw materials, and feed derived from GE plants or animals.
- e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable for GE animals.
- g) INTERNATIONAL TREATIES AND FORUMS: Burma has been a member of the World Organization for Animal Health (OIE) 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

FDA lists imported <u>food additives products</u> and <u>functional foods</u>, including microbial biotechnology-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 (IRs) and import health certificates (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 draft of the Biosafety Framework contains policies on the matter.
- b) APPROVALS/AUTHORIZATIONS: Burma follows the General Standards of For Food Additives according to the 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 <a href="link">link</a>. The Burma FDA has lists of imported GE microbes and/or derived food ingredients that are registered and used in Burma. Please visit the <a href="FDA website">FDA website</a> and <a href="here">here</a> for more information about all imported food additives. Registered microbial biotech-derived food ingredients include the following:
  - o Liquid Enzyme Alpha Amylase;
  - o Elco P 100 K (GE-L1-AAA) Enzyme protein + soy flour + calcium phosphate;
  - o Alphamalt BK 5020 (Baking Enzyme);
  - o Liquid Enzyme Preparation beta glucanase and hemicellulose;
  - o Food Additive: Enzyme Preparation Glucoamylase Solution;
  - o Enzyme Preparation for biscuit and cracker production;
  - o Flour Improver mixture of enzymes, ascorbic acid, wheat flour carrier);
  - o Premix Powder (Yeast Donut Mix);
  - Instant yeast;
  - o Super Alcohol Active Dry Yeast; and
  - o 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 REGULATION REQUIREMENTS: 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) RELATED 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 in the Draft Biosafety Framework **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 a consecutive period of 5 years. An extension may be obtained with the approval of NBC.

#### **GE Food, Feed and/or Processing**

- 1. Submission of the application to NBC.
- 2. NBC reviews the application and replies 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.

#### **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 Research Activities Undertaken by the Department of Agriculture, MOALI in 2023/24

- 1. DNA documentation of Myanmar orchid species
- 2. Morphology and Molecular Characterization of some *Bulbophyllum* species from Myanmar using RAPDs
- 3. Studying the genetic distance of Myanmar sesame varieties
- 4. Exploring Nutrition and Starch Paste Profiles of Myanmar's unique Indigenous Rice, Namathalay
- 5. Exploring the nutritional composition of Myanmar avocado varieties
- 6. New varieties innovation in Chrysanthemum (Chrysanthemum morifolium) by gamma radiation
- 7. Production of new sesame varieties through gamma radiation
- 8. Selection of potential chili mutation lines
- 9. Varietal collection of Chrysanthemum (*Chrysanthemum morifolium*) species and evaluation of their morphological characters
- 10. Conservation of new rice varieties produced by Plant Biotechnology Center
- 11. Conservation of rare species by tissue culture techniques
- 12. Innovative energy-efficient LED lights impact on in vitro culture of Myanmar local banana (*Musa* spp.) growth rate

## Biotechnology Research Activities Undertaken/Planned by the Department of Agricultural Research, MOALI in 2024/25

- 1. Identification of *Indica* Rice Varieties With Good Response Culturability by Using Anther Culture
- 2. Study On Gametoclonal Variation of Ta Yoke Hmwe Variety Derived from Anther Culture
- 3. Improvement of Sin Thu Kha early rice variety by using Anther culture
- 4. Preliminary study on Development of Double Haploid Maize Line by Anther culture
- 5. Somatic Embryogenesis in Coffee (Coffea canephora)
- 6. Development of Early Fusarium Wilt Resistant Mutant Banana Through Tissue Culture and Mutation Technology
- 7. In vitro mass Propagation of Sugarcane and Banana
- 8. Introgression of a Weak Allele of *Fasciated Ear 2 (Fea 2)* to Increase Kernel Row Number (Krn) and Yield in Elite Maize Hybrids through Marker Assisted Selection
- 9. Development of Brown Plant Hopper Resistant Rice Variety through Marker Assisted Back Crossing
- 10. Identification of Male Fertility And Cytoplasmic Male Sterility Traits in Backcross Population of Hybrid Rice by using Molecular Markers
- 11. Characterization of Male Fertility and Fertility Restorer Gene (*Rfs*) in Source Nursery of Hybrid Rice by using Molecular Markers
- 12. Marker Assisted Breeding for Salt-Tolerant Sin Thu Kha Rice Variety
- 13. Marker Assisted Breeding for Submergence Tolerant Paw San Yin Rice Variety
- 14. Study on Genetic Variation of the Maize Varieties for Heterotic Grouping

- 15. Development of Drought and Submergence Tolerant Rice variety through Molecular Breeding
- 16. Study on the yellow mosaic virus disease resistant gene in local mung bean or green gram (*Vigna radiata*) cultivars
- 17. Genetic Improvement of Soybean Rust (Phakopsora pachyrhizi) Resistance
- 18. Study of Zinc Content in colored rice varieties
- 19. Development of Hybrid Tomato with High yield and yellow leaf curl virus resistance
- 20. Molecular characterization of sunflower (Helianthus annuus L.) through SSR markers

#### **Attachments:**

No Attachments