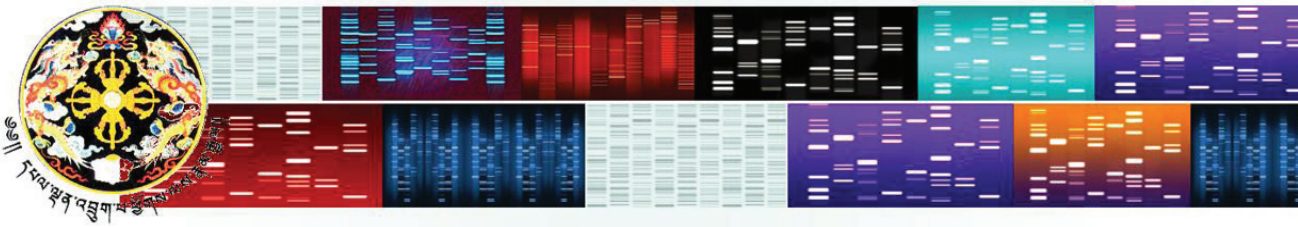

Guidelines for Handling Applications for GMOs/LMOs and Their Products

BHUTAN AGRICULTURE AND FOOD REGULATORY AUTHORITY (BAFRA)
MINISTRY OF AGRICULTURE AND FORESTS

FOREWORD

Bhutan Agriculture and Food Regulatory Authority (BAFRA), Ministry of Agriculture and Forests is committed to implement regulatory measures related to food safety and protection of human health and life of plants & animals in the Kingdom of Bhutan. BAFRA is also the national competent authority to implement the Cartagena Protocol on Biosafety (CPB) to ensure safe handling, transport and use of living modified organisms/ genetically modified organisms (LMOs/GMOs) resulting from modern biotechnology. The CPB defines a LMO "as any living organism that possess a novel combination of genetic material obtained through the use of modern biotechnology".

In line with its responsibilities, the "Guidelines for Handling applications for Activities involving Genetically Modified Organisms/Living Modified Organisms (GMOs/LMOs) and Products thereof" have been developed by BAFRA, to put in place an administrative framework for review of applications for activities involving GMOs/LMOs and products thereof in Bhutan. A structured approach for review of applications and decision making regarding various activities involving GMOs/LMOs in Bhutan is proposed to be implemented through a consultative process and involvement of stakeholders.

The guidelines is a step towards operationalizing an effective and robust framework for dealing with activities involving GMOs/LMOs and products thereof in Bhutan

Karma Dorji
Director General

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GUIDELINES FOR HANDLING APPLICATIONS FOR ACTIVITIES INVOLVING GENETICALLY MODIFIED ORGANISMS (GMOs)/LIVING MODIFIED ORGANISMS (LMOs) AND PRODUCTS THEREOF

1. INTRODUCTION

Modern biotechnology involving the use of genetic engineering/ recombinant DNA technology has emerged as a powerful tool with numerous potential applications in healthcare, agriculture, environment and process industry. The organisms obtained through the use of modern biotechnology, possessing a novel combination of genetic material are referred to as genetically modified organisms (GMOs) or living modified organisms[1] (LMOs). Biosafety concerns related to human health, environment and biological diversity associated with GMOs/LMOs and products thereof have led to development of systematic approaches to their safety assessment and elaborate regulatory system have been put in place by various countries to ensure safety of such organisms and products. The subject has assumed importance in view of several GMOs/LMOs getting approval across various countries, increased global trade and coming into force of the Cartagena Protocol on Biosafety (CPB)[2], an international agreement for regulating transboundary movement of LMOs.

Bhutan is a Party to the CPB and committed to meet the obligations of the Protocol to have a biosafety regulatory framework in the country. Several initiatives in this direction have been undertaken from time to time including issuing notifications under the existing acts, preparation of draft National Biosafety Framework in 2006, and preparation of draft Biosafety Bill, 2014.

The Bhutan Agriculture and Food Regulatory Authority (BAFRA) under the Ministry of Agriculture and Forests is the National Competent Authority for biosafety regulations in Bhutan and thus responsible for handling applications involving GMOs/LMOs and products thereof. While the formulation of regulatory

[1] A Living Modified Organism (LMO) is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology

[2] The Cartagena Protocol on Biosafety was adopted on 29 January 2000 and entered into force on 11 September 2003. The Protocol has been ratified by 167 countries. The Conference of Parties serving as Meeting of Parties (COP-MOP) ts the Governing Body of the Protocol and meets every alternate year to revtew the implementation of the Protocol. The text of the Protocol and other details can be accessed at https://bch.cbd.int/protocol/

framework is underway, BAFRA has founded pertinent to have guidelines for administrative procedures in place for its use by the competent authority in dealing with GMOs/LMOs and products derived from these organisms.

In view of the above, the “Guidelines for handling applications for activities involving GMOs/LMOs and products thereof” have been drafted for efficient handling of the applications so that decision making is undertaken with due consideration and the necessary information. These guidelines are necessary as the legal nature of the decisions requires well defined administrative procedures. Further, biosafety administrative procedures may involve a large volume of documentation including confidential business information and therefore a systematic approach is required to deal with the same.

As modern biotechnology is currently not practiced in Bhutan and the only source of GMOs/LMOs are from outside the country, regulation of imports is of the utmost importance. Further, the focus is primarily on food and feed items that are imported or would need to be imported. Accordingly, GMOs/LMOs for contained use and GMOs/LMOs for food, feed and processing are the most important categories to be regulated. GMOs/LMOs for intentional release (either for field trials or environment release) are not included taking into consideration the policies of Government of Bhutan, which clearly indicate that all such activities are not permitted. Further, in line with the Bhutan’s policies, the scope of the guidelines is restricted to administrative procedures for import and use of GMOs in agriculture.

2. OBJECTIVE

The objective of the “Guidelines for handling applications for activities involving GMOs/LMOs and products thereof” is to put in place an administrative system to handle applications or requests for approval/authorization for activities with GMOs/LMOs.

3. SCOPE

These guidelines apply to import, export and use of GMOs/LMOs and products thereof that may be intended for contained use or direct use in food, feed or processing. GMOs/LMOs for intentional release are not proposed to be permitted as per policies of Government of Bhutan.

The types of activities that may have safety assessment requirements include the following:

(i) Import and export of GMOs/LMOs
(ii) Transit
(iii) Contained use of GMOs/LMOs
(iv) GMOs/LMOs for food, feed and processing

4. KEY CONSIDERATIONS

i. The administrative process should enable efficient handling of the application so that decision making is undertaken with due consideration and the necessary information.

ii. The administrative procedure should meet the expectations of applicants and the general public, as well as any obligations under national legislation and international agreements.

iii. Various activities viz. laboratory research, field development and testing, general release and commodity imports have different information requirements as the specific knowledge is accumulated in line with progress in research and development.

5. ORGANIZATIONAL STRUCTURE

Administrative system for biosafety covers two distinct but interlinked activities viz. handling applications and decision making. The administrative office receives and processes applications; carries out routine biosafety

administration; and coordinates public input, risk assessment and decision making activities. It is also responsible for issuing biosafety communication to applicants and for coordinating consultation with stakeholders about biosafety processes. The decision making body reviews data on proposed activities involving GMOs/LMOs and approves or rejects them on the basis of the regulatory policies

In order to manage the handling of applications, BAFRA will establish a Biosafety Application Processing Unit (Biosafety Unit), which will have scientific and administrative officers. A Technical Working Group (TWG) shall be constituted by BAFRA to review applications and undertake safety assessment process. BAFRA will also maintain a list of additional subject specific experts related to biosafety assessment referred to as “Roster of Experts”, as activities involving GMOs/LMOs being an emerging area, inputs are often required from experts with experience in diverse disciplines.

The BAFRA will also establish a National Biosafety Commission (NBC) with representatives from concerned ministries and scientists, which is also apex body to take decisions as per the draft Biosafety Act, 2014. The NBC is the highest decision making body for issues related to biosafety and shall approve the annual work plans, programmes and mechanisms to implement biosafety related activities. Accordingly the NBC would be responsible for decision making on various applications besides finalizing guidelines and procedures. While the scientific officers shall be responsible for reviewing the application and interacting with decision making body, the administrative officer shall review the applications from the point of view of administrative compliance and also help in organizing meetings of concerned committees and facilitating interaction with experts.

Initially staffed with two scientific officers and one administrative officer, the Biosafety Unit will be responsible for:

- coordinating the receipt of applications;
- conducting administrative review of applications;

- verifying submitted documents;
- managing communication and correspondence with applicants;
- managing the tracking of applications;
- providing a secretariat function for the Technical Working Group and National Biosafety Commission (e.g. meeting coordination, report taking, document tracking);
- managing communication with stakeholders and posting the decisions on BCH.

6. TERMINOLOGY

i. "Applicant" means a person or agency, national or non-national that notifies its intent and/or applies for an approval to carry out any activity involving genetically modified organisms and products derived from genetically modified organisms.

ii. "Application" means the documentation that must be submitted to apply for an approval to conduct any activity involving genetically modified organisms and products derived from genetically modified organisms.

iii. "BAFRA" means the Bhutan Agriculture and Food Regulatory Authority.

iv. "Biosafety Clearing House" means the information exchange mechanisms established to facilitate the sharing of scientific, technical, environmental and legal information on, and experience with, genetically modified organisms.

v. "Contained use" means any operation within a secure facility, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

vi. "Genetically modified organisms (GMOs)" means any organism that possesses a novel combination of genetic material obtained through the

use of modern biotechnology techniques. Genetically modified organisms are also referred to as living modified organisms (LMOs).

vii. "Modern biotechnology" means the intentional manipulation of genes, cells and living tissue in a predictable and controlled manner to generate changes in the genetic make-up of an organism or produce new tissue and includes the application of:

(a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(b) fusion of cells beyond the taxonomic family, or

(c) mutagenesis that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

viii. "NBC" means the National Biosafety Commission.

ix. "Products derived from genetically modified organisms" means products derived directly from genetically modified organisms intended for food, feed and processing.

7. ADMINISTRATIVE PROCEDURES FOR HANDLING APPLICATIONS

The administrative procedures to be followed in handling applications are as follows:

i. Receipt of an application
ii. Screening for completeness
iii. Safety assessment
iv. Public participation
v. Decision making and communication

7.1 Receipt of an application:

All applications for approval of any activities using GMOs/LMOs will be submitted to BAFRA for processing by Biosafety Unit. Applications must meet the information and data requirements as prescribed by BAFRA. It is the

responsibility of applicants to prepare their own applications for submission. However, prior to formally submitting their application, applicant may like to have a pre-submission consultation with Biosafety Unit to ensure that it fulfills all the information requirements. All such consultations will be through proper appointments and in writing.

Appropriate proforma provided by BAFRA should be used for submission of applications. Suggested information requirements for import of GMOs/LMOs for contained use; for food/feed/processing and products derived from these organisms are placed at **Annex-1, 2 and 3.**

7.2 Screening for completeness

Biosafety Unit will complete an administrative review of each application to verify the application and enclosed documentation to ensure that each section has been completed. As the information requirements for applications will vary according to the proposed activity, it is important to understand the approval being sought as indicated below:

(i) What is the request of the applicant?
(ii) Does the proposed activity fall under the mandate of biosafety approval by BAFRA?
(iii) Does the application comply with the information requirements laid down for this type of activity?

Information requirements for each of the specific activities viz. import, export, LMOs for contained use, LMOs for food, feed and processing etc. will be provided in advance to the applicants. An indicative checklist for assessing administrative completeness of the application is placed at **Annex-4.**

Applications that are deemed complete will be entered into an application tracking system and an acknowledgement will be provided from the Biosafety Unit to the applicant within 10 working days from the date of receipt of the application. Applications that are deemed incomplete will be returned to the

applicant with an explanatory letter also within 30 days. Applicants will be permitted to re-submit applications without prejudice when errors or omissions have been corrected.

The conclusion that a certain application complies with the information requirements, does not mean additional information may not be requested by the reviewers or decision makers through BAFRA. Request for additional information can be made during screening for completeness stage as well as during the safety assessment and decision making process.

The guidance for assigning tracking codes is placed at **Annex-5.**

7.3 Safety assessment

As soon as it has been established that an application complies with the information requirements, the following steps are be taken:

(i) the applicant shall be informed that the request complies with the information requirements and that the procedure for handling or risk assessment has commenced according to safety assessment guidelines issued by BAFRA.

(ii) For initiating the risk assessment the Biosafety Unit will prepare a cover note (on each application) covering the following:

- the name of the applicant
- the type of application
- the name of the recipient organism, including whether the recipient organisms can cross fertilise with wild flora/fauna and/or with cultivated crops in the case of plants in the receiving environment,
- the inserted genes or sequences.
- Status of approval in country of origin

Such cover notes of the applications submitted by the applicant shall be provided as agenda notes for the meeting of TWG. This would facilitate a systematic risk assessment by the TWG.

(iii) On a case by case basis, scientific officers may seek comments from other subject specific experts. The opinion provided by experts shall be provided along with cover note to members of TWG.

(iv) The application and any accompanying information along with cover notes will then be sent to the members of TWG with a request for a safety assessment of the proposed activity;

7.3.1 Confidential business information

In view of the innovative nature of modern biotechnology, some of the business and research applications have technical, business and efficacy data that applicants may wish to keep confidential, in order to maintain a competitive advantage in the market place or to protect their right to patent the technology. Applicants may be allowed to mark information that they wish to keep confidential based on the accepted criteria stated in the guidance for safety assessment issued by BAFRA. However, Biosafety Unit may require applicants to substantiate why certain information needs to be kept confidential. In general, the following information is not kept confidential:

- The name and address of the application
- A general description of the LMO
- A summary of the risk assessment; and any risk management requirements.

When confidential business information is accepted in an application, it is marked as such in all documents distributed to reviewers and decision makers. In this way the information will not be withheld from regulators and should not affect their ability to regulate the activity. The confidentiality agreements with subject specific experts, members of TWGs and NBC should require the return or destruction of applications and the same shall apply both to soft and hard copies. The Biosafety Unit would follow up with reviewers and decision makers to confirm that the deletion and/or destruction of copies of applications has

happened after the review. Template of the confidentiality agreement/conflict of interest is placed at **Annex-6**.

7.3.2 Additional information requirements

It is common that during a safety assessment, the evaluators may require clarifications about information, data or studies and these can be requested from the applicant. Additionally, the evaluators may encounter deficiencies in the information provided by the applicant (e.g., a required study may not have been provided or required data may be missing). In both of these cases (clarifications and deficiencies) the safety assessment stops until the additional information is provided by the applicant. If the applicant cannot or does not provide this information within a reasonable amount of time, the application will be returned to the applicant and the file will be closed.

It may be kept in mind that technical information requirements depend on the nature of the application. As compared to application for LMOs for contained use, LMOs for food, feed and process will require more information. Regulators need to ensure additional information requests are realistic in terms of being available and being relevant to the assessment requirements for the activity and the level of risk posed by the GMO.

Applicants will not be permitted to communicate directly with members of the TWG or the NBC and vice versa. Communications between applicants, TWG and the NBC will be facilitated by Biosafety Unit and may occur during one or more stages:

- When product developers may seek guidance or clarification about information requirements
- Dossier development; and/or data compilation/dossier development
- During the safety assessment when the members may seek clarification or additional information from the applicant.

7.3.3 Safety assessment process

Once the application is provided to the members of the Technical Working Group, safety assessment process begins as per prescribed guidance for specific activities.

Safety assessment in the field of biosafety is a scientific process used to identify and evaluate the impacts that activities with GMOs/LMOs may have on the human and animal health and environment, including biodiversity.

To provide a meaningful tool for decision making, risk assessment needs to be carried out in a scientifically sound and transparent manner, and needs to make use of the best up to date scientific knowledge and experience.

Although the details of a risk assessment vary from case to case, the overall methodology followed in doing a risk assessment for GMOs usually involves a number of systematic steps.

In general the steps to be followed in risk assessment[3] are as follows:

1. Identification of potential adverse effects on the environment and human health.
2. An estimation of the likelihood of these adverse effects being realized.
3. An evaluation of risks based on the evaluation of the likelihood and of the consequences of the identified adverse effects being realized.
4. Consideration whether any identified risks are acceptable or manageable, including where appropriate, an identification of risk management strategies.
5. Assessment of the overall potential environmental impact.

- In addressing these steps, account is taken of the relevant characteristics of:
  - the recipient organism,
  - the inserted genes and other inserted sequences,

[3] Refer Codex principles and guidelines for foods derived from recombinant DNA plants in 2003 http://www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf for food and feed safety issues and Annex III to the Cartagena Protocol on Biosafety for environmental issues.

- the resulting GMO,
- the application (e.g. contained use or FFPs)
- the receiving environment,
- the status of approval and use in other countries

The actual steps to be followed will comply with guidelines adopted by BAFRA.

7.4 Public participation

Mechanism for public participation would vary from case to case depending on the proposed activities and the affected stakeholders. It is important to have Standard Operating Procedures (SOPs) for obtaining and processing public inputs to ensure that mechanism and end points are well defined.

In general the information about the applications along with the observations of TWG shall be placed on the website for a period of 30 days for comments from public at large. On a case by case basis the organizations/stakeholders may be informed about the public notice through mailers by Biosafety Unit.

7.5 Decision making and communication

The final decision to approve or reject will be taken by NBC based on regulatory policies of Bhutan and taking into considerations recommendations by TWG, public input and any other issues such as socio-economic considerations, availability of alternate technologies to address same issues, comparison with existing practices etc.

Once the decision has been made about a specific application, it is the responsibility of Biosafety Unit to compile decision documents including the steps that were followed. The decision will include summary of the risk assessment prepared by Biosafety Unit and risk management measures that may be needed to carry out the particular activities. Format of the decision document and the permit letter are placed at **Annex-7 and 8.**

After the approval by BAFRA, the Biosafety Unit will communicate the decision to the applicant as below:

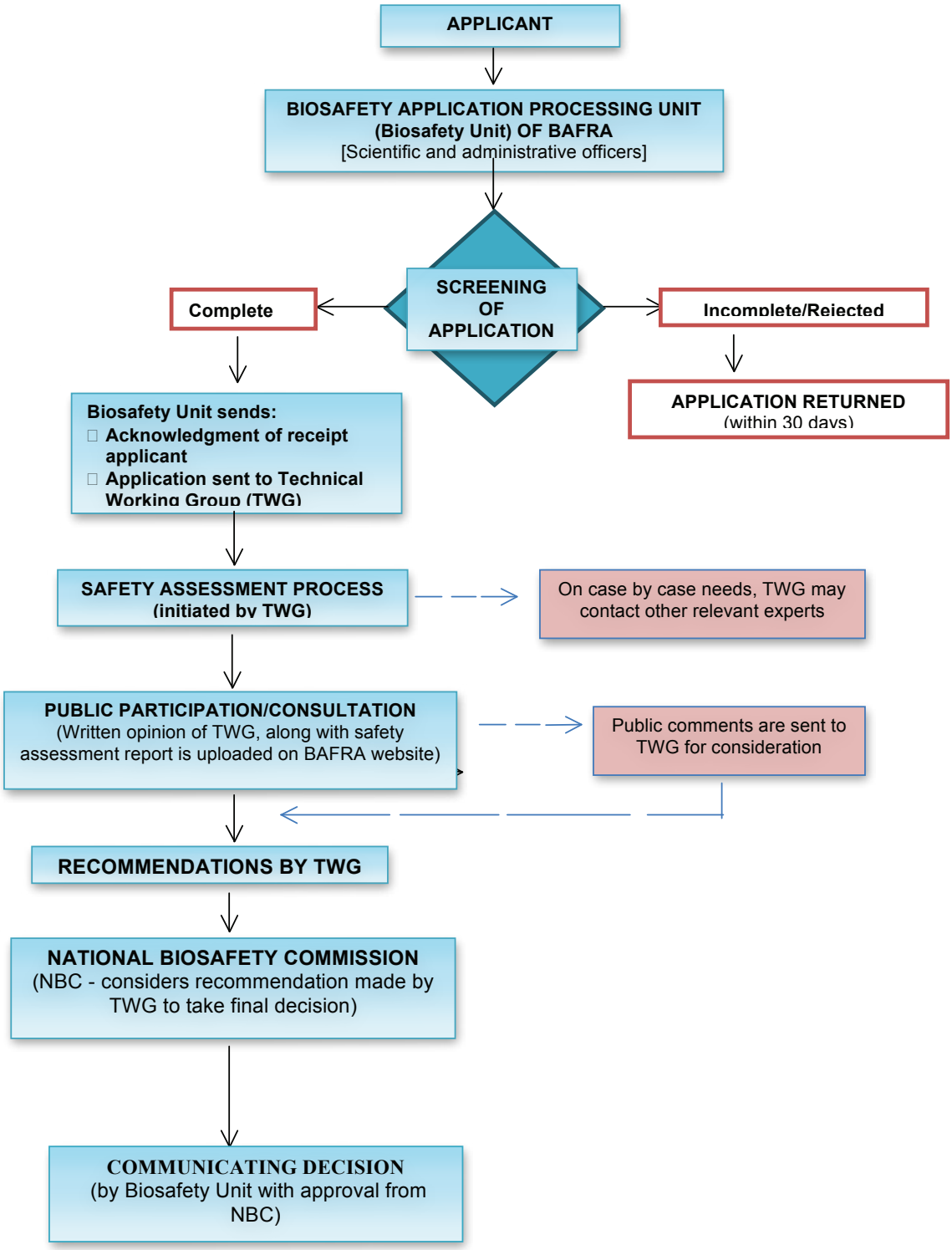
- inform the applicant by - issuing a rejection letter,
  - issuing a permit letter or
  - other form of approval, with or without terms and conditions
- make the decision public
- make the decision available to the Biosafety Clearing House (BCH)

The above mentioned administrative procedures for handling applications are summarized in the table and a flow diagram below:

Box no 1: Steps to be followed by BAFRA for handling applications involving GMOs/LMOs and products thereof

1. Application submitted to BAFRA by applicant.
2. Assess whether approval for the proposed activity is required, and whether the application meets the requirements of the regulations.
   - Acknowledge receipt of the application or issue a letter requesting missing information needed to fulfill the requirements for review and decision making
   - Give the application a tracking code and enter its details into an administrative database linked to a document tracking system
3. Biosafety Unit arranges for a safety assessment review to be done by TWG.
   - Liaise with the independent experts (Roster of experts) on a case by case basis to carry out the safety assessment
   - Where an application contains Confidential Business Information (CBI) ensure that confidentiality forms are signed
   - Ensure that the safety assessment is as per prescribed guidelines of BAFRA
4. Where information is found to be missing or clarification is needed during the safety assessment process, request the information from the applicant.
   - If necessary, schedule a meeting with the applicant or call for presentation to Biosafety Unit
5. Public participation would be carried out on a case by case basis.
6. Call for public input
   - Ensure that a public copy of the application that does not contain any confidential business information (CBI) is available for public review
   - Receive and document public input before directing this to the TWG
7. Incorporate public comments/queries and make recommendations.
8. Call the meeting of NBC when the information about scientific review, public consultation/participation and any other issues such as socio-economic considerations.
9. Prepare the decision document.
10. Inform the applicant.
11. Make decisions publicly available, on the BAFRA website and BCH.

FIGURE 1: FLOW CHART ON PROCESS FOR HANDLING APPLICATIONS



8. TIME PERIOD

The timelines generally start at the receipt of an application. BAFRA may establish time limits for various steps of handling applications and decisions to be taken. The timeframes for specific decisions have been stipulated in CPB. The following table provides timeframes for applications relevant to this guidance document as obligated under CPB for Parties:

Table 1: Time period for specific decisions as obligated by the Cartagena Protocol on Biosafety

Regulatory activity	Timeframe	Reference
Acknowledgement of receipt of notification and how to proceed with the first intentional transboundary movement of a LMO	90 days	Article 9(1)
Take a decision on a GMO import for food, feed or processing (applicable to developing country Party or a Party with an economy in transition, in the absence of a domestic regulatory framework)	270 days	Article 11(6)
Inform the BCH of a decision to approve a LMO for domestic use as food, feed or processing, including placing on the market	15 days	Article 11(1)
Notify an applicant of a change in decision regarding a transboundary movement	30 days	Article 12(1)
Party response to changed decision on transboundary movement	90 days	Article 12(3)

Annex-1

APPLICATION FORM FOR IMPORT OF GMOs/LMOs FOR CONTAINED USE IN BHUTAN

1. Name of the applicant: _____

   Designation: _____

   Contact Address: _____

   Telephone No: _____

   Fax No: _____

   Email: _____

2. Objective of importing GMOs/ LMOs (in 4-6 lines only):

3. Description of the GMOs/LMOs intended for contained use (in scientific terms):

4. Quantity of GMOs/LMOs to be imported: (Please specify):

   _____

   _____

5. Status of approval in exporting country (Provide supporting documents):

   _____

   _____

6. Whether the proposed GMOs/ LMOs was imported earlier:
   ☐ Yes ☐ No

   If yes, provide the copy of relevant permit issued previously and quantities imported (please specify).

   _____

7. Proposed work plan for imported GMOs/ LMOs in contained facility:

8. Source and transport details:

8.1 Source of GMOs/LMOs proposed to be imported (provide contact details of exporting agency):

_____

_____

8.2 Mode of Transport (Air / Road): _____

8.3 Port of entry in Bhutan: _____

8.4 Safety norms/storage conditions to be observed during transit:

_____

_____

9. Please indicate the level of biosafety containment proposed with respect to imported GMOs/ LMOs:

10. Proposed decontamination and disposal management mechanism to be applied:

11. Proposed risk management strategies / practices (Provide information of the potential risks):

12. Emergency contact person and his/her details:

_____

_____

13. Any other relevant information:

Instructions to the Applicant

a) The suggested information requirements are intended for use of GMOs/ LMOs for contained use in Bhutan.

b) Please answer all questions appropriately and provide reasons why a particular question is not applicable.

c) The consignment may NOT be used for propagation in Bhutan

Annex-2

APPLICATION FORM FOR IMPORT OF GMOs/LMOs FOR FOOD/FEED/ PROCESSING

1. Name of the applicant: _____

   Designation: _____

   Contact Address: _____

   Telephone No: _____

   Fax No: _____

   Email: _____

2. Objective of importing GMOs/LMOs (in only 4-6 lines) :

3. Description of the GMOs/LMOs intended for food/feed/processing:

4. Quantity of GMOs/LMOs to be imported (Please specify):

   _____

   _____

5. Status of approval in exporting country (Provide supporting documents)

   _____

   _____

6. Whether the proposed GMOs/ LMOs was imported earlier:

   ☐ Yes ☐ No

   If yes, provide the copy of relevant permit issued previously and quantities imported (please specify).

_____

7. Proposed work plan for imported GMOs/ LMOs for use as food/ feed/ processing:

8. Approved use(s) of the GMOs/LMOs:

9. Source and transport details:

9.1 Source of GMOs/LMOs proposed to be imported:

- Name of the Agency:_____
- Contact person's: _____
- Address: _____
- Telephone No.: _____
- Fax No.: _____
- E-mail: _____

9.2 Mode of Transport (Air / Road): _____

9.3 Port of entry in Bhutan: _____

9.4 Safety norms to be observed during transit (if any):

_____

_____

9.5 Storage conditions to be observed during transit (if any):

_____

_____

10. Effects of processing:

10.1 Whether further processing is envisaged after import. If so details of the same.

10.2 Description of proposed processing technology, with special attention to the steps which may lead to significant changes in the product content, quality or purity.

10.3 Assessment of whether or not the processing and/or preserving technologies applied are likely to modify the characteristics of GMO/LMO and products compared with their respective conventional counterparts.

11. Whether the gene/events from which the product has been derived is in commercial production and has been approved for marketing in the country of origin/export:

12. Whether the product has been approved for consumption (food/feed) in countries other than producing countries. If so, details of the same:

13. Reports of Environmental and Food/feed safety assessment studies conducted in the country of origin/export:

14. Proposed decontamination and disposal management mechanisms, wherever applicable:

15. Proposed risk management strategies / practices:

16. Emergency contact person and his/her details:

17. Any other relevant information:

Instructions to the Applicant

a) The suggested information requirements are intended for use of GMOs/ LMOs for food/feed/processing in Bhutan.

b) Please answer all questions appropriately and provide reasons why a particular question is not applicable.

Annex-3

APPLICATION FORM FOR IMPORT OF GMOs/LMOS FOR PRODUCTS DERIVED FROM GMOs/LMOs

1. Name of the applicant: _____

   Designation: _____

   Contact Address: _____

   Telephone No: _____

   Fax No: _____

   Email: _____

2. Objective of importing products derived from GMOs/ LMOs:

3. Description of the products derived from GMOs/LMOs:

4. Details of GMOs/LMOs from which the product has been derived (in scientific terms):

5. Quantity to be imported: (Please specify):

   _____

   _____

6. Whether the proposed products derived from GMOs/ LMOs was imported earlier:

☐ Yes ☐ No

If yes, provide the copy of relevant permit issued previously and quantities imported (please specify):

_____

7. Proposed use(s) of imported products:

_____

_____

8. Source and transport details:

8.1 Source of products proposed to be imported:

- ☐ Name of the Agency: _____
- ☐ Contact person's name: _____
- ☐ Address: _____
- ☐ Telephone No: _____
- ☐ Fax No: _____
- ☐ e-mail: _____

8.2 Mode of Transport (Air / Road): _____

8.3 Port of entry in Bhutan: _____

8.4 Storage conditions to be observed during transit (if any):

_____

_____

9. Status of approval in exporting country (Provide supporting documents):

_____

_____

10. Whether these products derived from GMOs/ LMOs have been approved for consumption in countries other than producing countries. If so, details of the same:

_____

_____

11. Reports of food/feed safety assessment studies of the GMOs/LMOs from the country of export:

12. Proposed risk management strategies / practices:

13. Emergency contact person and his/her details:

14. Any other relevant information:

Instructions to the Applicant

a) The suggested information requirements are intended for import of products derived from GMOs/ LMOs in Bhutan.

b) Please answer all questions appropriately and provide reasons why a particular question is not applicable.

Annex-4

CHECKLIST FOR ASSESSING ADMINISTRATIVE COMPLETENESS

An indicative checklist for assessing administrative completeness of the application to assist both the applicant and the officers in Biosafety Unit is as follows:

S. No.	Title	Yes	No
1.	Applicant has applied in the proforma specific to the activity for which approval is sought		
2.	Contact details of applicant, signatures have been provide		
3.	Information about the GMOs/LMOs		
4.	Food and feed safety assessment report (Wherever applicable)		
5.	Environment safety assessment report (Wherever applicable)		
6.	Regulatory status in the exporting country		
7.	Approved use of the GMO in the exporting country		
8.	Status of approval in other countries		
9.	Transport details and tentative date of shipment		
10.	Any information to be treated as confidential business information should be clearly marked "CBI" in the application		
11.	Evidence of application fees paid as prescribed in the regulation Revenue receipt no. _____ Date: _____		
12.	Declaration from the applicant		

Annex- 5

GUIDANCE FOR ASSIGNING TRACKING CODES

The Biosafety Unit will record the application by assigning a document tracking code on receipt of the application for approval.

Issue of a tracking code is useful for systematically keeping record of applications, track its movement through the various steps involved in the handling of applications for grant of permit and the status of their administrative progress through the biosafety regulatory system.

The tracking code is generally made up of the following pieces of information:

1. Application receiving date
2. Submitter/Applicant
3. Number of application from that organization in that year
4. Activity code

1. Application receiving date

The date is commonly written as date/month/year as given below:

For example: 2 May 2014

2. Applicant/Submitter

The applicant or submitter is commonly a letter code that can be recognised as being specific to the organization/industry name.

For example: Bhutan Agro Industry Limited might be BAI.

3. Number of applications from the organization in that year

The submission number is the number of applications from the organization in a particular year. The submission number can be a two digit number to take into account multiple applications from a particular organization in a year.

For example: BAI01 – 01for the first submission from the department '01" of the Bhutan Agro Industry Limited in that year.

4. Activity Code

The Activity code is useful to quickly identify applications for specific types of approvals.

For example a common code is:

IM = Import of GMOs
EM= Export of GMOs

TS = Transit of GMOs
FFP = LMOs for food, feed and processing
CON = LMOs for contained use
OA = any other activity

The tracking code for the first application from BAI department “01” for LMOs for food, feed and processing received on 2 May 2104 would look like this:

BAI- 01- FFP

This code would appear on the front page of all regulatory documents related to this particular application (safety assessment, public participation, seeking additional information, communicating decisions) and it would be used as a reference in all correspondence.

Annex-6

TEMPLATE OF THE CONFIDENTIALITY AGREEMENT/ CONFLICT OF INTEREST FOR MEMBERS OF TECHNICAL WORKING GROUP AND NATIONAL BIOASFETY COMMISSION

As a member of the TWG/NBC, constituted by the BAFRA, Ministry of Agriculture and Forests, I am aware of my obligations in respect of confidentiality of information, issues and other matters placed before the TWG/NBC and discussed thereupon, during my tenure of membership.

I hereby, solemnly agree and undertake to maintain the confidentiality of proposals, Intellectual Property (IP), commercial business information (CBI) and other related information made available to me for review, reference or discussion.

I further undertake not to divulge the opinions expressed by other members of the TWG/NBC or contents of the recommendations of TWG at any time to any person, press or media, in any manner unless otherwise published by the NBC Secretariat on the official website of BAFRA.

Executed at: __(Place) on __ (Date)
Signature :_____

Name & Address (with e-mail ID & contact no.):

Annex-7

FORMAT OF THE DECISION DOCUMENT

The Format of the decision document shall consist of:

a) Summary of the application

Particulars of the applicant's request:

(i) Name of the applicant _____

(ii) Title of the application _____

(iii) Tracking code _____

(iv) Short description of the applicant's request

(v) Short description of the GMO/LMO or product

b) Procedures followed during the evaluation of the application

- Stipulate all dates and actions involved during the evaluation process

c) Status of approval and use in other countries, particularly country of origin

_____

d) Summary of safety assessment

e) Risk management measures, if required

f) Any other specific information applicable for the case.

Annex-8

FORMAT OF THE PERMIT LETTER

Permit number: | |

Date of issue: _____

Date of expiry: _____

Name: _____

Organization: _____

Address: _____

_____

Phone, fax & email: _____

Subject: _____

AUTHORIZATION: In accordance with the _____ (name of regulation) of Royal Government of Bhutan and powers conferred through the biosafety legislation/rules issued by the Ministry of Agriculture and Forests, Bhutan based on the recommendations of the National Biosafety Commission (NBC) in its meeting held on _____, the Bhutan Agriculture and Food Regulatory Authority (BAFRA) hereby accords the authorization to (Name of organization) _____ to receive (Name of product) _____ from (Name of source agency) _____ for (purpose) _____ with properties indicated below, subject to the conditions mentioned in this letter.

PERIOD: The permit letter shall be in force from ____ to _____ unless it is sooner suspended or cancelled under the said rules/legislation.

Description of GMOs/LMOs/Materials

1. **GMOs/LMOs/Material(s) to be received:** _____
2. **Quantities to be received:** _____
3. **Purpose:** _____

4. **Permittee**

   Name: _____

   Organization: _____

   Address: _____

   Phone, fax & e-mail: _____

5. **Source of GMOs/LMOs/material(s):**

   Name: _____

   Organization: _____

   Address: _____

   Phone, fax & e-mail: _____

6. **Type of permit:**

   The permission is granted for receiving of (Name of the GMOs/LMOs and product thereof) _____ by (Name of the organization) _____ within a period of _____ and in a single shipment/ a maximum of _____ shipments. .

7. **Condition(s) of issuance:**

8. **Handling and packing instructions**:

   The above _____ mentioned here shall be handled, packaged and transported as

   Kindly acknowledge the receipt of the same

(BAFRA)

❋❋❋


NATIONAL BIOSAFETY FRAME WORK PROJECT
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