



Biosecurity and Food Safety Index of Bhutan

2018-2019

Bhutan Agriculture and Food Regulatory Authority

Ministry of Agriculture and Forests

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Introduction

BAFRA is guided by the Biosecurity Policy of the Kingdom of Bhutan 2010 to implement biosecurity and food safety measures in the country. The Biosecurity Policy of the Kingdom of Bhutan 2010 designates BAFRA as the National Competent Authority to coordinate all biosecurity related activities, sanitary and phytosanitary measures effectively to protect the health and life of humans, farming systems and the environment including the national biodiversity from risks of entry, establishment and spread of exotic pests, diseases and invasive alien species thereby promoting safe trade and ensuring healthy ecosystem. The Biosecurity Policy of the Kingdom of Bhutan 2010 is supported by more than 10 acts dealing with different aspects of management of biosecurity, sanitary and phytosanitary aspects in the country. Further, the different Act are supported by rules and regulations, manuals, standard operating procedures and checklists serving as the prescription manual for regulatory authority and relevant stakeholder's in implementing biosecurity and food safety measures.

At the national level, BAFRA works closely with the Departments headed by the board members as well as other departments and non-departmental agencies viz. Department of Industries and the Office of the Consumer Protection under the Ministry of Economic Affairs, Department of Law and Order under Ministry of Home and Cultural Affairs, Department of Agriculture Marketing and Cooperatives, National Biodiversity Centre, National Organic Program and Food Corporation of Bhutan Ltd. under the MoAF, Office of the Attorney General, National Environment Commission, Bhutan Standards Bureau etc.

At an international level, BAFRA has developed Institutional linkages with Food Safety and Standards Authority of India, Export Inspection Council of India, Department of Agriculture Extension of Bangladesh, Korea Biosafety Clearing House under KRIBB, DNVGL (an international accredited registrar and classification society). In addition, it also functions as National Contact Point to Codex Alimentarius Commission (FAO/WHO), the International Plant Protection Convention, International Health Regulations, Sanitary and Phytosanitary Agreement of WTO, Cartagena Protocol on Biosafety and International Network of Food Safety Authorities. BAFRA is also the national focal point for the International Plant Protection Convention (IPPC), Codex Alimentarius Commission (CAC), National Enquiry Point for World Trade Organization-Sanitary and Phytosanitary Agreement (WTO-SPS agreement), International Food Safety Authorities Network (INFOSAN) for International Health Regulations (IHR) and the Cartagena Protocol on Biosafety (CPB) for Conventional Biodiversity (CBD).

For the implementation mandates of biosecurity and food safety measures at national and international level, BAFRA has two Divisions: Quality Control and Quarantine Division (QCQD) and Analytical and certification Division (ACD). There are four Sections (Plant, Livestock, Food and Biosafety) under QCQD and two Sections (Certification and Standards Sections) and the National Food Testing Laboratory (NFTL) under ACD. Analytical Services related to food is provided by NFTL, while for analysis of quarantine samples, BAFRA take the services of National Centre for Animal Health (NCAH) and RNR RDC, Bajo of the Department of Livestock and Department of Agriculture respectively.

Livestock Section

This Section is responsible for implementing animal biosecurity, veterinary public health and animal welfare aspects of the overall mandates of BAFRA. Animal Biosecurity measures are implemented in line with the Biosecurity Policy of the Kingdom of Bhutan 2010, Livestock Act 2001, Livestock Rules and Regulations 2017 and other tertiary legislations developed under the Act.

Animal Biosecurity measures implemented by BAFRA are:

- Prevention of transboundary movement of animal diseases: To achieve this, risk assessment is being carried out for all animals and animal products meant for import. Import is allowed through a permitting system with import conditions which must be endorsed in the sanitary certificate by competent authority of the exporting country. Imported animals undergo compulsory 15 days of quarantine checks to minimize risk of disease import.
- Compartmentalization and restricting the spread of animal diseases already prevalent in the country: Some regions in Bhutan are endemic to certain animal diseases. Movement restrictions are placed and movement of animals from Dzongkhag to Dzongkhag is allowed following risk assessment and with permitting system.
- Implementing control measures at times of disease outbreaks: Based on the type of disease involved, various measures are being enforced viz. stamping out followed by mopping operations, surveillance and monitoring to find new cases, quarantine and movement control of susceptible animals and animal products till disease subsides.
- Advocating and implementing animal farm biosecurity measures: Continuous advocacy program on farm biosecurity is being conducted for livestock farmers. Efforts are also made to monitor on farm biosecurity in livestock farms using prescribed checklist.

Veterinary public health measures implemented by BAFRA:

- Inspection of facilities related to production, storage and marketing of animal, animal products, animal feed on a regular basis to ensure that the establishment complies with the requirements of the relevant standards. In addition, the officials also carry out certification for production, processing and marketing of animal and their products.
- Sampling and testing of the livestock product such as meat, milk, and fish periodically for contamination (physical, chemical, & microbiological), adulteration and drug residues. Based on the test result, the risk management actions such as imposing ban, removal from market (recall), seize and destruction are implemented.
- Enforcing import regulation by following the import standards and procedures. The establishments in the exporting countries supplying animal and its products to Bhutan are registered with BAFRA. During the registration process, the biosecurity status of the farm, HACCP system and minimum hygiene practices are taken into consideration which is further subjected to document verification (test results), inspection, and certification of products at the entry point. For the export of livestock product, BAFRA facilitates in country testing and certification of products as per the import requirements of the importing country.
- Providing education and advocacy programs on food safety regulatory requirements especially concerning food of animal health. BAFRA staff visits, schools, farmers group, festivals and other gatherings to advocate the general public on food safety and animal biosecurity.

Animal welfare regulations - Animal welfare is a complex and multifaceted issue which involves scientific, ethical, economic, cultural, social, religious and political dimensions. The animal welfare standards are not sanitary (health) measures but they also have an important role in international trade because they are the only global, science-based standards agreed by the trading nations of the world. To facilitate international and domestic trade, BAFRA implements animal welfare standards for farm animals and companion animals as per the Livestock Act 2001 and Bhutan animal welfare standards and guidelines.

Plant Section

The Plant Section is responsible for implementation of the provisions under the Plant Quarantine Act of Bhutan 1993, the Seeds Act of Bhutan 2000, and the Pesticide Act of Bhutan 2000 and its secondary and tertiary regulations. In order to effectively protect the health and life of humans, plants and animals including the environment from risks of entry, establishment and spread of exotic pests and diseases, the section implements plant biosecurity measures designed as per the

quarantine laws of Bhutan. Effective implementation of plant quarantine laws augments trade in plant and planting materials and make it safe for agricultural development by ensuring that serious pests, diseases and weeds are not introduced to pest free areas, and also export such problems to other countries are prevented. In addition, areas under domestic quarantine are restricted to movement of plants and plant materials including risk goods to reduce the flow of pest and disease. Containment programs are implemented to mitigate the spread of the established pest and disease, with an ultimate aim to eradicate pests and diseases.

The seed legislations are enforced for formal certification of agricultural, forestry and fodder seeds. It provides a quality assurance system of the seeds that are grown at larger scale for commercial purpose. The purpose of seed certification is to maintain and make available to the public/farmers a high-quality seeds of notified kind and varieties which in turn is critical for good crop yields and earnings, and also to reduce the odds of crop failure. Having in place the seed certification system also facilitates the development of a private seed sector for the purpose of food security and economic development. Seed certification activities includes registration of seed growers/ nursery operators, field inspection and monitoring, seed processing, seed sampling and testing as per the prescribed minimum standard requirements for seeds and planting materials and, followed by issuance of seed certificate. In addition, imported seeds and planting materials are also regulated against the compliance to minimum standard requirements. BAFRA regulates the use of agro-chemicals in the country to protect human health and the environment from risks associated with pesticide use and its deleterious effects in the long run. Bhutan has been gearing up towards organic agriculture production due to increased food safety and environmental awareness. She envisions to becoming 100% organic in the near future. However, there is an extreme need to mainstream organic certification acceptance among the organic farming communities in the country to achieve economic self-reliance through increased organic production and ecological services thereof, this section along with standard and certification services of BAFRA provides the organic third-party certification. It involves field inspection of farm operations as per the Bhutan Organic Standards to ensure long-term sustainability of the environment, including soil, water, air and biodiversity. It also aims to produce food while establishing an ecological balance to prevent soil fertility or pest problems. In addition, it also encourages soil fauna and flora by improving soil formation and structure, ground water contamination by prohibiting the use of synthetic fertilizers and pesticides, mitigating the greenhouse effect and global warming through its ability to sequester carbon, create suitable habitats for wildlife by using adaptable and diverse combination of available animal and plants.

Food Section

The food Section is responsible for implementing the Food Act of Bhutan 2005 to ensure safe and quality food in the country for building a healthy population in the country. The implementation of the Food Act 2005 is supported by its rules and regulations, various guidelines and standards. This section is also responsible for ensuring the manufacture of safe and quality food commodities through implementation of various food safety measures in an effort to facilitate safe food trade. All food businesses are registered with BAFRA for proper co-ordination of surveillance, monitoring and inspection. The inspections are planned by respective field offices on the risk based approach where the food establishments producing high risk products or have records of failure are inspected more frequently. BAFRA also conducts training of food handlers on basic food hygiene and sanitation. All parties involved in food supply are adequately trained through food handlers training programs and other food safety awareness programs to make sure that they understand their primary responsibility in ensuring safe food.

The food legislations require all food business to be license. For the purpose, the Food Business Licensing has been established based on GHP/GMP Criteria. So far, 18 food processing units have been licensed. The informal food businesses such as street vendors, temporary food sheds and home-based food manufacturers are registered with district BAFRA field offices for the purpose of monitoring and also training of food handlers. BAFRA is also involved in the events such as mass catering during Menlom Chenmo, visit of delegation, important celebration to ensure food safety through inspection and testing.

BAFRA also carry out random testing of food categories based on the global food safety issues and take regulatory measures based on the reports such as ban on some vegetables and seaweeds. The commodities are tested in the field offices using rapid test kits for screening and referred to laboratories for confirmation. BAFRA carry out inspection and sampling for regulatory purpose, to address the complaint received and as part of surveillance activities to maintain the process and product conformity.

The foodborne outbreaks are investigated as per the Food Safety Investigation Manual. There have been few sporadic food poisoning cases such as salmonella poisoning case from the cake prepared in one of the bakeries in Thimphu. The case was investigated and managed effectively in collaboration with ministry of health. BAFRA implements food labelling requirement as mandated by Food Act of Bhutan and its regulations. The food section is also responsible for

handling matters related to Codex and INFOSAN. All codex and INFOSAN related activities are carried out to ensure that our standards/procedures/protocols are in line with available scientific information and as per the international food safety norms.

Biosafety (GMO) Section

This section is responsible for implementing activities related to Genetically Modified Organisms (GMO) as per the Biosafety Act of Bhutan and its Rules and Regulations to protect human, animal and environmental health from the unintended effects of GMOs. Bhutan has adopted a precautionary policy concerning Genetically Modified Organisms (GMOs), with the aim to protect, conserve and safeguard the biodiversity in the country and promote organic agriculture. As such the cultivation, import and distribution of genetically modified crops are currently prohibited in Bhutan (Biosafety Act, 2015). However, genetically modified (GM) foods and feeds in non-viable forms are permitted if its safety has been assessed by Biosafety Technical Working Group and approved by the National Biosafety Board, while the environmental release of viable genetically modified organisms (GMOs) is completely prohibited. Ensuring the safety of imported GM food in the market is one of the main priorities for BAFRA, especially given Bhutan's reliance on significant imports to meet the food needs.

This section will facilitate implementation biosafety activities as per the following documents;

1. Risk Assessment of Food and Feed Products Derived from Genetically Modified Plants
2. Guidelines for handling applications
3. Guideline on Environmental Risk Assessment of Genetically Modified Plants
4. Guidelines for Inspection and Monitoring of GMOs/LMOs
5. Manual for training workshop on GMOLMO-Handling of Applications and Inspection

This section also keeps abreast of the developments in the area of Biosafety at international level by closely monitoring FAO GM-platform, CBD website, BCH website, etc and accordingly prepares to apprise National Biosafety Board.

Certification Section

The Certification Section under BAFRA is mandated to promote goods and products related to food, agriculture and livestock, through inspection and certification for safety and quality. It functions as the inspection and certification body for food, agriculture/livestock products, for agricultural production systems such as Organic and Good Agricultural Practices (GAP). It also facilitates and promotes food trade through standardization and implementation of internationally recognized quality and safety management systems.

To assist the food industries and commerce in Bhutan, BAFRA has launched Product Certification schemes which are implemented in conformity with ISO IEC 17065:2012 to provide third party mark of certification. The certification demonstrates that the food industries have implemented and are operating their processes, activities and operations in accordance with the certification marks. The accreditation of certification services provided by BAFRA (certification of food product, process service or food safety management system) as per international norms will broaden the market acceptability of Bhutanese products across the world. BAFRA is currently accredited for ISO/IEC 17065:2012 by National Accreditation Board for Certification Bodies (NABCB), India since 2018 for packaged drinking water, packaged natural mineral water and fruit juices. The Certification Section of BAFRA undergoes annual compliance audits conducted internally and by the accreditation body, enabling the food business operators to receive a credible food safety certificate for their operations, providing their consumers with enhanced confidence regarding food safety.

Laboratory Section

National Food Testing Laboratory (NFTL), BAFRA, MoAF, Yusipang was established to provide food testing services for the country with an objective to provide safe food thereby protecting public health. NFTL functions under Food Safety and Quality Division, under BAFRA, and it provides technical backstopping to BAFRA and facilitates trade by providing the analytical services.

To gain international recognition for its commitment to quality, competency and reliable results generated, NFTL is accredited for ISO/IEC 17025: Requirements for Testing and Calibration Laboratories since 2012 and it is reassessed regularly by the accreditation body to ensure the continued compliance to the requirements. As of now there are 32 chemical, 11 microbiological and 4 GMO accredited test parameters accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL), India. It is important to increase the testing scope of NFTL and develop continually with the state-of-art facilities and trend of changing science and technology. Thus, NFTL is striving for its development in terms of testing scope, laboratory facilities and competency in analytical services continually.

National Biosecurity Index

Biosecurity risks are increasing due to increased global trade and travel, increased agricultural expansion and intensification, increased urbanization close to farmlands, and other factors such as climate change. As a consequence, the country experience outbreaks of Giant African Land Snail (GALS), Citrus Huanglongbing, Spruce bark beetle, Brucellosis, Avian Influenza, Rabies, as well as food borne diseases and these major biosecurity incidents continue to test public confidence in the national biosecurity arrangements. Bhutan's biosecurity system continues to protect the nation from many exotic pests and diseases. Some of the benefits includes:

- Reducing the cost of agricultural production
- Reducing the impact of pests and diseases on our environment (including associated negative impacts on agricultural productivity and amenity)
- Safeguarding the health of our community
- Supporting animal and plant health

Bhutan's biosecurity system must remain strong and focused to build the national capacity and capability required in the face of inevitable and growing biosecurity risks. As per the FAO (2018), transboundary plant pests and diseases can spread to several countries and reach epidemic proportions if control measures are not put in place. Such plant pests and diseases outbreaks can cause huge losses to crops and pastures, threatening the livelihoods of vulnerable farmers and the food and nutrition security of millions at a time. Bhutan cannot be an exception. Bhutan has been witnessing increased trade volume of plants and plant products over the years. Such trade has associated risks with it as they may serve as a pathway for introduction and spread of plant exotic pests and diseases impacting the forestry and agriculture resources including the environment of our country. Some are surmised to be exotic which may have been introduced and established through import of plant and their materials (e.g. Giant African Land Snail outbreak in Gyalpozhing since 2010). In addition, other consequences of under-resourced and neglected plant biosecurity system in the country is introduction of Cryptomeria, Poplar, Thuja and Eucalyptus and its rippling effects to the environment and society which has been realized only now. Therefore, on the other hand it is a positive pointer and well timed for us to establish and put in place required biosecurity system to counteract such risks posed.

For the reasons aforementioned, the national biosecurity index is included as one of the KPIs under the result (outcome 1) for "Food and Nutrition Security Programme" in 12 Five Year Plan. In line, the same KPI was reflected in 2018-2019 APA at ministry level. Subsequently, the departmental KPIs at output level was designed as an indicator to measure the national

biosecurity index. For 2018-2019, the target of national biosecurity index was set at ≥ 80 . Following are the list of indicators for measuring the national biosecurity index which was taken at departmental level and included as department KPI for 2018-2019.

1. Timeline by which Biosafety Communication Strategy document drafted

The Communication Strategy on Biosafety (GMOs) has been developed as a result of the scoping mission organized by FAO's Regional Office for Asia and Pacific from 22-26 October, 2018. A National consultation on 'GMO communication strategy and incident response plan' was held on 29 October 2018 in Thimphu, attended by the members of the Biosafety Technical Working Group, BAFRA officials from Head Office and border offices, relevant stakeholders from within the various Ministries and FAO resource persons. The main objective of this communications strategy is to meet the legal obligations of BAFRA as the competent authority in Bhutan. Summarizing the legal requirements quoted in the earlier section, this entails the following objectives:

- Inform the higher authorities and the general public (particularly, the education sector) on the state of the art and social impact of modern biotechnology.
- Advocate public awareness on biosafety.
- Perform public consultation as a component under risk communication.
- Enforce labeling requirements.
- Ensure public access to information on GMOs as well as their regulation and its use in Bhutan.
- Encourage public participation for any other issue related to GMO.

As per 2018-2019, the weight allocated is 5 and should be completed before 15 May 2019 for excellent, 31 May 2019 for Very good, 16 June 2019 for Good and 30 May 2019 for fair rating. The activity was completed in October 2018 for which the rating excellent rating is given as per the 2018-2019 timeline.

A. Timeline by which GMO surveillance is being carried out

Bhutan import huge amount of rice for consumption and it is possible that some viable rice seeds may be imported due to globalization of food import and export. Biosafety Act of Bhutan 2015 and its Rules and Regulations 2018 completely bans any activities involving Genetically Modified Organism (GMO) in viable forms. Any import of products derived from GMO needs to undergo rigorous risk assessment and need to be ultimately approved by the National Biosafety Board. To carry out this activity, 1600 numbers of test kits were procured with funding support

from EU-RDCCRP and distributed 50 numbers of test strips each to 32 BAFRA field offices (List attached). The test kits were purchased from Romer Labs Singapore Pte Ltd. The objective of this study is mainly to carry out surveillance on LLRice in Bhutanese markets. Since the results from all BAFRA field offices showed negative for Phosphinothricin N-acetyltransferase (PAT) protein in all rice samples tested, it is inferred that there is no import or introduction particular transgenic rice into the Country.

In 2018-2019, the timeline line for completion of this activity was reflected 15 May 2019 for excellent rating. Since the activity was completed in April 2019, 100% rating is assigned.

2. Timeline by which amendment of guidelines for export inspection and certification of Ophiocordyceps sinensis (NWFP) completed and put up for RNR-GNHC endorsement

BAFRA has been involved in inspection of Cordyceps since 2004 to facilitate trade. Moreover, the Biosecurity Policy of the Kingdom of Bhutan, 2010 mandated BAFRA to involve in the implementation of or designated to implement various Acts framed by the Ministry of Agriculture and Forests. Though the Department of Forest and Park Services (DoFPS) is responsible for the Forest and Nature Conservation Act, BAFRA is mandated to implement import and export provision of the Acts. Therefore, to ensure that the Cordyceps exported from Bhutan and its sale in domestic market are being collected legally “The Export Certification Procedure for *Ophiocordyceps sinensis* (Yartsa Guenboop), 2014’ has been formulated and implemented. However, over the years of its implementation BAFRA has experienced several challenges in the field. The lack of proper guideline on quality standard has hindered BAFRA in categorization of quality parameters during inspection and certification, thereby challenging BAFRA’s mandate to facilitate development of agro based industries to promote trade and market access through standardization and implementation of quality assurance. Moreover, the existing procedure does not have clear direction for legal provision and it duplicates the activity prescribed in the “Cordyceps Marketing Guideline, 2010”. Therefore, in order to streamline the procedures, strengthen coordination with other line departments and accommodate the challenges faced in the field, “the Export Certification Procedure for *Ophiocordyceps sinensis* (Yartsa Guenboop) - 2014 “has been revised.

This guideline which was endorsed by 103th RNR –GNHC committee and will serve as the guiding reference for BAFRA to carry out effective and efficient inspection and certification of Cordyceps and for those individual interested in Cordyceps business. The activity was completed in April 2019 and therefore a 100% rating is assigned (timeline for completion of the activity for excellent rating was reflected before 15 May 2019).

B. Timeline by which the development of the database on plant quarantine pests and diseases completed

The quarantine pest and disease database is of utmost importance to effectively implement the Plant Biosecurity activities. The primary aim behind developing this database is to serve as a reference point of material to the plant quarantine inspectors. It will greatly assist them in implementing the tasks of plants and planting materials inspection at the point of entry, and in the areas where domestic quarantine measures are implemented. In addition, it can also help in the information exchange among various stakeholders for the movement of plants and planting materials between Bhutan and outside world. Thereby, enhancing trade in plant and planting materials and make it safe for agricultural development mainly by ensuring that serious pests, diseases and weeds are not introduced to pest free areas, and also export such problems to other countries are prevented. It will aid in safeguarding the forestry and agricultural ecosystem of our country.

It is also expected to serve as a data repository wherein hosts of emerging or potential plant quarantine pests, diseases and weeds information can be updated and made available as and when necessary by the National Plant Protection Organization of the country. The database will contain list of pests and diseases information mostly not present in the country and a few pests that are under official regulation in the country which are of quarantine importance. It covers agricultural, horticultural and forestry crop's pest-specific information, such as identity (name) of pests, host plants, description of main symptoms, pictures, distribution, maps (only for regulated pests in the country), means of spread, phytosanitary risks and phytosanitary measures.

Timeline for completion of this activity in 2018-2019 was stipulated as 7 June 2019 for excellent rating. The activity was completed on 1st week of June, 2019 and 100% rating is assigned.

3. Timeline by which Organic certificate is renewed for farmers group at Gasa and issuance of a new organic certificate for farmers group at Logchina, Chukha

Bhutan Agriculture and Food Regulatory Authority (BAFRA) under the Ministry of Agriculture and Forests (MoAF) is a CB that provides organic third-party certification. Organic certification is a process wherein a certification body (CB) gives a written assurance (to the buyer and seller) that a clearly identified process has been methodically assessed to provide adequate confidence for the specified products with specific requirements.

The Organic Certificate of Rangzhin Sanam Deutshen, Gasa was renewed on 25 September, 2018 after fulfillment of all the requirements mentioned in the Bhutan Organic Certification Guideline. Some of the major activities involved are as follows:

- Issuance of notification for organic certificate renewal
- Re-certification onsite assessment visit and submission of duly filled farm appraisal report by the organic inspectors to BAFRA, HQ
- Final onsite farm unit visit and submission of duly filled farm appraisal report by the organic inspectors to BAFRA, HQ
- Organic Certification Committee meeting for taking decision on the organicness of the farm unit
- Renewal of Organic Certificate

Dzedokha Pachang Deutshen of Logchina Gewog, Chukha was awarded Organic Certificate on 15th April, 2019 for complying with the requirements of Bhutan Organic Certification Guideline. The major activities undertaken were:

- Review of the applications and other prerequisites for registering with BAFRA for Organic Certification
- Preliminary farm unit assessment and submission of duly filled farm appraisal report by the organic inspectors to BAFRA, HQ
- Final onsite farm unit assessment and submission of duly filled farm appraisal report by the organic inspectors to BAFRA, HQ
- Organic Certification Committee meeting for taking decision on the organicness of the farm unit
- Grant of Organic Certificate

Timeline for completion of this activity in 2018-2019 was stipulated as 15 April, 2019 for excellent rating. The activity was completed well on time and 100% rating is assigned.

4. Timeline by which training on GMO Food Safety Assessment for BAFRA officials and stakeholders conducted

Upon the official request of the Royal Government of the Kingdom of Bhutan, a national training workshop entitled “training on genetically modified (GM) food safety assessment, risk communication and advocacies programme” was co-organized by the Bhutan Agriculture and Food Regulatory Authority (BAFRA) and the Food and Agriculture Organization of the United Nations (FAO) on 23 – 27 July 2018 in Thimphu, Bhutan. Eight-nine participants comprising members of the Bhutan Biosafety Technical Working Group (TWG), BAFRA officers and

inspectors from various stations in Bhutan, relevant stakeholders, and resource people attended the workshop. The objectives of the workshop were to provide: 1) an understanding of the relevant rules and regulations concerning GMOs and GM products in Bhutan; 2) an understanding of the internationally accepted principles of GM food safety assessment, risk management and risk communication and information on challenges involved in enacting these principles; 3) an understanding of the required expertise and types of experts for undertaking GM food safety assessments so that possible shortcomings in assessment capacity/resources in Bhutan could be identified; 4) hands-on experience in extracting relevant safety information from condensed GM food case studies and presenting the information in a simple and concise way; 5) general information about biosafety and biotechnology in the international arena with particular emphasis on communication; and 6) a way forward for BAFRA to conduct any suggested follow up activities.

The training involved presentations and case studies, interspersed with facilitated discussion, to introduce participants to the concept of a GM food safety assessment and the principles underlying the communication of information on GM organisms and their products. A number of areas were identified for improvement in the areas of risk analysis around GM foods and particularly focused on expertise for safety assessment, detection strategy, and communication. It was acknowledged that lack of practice in assessing a GM food application presented a significant barrier to being able to test the rules, regulations and documents that have been developed. While some initiative needs to be taken by the local authority to address these gaps, FAO will assist for the remainder of 2018 with the development of a biosafety communication strategy document, the development of an incident management plan and the procurement of a suitable GM food dossier that could be used by the TWG for producing a practice safety assessment.

As per the 2018-2019 timeline, the activity was completed in July 2018 for which an excellent rating is assigned.

5. Timeline by which awareness on Biosafety Rules and Regulations 2018 conducted for BAFRA field officials (Plant, Livestock and Food officials)

To improve the proficiency of BAFRA officials in implementing the biosafety rules and regulation 2018, a one day awareness training was conducted in two batches for BAFRA officials. The First batch of training was conducted in November 2018 for the officials at interior districts and the second batch was conducted in January 2019 for officials at entry points. A total

of 78 officials attended the awareness training. The participants were made aware on the following documents:

- Guidelines on risk assessment of food and feed
- Guidelines on Environment risk assessment of GM plants
- Guidelines for inspection and monitoring of GMOs-LMOs
- Guidelines for handling applications for GMOs
- Biosafety Rules and Regulations 2018

As per the 2018-2019 timeline, the activity must be completed before 15 February 2019 for excellent (100%) rating. Since both the batches of training was completed before January 2019, 100% rating is assigned for this activity.

6. Timeline by which Biosafety Incident Management Plan drafted

An increasing number of GM events are being released for commercialization in several countries, including major food producing countries. As a consequence, the global supply of certain food and feed (particularly those derived from soy, maize) are mostly composed of GM material, both at commodity level as well as in processed food. In addition, GM products are also found to be present in certain countries in minor quantities, in the production of a diverse range of food and agricultural plants, such as apple, potato, sugarcane, cotton, beans, brinjal, papaya, sweet pepper, etc.

Since these products are being approved in an asymmetric or asynchronous fashion by different countries, there are increasing occurrences of GMO incidents in countries that have not approved the products but nevertheless, they are found in their food supply or environment. Moreover, in food, the issue is further complicated by the fact that some countries import food commodities, which are then mixed in processed food and re-exported; this complicates the possibility of the third countries to anticipate the possibilities of the imported processed food to contain GM ingredients.

Therefore this document on Biosafety Incident Management on Bioasfety was developed to guide field officials in managing incidents of low level presence of GMO events in food and feed commodities in the country. The document was drafted and floated for in house consultation (BAFRA) officials. This activity was completed in October 2018 for which 100% rating is given as per the 2018-2019 timeline.

7. Timeline by which Training Workshop on GM Food Safety Assessment: Using a real Case Study conducted

Upon the official request of the Royal Government of the Kingdom of Bhutan, a training workshop entitled “Training workshop on GM food safety assessment: Using a real case study” was co-organized by the Bhutan Agriculture and Food Regulatory Authority (BAFRA) and the Food and Agriculture Organization of the United Nations (FAO) on 4 – 15 February 2019 in Paro, Bhutan. A total of 12 participants comprising Bhutan Biosafety Technical Working Group (TWG) members or their nominated representatives and BAFRA officials attended the workshop, which was run by an FAO Technical Panel Expert from Food Standards Australia New Zealand assisted by an FAO Food Safety Officer.

The International Rice Research Institute had provided its complete regulatory dossier (already submitted formally to several regulatory agencies) on biofortified rice event GR2E (Golden Rice) as an in-kind contribution to FAO, for the express purpose of providing an example of a ‘real’ application for developing countries to work through. Using this dossier, workshop participants were able to meet the objectives of the workshop, which were to provide:

- An understanding of the various techniques that are used to generate the data for a genetically modified (GM) food application;
- An appreciation of how to go about assessing the safety data
- An understanding of the administrative, legal and communication activities associated with handling a GM food application
- Recommendations for finalizing a guideline and information document for potential applicants.

This activity was also completed in February 2019. A 100% rating is assigned as per the timeline reflected in 2018-2019.

8. Timeline by which baseline information study on biosecurity practices in the livestock commercial farms conducted

As per the Biosecurity Policy of Bhutan, one of the main mandates of BAFRA is to implement sanitary and phytosanitary measure effectively to protect the health and life of humans, animals, and the environment including the national biosecurity from the risk of entry, establishment and spread of exotic pests and diseases, and invasive alien species to promote and facilitate international trade. Any biosecurity breach has the capacity to disrupt trade at domestic and international level, increase the cost of production and affect our unique and pristine environment. Effective biosecurity underpins the country’s reputation as a supplier of clean safe, high quality food, which enables access to valuable markets and trade arrangements.

Therefore, it is imperative to understand and assess the biosecurity practices in the livestock commercial farms and evaluate their perception on Bhutan biosecurity system. The information will help BAFRA in identifying biosecurity risks, gaps in biosecurity system and accordingly come up with good recommendations in strengthening Bhutan biosecurity system. The objective Farm Biosecurity Survey are:

- To train BAFRA staff in establishment of a statistically sound system of data collection, data design and management.
- To meet data requirements of BAFRA, leading to a farm register & covering structural characteristics of operational farming in the country.
- To establish baseline information on On-farm Biosecurity in commercial livestock farms in the country
- To assess current knowledge and understanding on animal biosecurity system
- To study what kind of biosecurity practices being used by livestock farmers
- Study monitoring habits and reporting of pest and diseases in the livestock farms.

A cross sectional study was conducted from Jan-Feb 2019 in 20 districts for livestock commercial farms (dairy, poultry and pig farms) meeting the definition of the study. The data were collated and analyzed and report published on 10 May 2019. This activity is also completed well within the documented 2018-2019 timeline for excellent rating. Therefore **100%** rating is given for this activity.

9. Timeline by which guideline for safe retailing of meat and meat products is drafted

Meat and meat products processed at slaughter or cut-and-wrap facilities in meat shops have the potential to be contaminated with hazards like biological, chemical and physical contaminants if not handled, stored and transported under appropriate conditions. Inadequate controls to protect meat can jeopardize the safety of meat products and create unacceptable levels of risk for consumers. If meat products are not maintained at appropriate working conditions including temperature, spoilage of meat due to multiplication of disease-causing microorganisms or parasites, presenting a risk to human health. Transportation of meat and meat products under appropriate conditions will reduce the level of contamination significantly.

In view of this, the guideline for safe retailing of Meat and Meat products is developed with the objective to disseminate practical information on meat hygiene and meat technology to meat handlers. The guideline encompasses basic techniques and the respective hygienic regulations, applicable to both the small-scale and medium-sized retail meat shop. Adherence to these basic guidelines would contribute to the production of safe, good-quality meat and meat products in

the country. In addition, this guideline will assist those who handle, transports, distributes, stores and sell meat and meat products to ensure that meat intended for human consumption and destined for sale have been operated at licensed meat shop under the supervision by BAFRA officials. Meat in the retail meat shops should be inspected, and certified as wholesome and fit for human consumption, which is an important quality-control step to ensure meat safety. This guideline applies to everyone who handles, transports, distributes and stores meat and meat products for public sale. This includes owners and operators of food premises, such as licensed slaughter facilities, butcher shops, licensed meat shop, food retailers and those who transport meat products to any of these facilities.

This activity was completed in January 2019 which includes drafting and taking up consultation with meat shop owners. As per the 2018-2019, **100%** rating is assigned for this success indicator (15 May 2019 - Excellent rating).

Calculation of National Biosecurity Index

$$\begin{aligned}\text{NBI} &= (\text{Sum total weight of SIs} / \text{total weight of SIs under National Biosecurity Index KPI}) \times 100 \\ &= (53/53) \times 100 \\ &= 100\%\end{aligned}$$

Therefore the National Biosecurity Index for 2018-2019 is 100%.

National Food Safety Index

Food safety is an area of high relevance to today's time when we are faced with increasing food safety threats leading to food poisoning/food borne diseases. An unprecedented number of disease outbreaks have occurred both within the country and internationally due to both microbial and chemical contaminants including known pathogens such as E.coli, listeria and salmonella, as well as new threats such as avian influenza and bovine spongiform encephalopathy (mad cow disease). Chemical threats continue to exist from the application of pesticides and other chemicals introduced or naturally present in the environment including polychlorinated biphenyls and heavy metals. The technology such as nanotechnology and biotechnologies introduce new and at times undiscovered risks to the food system. Other challenges include the emergence of new threats to food safety and consumer health due to changing lifestyle and food habits, the continued evolution of Bhutan into a modern society and ensuring coordination of a vast network of food safety services across the food system.

Food safety requires a coordinated vision right from the government level to the farm production level ascertaining the commitment of all the multi-sectoral stakeholders in the food chain. Being

the food safety authority, BAFRA has been implementing the Food Act of Bhutan 2005 and the Food Rules and Regulations of Bhutan 2017; however, due to the lack of an overall guiding policy, there is lack for coordinated approach and information network for food safety involving important stakeholders from farm to fork. The Coordination and implementation of food safety measures in Bhutan faces a number of challenges such as incomplete food legislations; absence of a national food control strategy; poorly defined and overlapping mandates among agencies involved; limited infrastructure, equipment, supplies, skilled personnel; inadequate scientific and technical resources for food inspection and compliance; limited knowledge about, and ability to comply with, food quality and safety assurance systems; weak capacity to participate fully in international bodies and agreements governing trade in food.

For the reasons aforementioned, the national food safety index is included as one of the KPIs under the result (outcome 1) for “Food and Nutrition Security Programme” in 12 Five Year Plan basically to address the issues aforementioned. For 2018-209, nine indicators are included as SIs to establish the National Food Safety Index. The same SIs are spread over 5 years time interval to achieve the target. For 2018-2019, the national food safety index target is set at >80%, so that in the initial fiscal year, the necessary enabling instruments are developed. Following are the nine indicators for 2018-2019 national food safety index.

10. Gap analysis and identification of the accreditation body to accredit BAFRA for Organic certification completed.

An international consultants were fielded in by BAFRA for the purpose of carrying out a gap analysis of the existing certification system and aligning to the international standard practices (ISO 17065). The consultants developed organic product certification scheme, manual, guidelines, procedures and forms and formats. Following which, several technical workshops and trainings on organic certification were conducted for BAFRA officials to enhance their competencies.

The National Accreditation Board for Certification Bodies (NABCB) under Quality Council of India had been identified as the accrediting body of BAFRA for Organic certification.

As per the timeline in 2018-2019, this activity is assigned 100% rating (100% rating if 80-100% of organic product certification is completed).

11. An analysis and identification of accreditation body to accredit BAFRA for Bhutan-Good Agricultural Practices certification completed.

An international consultants were fielded in by BAFRA for the purpose of carrying out a gap analysis of the existing certification system and aligning to the international standard practices (ISO 17065). The consultants developed BhutanGAP product certification scheme, manual, guidelines, procedures and forms and formats. Following which, several technical workshops and trainings on BhutanGAP certification were conducted for BAFRA officials and extensionist to enhance their competencies.

The National Accreditation Board for Certification Bodies (NABCB) under Quality Council of India had been identified as the accrediting body of BAFRA for BhutanGAP certification.

As per the timeline in 2018-2019, this activity is assigned 100% rating (100% rating if 80-100% of BhutanGAP product certification is completed). This activity was completed before the timeline.

12. Initiate certification requirements for import of food commodities from India in collaboration with EIC as per national requirement

As reflected in 2018-2019 APA, BAFRA has initiated certification requirement for import of three food commodities in collaboration with export inspection council as per the requirement. The three food products were chilled fish which includes frozen fish and crustaceans, animal feeds including feed additives and pre-mixture and dairy products. For chilled fish and animal feeds, the visit of EIC to Bhutan, agreement of national requirements and implementation of the requirements were done in August 2018 and May 2019 respectively. For dairy products, the initiation of certification requirements was started in February 2019. In April 2019, the team from BAFRA visited EIC head quarter in Delhi to discuss on the meeting the national requirements. As per the 2018-2019 timeline, 100% rating is assigned (initiate certification of 3 food products with EIC - Excellent).

13. Nos of laboratory Officials provided application training on heavy metal detection system

A total of 11 laboratory staff from national food testing laboratory was trained on heavy metal detection system using atomic absorption spectrophotometer from 6-10 May 2019. The training was conducted by NFTL using technical assistance from Mumbai, India who is expert in administering such training. The activity was completed well before 2018-2019 timeline for which 100% rating is assigned.

14. Nos of registered Food business assessed for issuance of food safety licenses

A total of 11 food businesses were issued with food safety license based on good manufacturing practices and good hygienic practices. As per 2018-2019, issuance of food safety license for 10 food business is rated as excellent for which the 100% rating is assigned for this activity.

15. Timeline by which food safety indicator pilot testing is initiated

Thirty eight officials are attending the first consultative workshop to develop a set of potential national food safety indicators with a One Health approach that can be used to assess the effectiveness of the national food safety systems. The goal of strengthening the national food control system was discussed during the FAO regional workshop on food safety indicators in the Asia Pacific held in Singapore where participants from the member countries finalised around 40 draft food safety indicators. Bhutan along with Cook Island, Philippines and South Korea volunteered to conduct the pilot projects to develop the national food safety indicators and verify its usefulness. Although, the Bhutan Agriculture and Food Regulatory Authority (BAFRA) has been continuously implementing the food safety measure throughout the country to ensure public health, there are no indicators to measure how far we have improved in terms of food safety. The development of food safety indicators will help Bhutan to review its current status of food safety, help identify the areas that need interventions and serve as a tool to mobilise resources for food safety. A technical working group has been also formed to ensure that the Bhutan adopts the best suitable food safety indicators. BAFRA is the national food control authority in the country. It carries out the border control inspections, inspect trade outlets for food safety and ensure that food processing businesses comply with food safety and hygiene standards as per the Food Act of Bhutan 2005. However, the act does not provide provisions for undertaking surveillance of food hazards or stipulate a risk-based approach to prevent, detect or control food hazards along the food supply chain. This activity was completed in 2 May 2019 at Paro. As per the 2018-2019 timeline, for excellent rating the activity has to be completed before 15 May 2019 and since it is completed on 2 May 2019, 100% rating is assigned.

16. Timeline by which sampling criteria and procedure documents developed

This Manual sets out how risk-based decisions are made to determine which imported food consignments should be inspected and how to interpret and gather data to assist in decision making over time. This is the most important decision framework for the implementation of a risk-based imported food inspection program. This Manual recognises that food imports must be assessed to ensure that it does not impose Biosecurity risk and complies with Bhutan food standard or other relevant standards. Those food imports identified as very high risk for Biosecurity concerns, 100% of imports may need to be inspected by the BAFRA inspectors.

The biosecurity managers will determine whether any pests or diseases are a critical biosecurity concern for Bhutan. If a specific pest or disease is identified as biosecurity concern, the managers will need to consider the appropriate level of protection (ALOP) needed. The managers will need to determine how this ALOP can be measured in inspection procedures. The biosecurity risk assessment and its management will be dealt as per the applicable Rules and Regulations of Bhutan. As reflected in 2018-2019 APA plan, the activity was completed in March 2019 with release of information in media press. Therefore, we have assigned 100% rating for this activity (15 May 2019 - Excellent rating as per 2018-2019 timeline).

17. Number of new test parameters introduced

A total of 16 new test parameters were introduced in National Food Testing Laboratory in 2018-2019 against the 10 test parameters reflected in APA for excellent rating. The details are furnished below:

Labs	Number of test parameters introduced
Contaminants	1 (Mercury)
GMO	3 (DAS40278-9 maize event, DP356043 soya event and GTS4032-soya event)
Nutrition	4
Residue	8 (Methionyl, Chlorpyrifos, Carbaryl, Endosulfan, Aldicarb, Dimethoate, Carbofuran, Cypermethrin)

For this activity 100% rating is assigned.

18. Timeline by which the heavy metal detection system is procured and commissioned

The heavy metal detection system (atomic absorption spectrophotometer) was procured by National Food Testing Laboratory from Menzang Enterprise. Along with the supply, the installation of the device with testing was done and handing taking done on 10 May 2019. As per the 2018-2019 timeline, procurement, commissioning of the equipments must be conducted before 15 May 2019 for excellent rating. Since the activity was completed before 15 May 2019, 100% rating was assigned.

Similarly, the national food safety index can be calculated as follow:

Calculation of National Food Safety Index

NFSI = (Sum total weight of SIs/ total weight of SIs under National Food Safety Index KPI) x100

$$= (47/47)*100$$

$$= 100\%$$

Therefore the National Food Safety Index for 2018-2019 is 100%.

Conclusion:

The national food safety index and national biosecurity index are the two broad indicator to assess the progress and status of the national biosecurity and food safety measures.