2017 User's Guide

to Biosafety Regulatory Process for Genetically Engineered Plants in Bangladesh

Table of Contents

About this Document

This document is intended to serve as an informational resource for applicants and other stakeholders interested in understanding the regulatory processes associated with biosafety regulation in Bangladesh. This is not a legally binding document. Nothing contained in this guidance should be construed to create any new obligations on applicants or the government, nor to alleviate any existing obligations contained in the Biosafety Rules of Bangladesh, Biosafety Guidelines of Bangladesh or other relevant Acts, Rules or Guidance.

Instead, this guidance has been constructed based on a review of existing regulatory documents, as well as consultations with regulators and stakeholders to build an understanding of how the process of submitting an application to the biosafety regulatory system is presently operating. As such, this is intended to be a "living document" and may be changed or updated to reflect any changes or refinements to the regulatory process.

The current document describes the practices and regulatory process for applications involving genetically modified plants. It addresses applications for confined field trials, renewal applications for confined field trials, applications for environmental release for cultivation, importations for use in food, feed and processing, or importations for release into the environment.

Biosafety Regulation in Bangladesh

Biosafety in Bangladesh is governed by the Biosafety Rules of Bangladesh, promulgated under the Environment Conservation Act (1995) and published in the National Gazette in 2012. These rules codify the regulatory structures and processes contained in the Biosafety Guidelines of Bangladesh (2008). The policy and decision-making body for biosafety is the National Committee on Biosafety (NCB), chaired by the Secretary of the Ministry of Environment and Forests. The NCB is intended to meet four times a year. The work of the NCB is supported by a technical committee called the Biosafety Core Committee (BCC). This group of technical experts, at the request of the NCB, is responsible for reviewing the technical information submitted with applications and making recommendations to the NCB. The constitution of the NCB and the BCC are both laid out in the Biosafety Guidelines of Bangladesh.

The Biosafety Guidelines of Bangladesh also require any institution working with genetically modified organisms to establish an Institutional Biosafety Committee (IBC). This committee reviews potential uses of GMOs for biosafety purposes and is envisioned to serve as the applicant to the Bangladesh regulatory authority.

For crops that are intended to be imported for research, tested or released into the environment for cultivation in Bangladesh, these must enter the system through the National Technical Committee on Crop Biotechnology, within the Ministry of Agriculture.

Confined Field Trials

Process Description

The conduct of confined field trials is normally a significant component of the research and development of GM plants. These trials allow researchers to collect valuable biosafety data which will provide support to any future applications for commercial releases as well as to evaluate the agronomic characteristics of the plant. The requirements for maintaining confinement for a field trial are much more complex than for maintaining containment of GE plants under laboratory conditions or for the safe handling and transfer of materials through importation and export, and will in most cases be species specific. This means that field trial applications will require greater attention on the part of the NCB, and may well require more time to review – particularly for first time applications.

Under the Biosafety Guidelines, applications for confined field trials and unconfined field releases are grouped together, and require the following information:

a) Title of the project

b) Name and address of the Chief Investigator

c) Objectives of the project (overall and specific)

d) Intended date of commencement

e) Intended date of completion

f) Location of release with area to be covered

g) Time of release (Date)

h) Expected date of completion of release

i) Information on similar release elsewhere with adverse effect observed (if any)

j) Experimental details with quantity of materials to be released (number, weight, size etc.)

k) Is future field release of the same material expected? If yes, include amount, time location and period of release

l) What is the intended output of the field release?

m) Precautionary measures to be taken as per Biosafety Guidelines in case of adverse situation

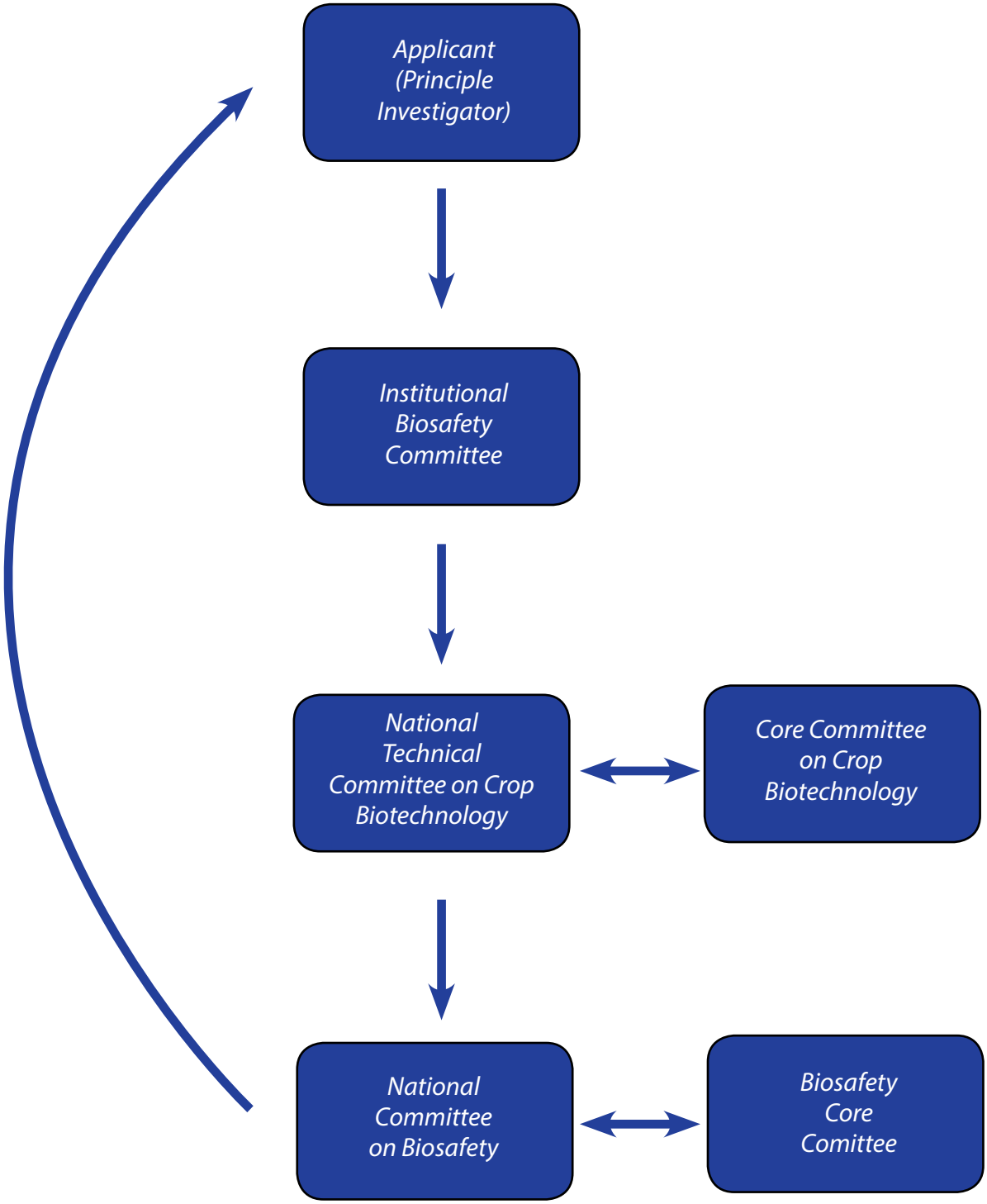
n) Additional information (if any)

Regulatory Process Outline

Expected Timeline: 180 Days

1. The Principal Investigator submits a detailed field trial application to the IBC.
2. The IBC, after review, forwards the application to the Secretary, Ministry of Agriculture serving as the chair of the National Technical Committee on Crop Biotechnology (NTCCB).
3. The NTCCB shares the application with a core committee, chaired by the Executive Chairman, Bangladesh Agricultural Research Council (BARC) for technical review. The core committee reviews the dossier and provides feedback to the NTCCB- specifically detailing any environmental safety concerns related to the application that should be highlighted at the NCB.
4. After a 60 day review, The Ministry of Agriculture forward the application to the NCB and to the BCC.
    a. The Member Secretary of the NCB acknowledges receipt of the application and distributes to the BCC.
    b. The BCC conducts it's initial review (30 day) and may request a meeting with the Applicant to review the conditions of the trial.
    c. The BCC prepares a recommendation and submits it to the NCB (30 days).
5. The application is received by the NCB and reviewed for completeness. A letter acknowledging receipt is sent to the applicant.
6. The application is forwarded to the BCC. The application materials are reviewed in the context of confinement conditions appropriate for the crop being trialed.
7. The BCC submits its recommendation to the NCB.
8. The NCB makes a determination in consideration of the application and the recommendation of the BCC (60 days). The NCB may recommend:
    a. The trial be allowed to be conducted as proposed.
    b. The trial not be allowed.
    c. The trial be allowed with certain additional condiations
    d. The decision will be postponed pending further information from the applicant.
9. If the trial is approved, the NCB identifies a three member Field Level Biosafety Committee to monitor the performance of the field trial.

Diagram I: The Regulatory Process of Confined Field Trial Applications in Bangladesh



Submitting Applications

Institutional Biosafety Committees should submit applications for CFTs to the Ministry of Agriculture. The receiving official at the Ministry of Agriculture is the Secretary, who serves as the chair of the National Technical Committee on Crop Biotechnology.

Two copies of the application should be sent through the mail. The ministry may request additional copies. An electronic copy should also be sent to secretary@moa.gov.bd.

The application should be addressed to:
Chairperson
National Technical Committee on Crop Biotechnology (NTCCB)
Ministry of Agriculture
Bangladesh Secretariat
Dhaka-1000

The applicant should expect to receive a letter confirming the receipt of the application from the office of the Secretary. The review is expected to take 90 days to complete. When it is completed the Ministry of Agriculture will forward the document to the Secretary of the Ministry of Enviornment and Forests, who serves as the chair of the National Committee on Biosafety. The applicant will be notified that the document has been forwarded to the NCB by the Member Secretary of the NTCCB

Review of the application by the NCB is also expected to take 90 days.

Renewal Applications

(Pending revision to the Biosafety Guidelines)

For continuations of previously approved field trials, following the same protocols, then an expedited review process may occur. If the trial is reviewed by the BCC without any objection then permission to continue the trial may be granted by the Department of Environment, subject to review by the NCB.

Importation of LMOs for Direct Use as Food, Animal Feed or for Processing

The importation of LMOs for direct use as food, animal feed or for processing (FFPs) is considered under Article 11 of the Cartagena Protocol on Biosafety.

Process Description

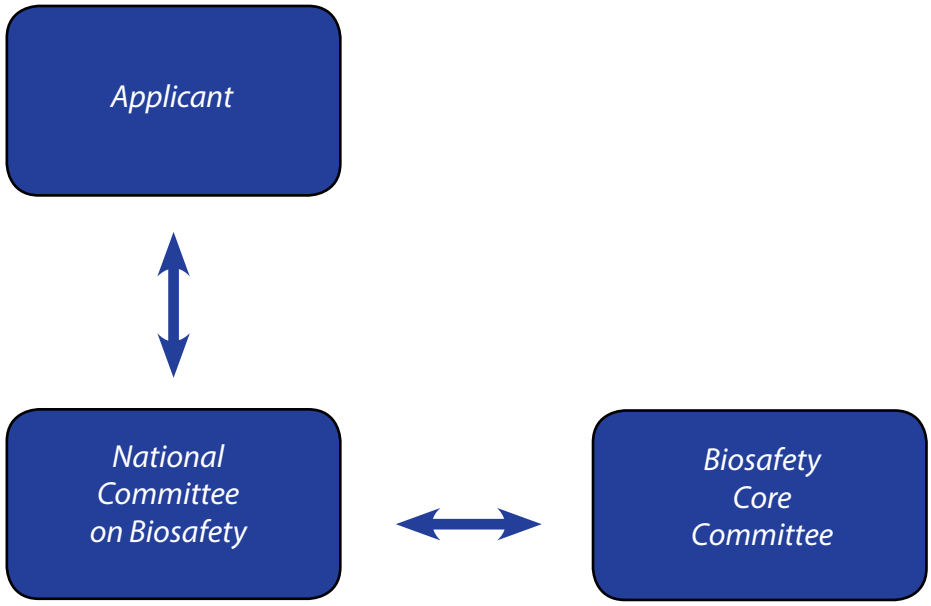
An applicant would apply for an import permit through the NCB. The NCB would forward the application, along with technical information to the BCC for their review. The BCC has 60 days to review the application and provide questions to the applicant. A BCC report is then sent back to the NCB, which has 30 days to review the results and issue a decision on the importation of the LMO for use in FFP.

Regulatory Process Outline

Expected Timeline: 90 Days

1. The application is received by the NCB and reviewed for completeness. A letter acknowledging receipt is sent to the applicant.
2. The application is forwarded to the BCC. The application materials are reviewed in the context of the Bangladesh Guidelines for the Safety Assessment of Food and Feed derived from GE Plants by the BCC and any additional technical experts invited by the BCC for the purposes of the review.
3. The BCC forwards a recommendation to the NCB, which takes a decision on the importation.
4. The decision is communicated back to the applicant, along with any conditions associated with an import approval. The decision will indicate the scope of the approval (e.g. whether it encompasses a single importation, or multiple importations, the duration of the approval etc.).

Diagram II: The Regulatory Process of Importation of LMOs Applications in Bangladesh



Submitting Applications

The importer should submit applications for CFTs to the Ministry of Environment. The receiving official at the Ministry of Environment is the Secretary, who serves as the chair of the NCB.

Two copies of the application should be sent through the mail. The ministry may request additional copies. An electronic copy should also be sent to secretary@moef.gov.bd.

The application should be addressed to:
Chairperson
National Committee on Biosafety (NCB)
Ministry of Environment and Forests (MOEF)
Bangladesh Secretariat
Dhaka-1000

The applicant should expect to receive a letter confirming the receipt of the application from the office of the Secretary. The applicant will be notified that of a decision by the Member Secretary of the NCB.

Review of the application is expected to take 90 days.

Renewal Applications

(Pending revision to the Biosafety Guidelines)

For continuations of previously approved field trials, following the same protocols, then an expedited review process may occur. If the trial is reviewed by the BCC without any objection then permission to continue the trial may be granted by the Department of Environment, subject to review by the NCB.

Cultivation Approvals

Cultivation approval refers to the approval for planting in Bangladesh in a commercial context for use by farmers or growers. This can include releases that occur with or without restrictions or risk management measures, but they are not subject to the strict confinement conditions applied to confined field trials. As such, the exposure to the environment is expected to be high, and the resulting agricultural products may be intended to enter the food supply. The general flow of regulatory documents would be expected to be the same as for confined field trials, with the addition of a food safety committee (if necessary) and extended timelines to allow for the review of complex materials.

Process Description

An applicant would assemble the data in support of their application, including data from confined field trials, laboratory work, and prior publications in accordance with the Bangladesh Guidelines for Environmental Risk Assessment of GE Plants, and (if applicable) the Bangladesh Guidelines for the Safety Assessment of Foods Derived from GE Plants.

Regulatory Process Outline

Expected Timeline: 180 Days

1. The application is forwarded to the IBC.
2. The IBC, after review, forwards the application to the Secretary, Ministry of Agriculture serving as the chair of the National Technical Committee on Crop Biotechnology (NTCCB).
3. The NTCCB shares the application with a core committee, chaired by the Executive Chairman, Bangladesh Agricultural Research Council (BARC) for technical review. The core committee reviews the dossier and provides feedback to the NTCCB – specifically detailing any environmental safety concerns related to the application that should be highlighted at the NCB.
4. After a 60 day review, The Ministry of Agriculture forwards to the NCB, along with any recommendations from the National Technical Committee on Crop Biotechnology.
5. The NCB reviews the application to ensure that it contains all the required information. A letter acknowledging receipt is sent to the applicant. If the application is not deemed to be complete, a listing of the deficiencies is returned to the applicant. At this point, the applicant can address the deficiencies and submit a revised application back to the NCB directly.

6. The NCB forwards the complete application to the BCC. The BCC has 30 days to review the data to determine if the GM plant poses environmental risk, in accordance with the Bangladesh Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants and prepares a recommendation for the NCB. If the crop will be used to produce food, it is also reviewed in accordance with the Bangladesh Guidelines for the Safety Assessment of Food and Feed derived from GE plants.

7. The BCC issues a recommendation to the NCB.

8. Informed by the application and the technical opinions of the BCC, the NCB issues a decision back to the applicant (60 days)

    a. The GM plant is authorized for release without conditions.

    b. The GM plan is authorized for release with conditions.

    c. The GM plant is not authorized for release.

Submitting Applications

Institutional Biosafety Committees should submit applications for cultivation approval to the Ministry of Agriculture. The receiving official at the Ministry of Agriculture is the Secretary, who serves as the chair of the National Technical Committee on Crop Biotechnology.

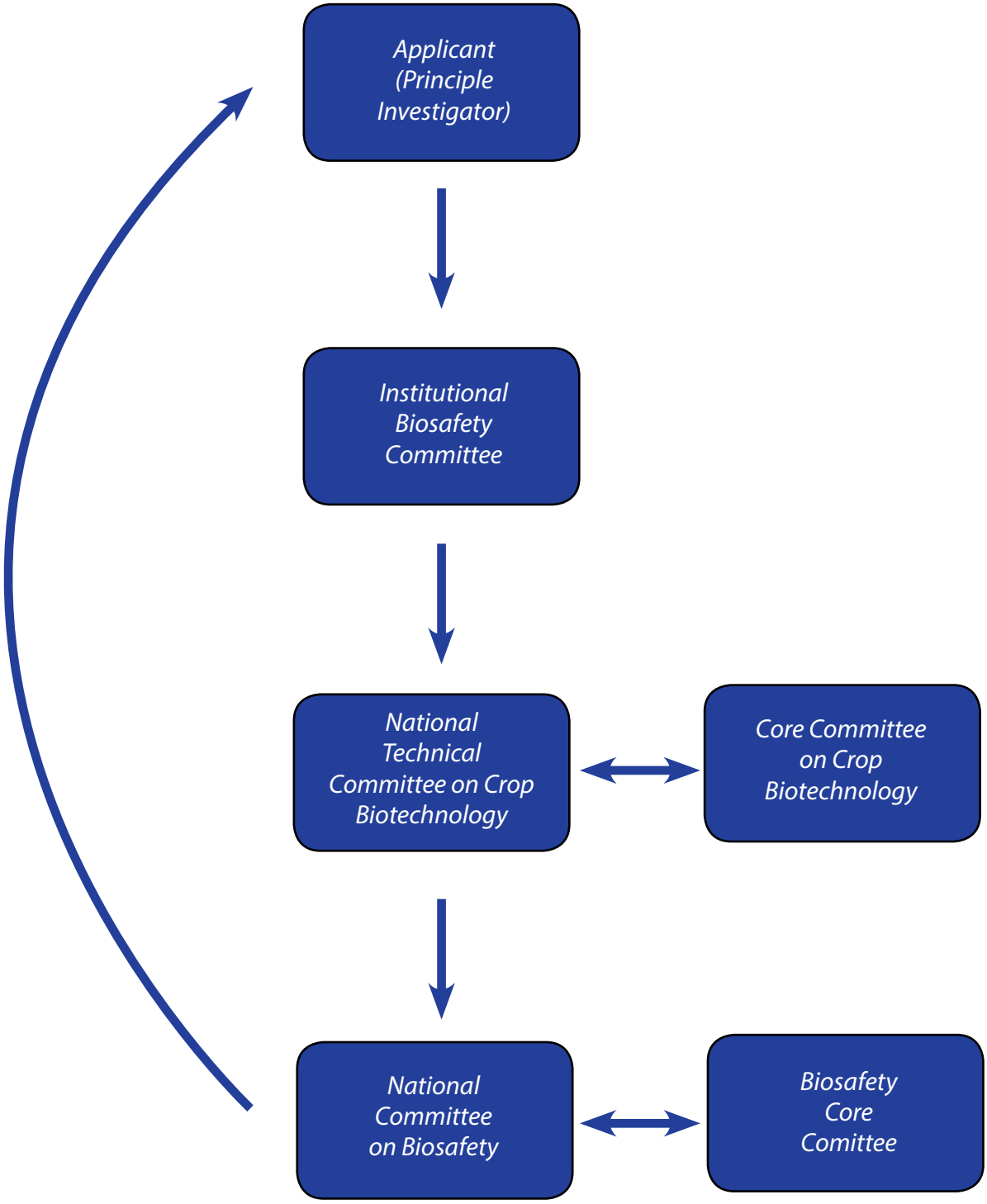
Two copies of the application should be sent through the mail. The ministry may request additional copies. An electronic copy should also be sent to secretary@moa.gov.bd.

The application should be addressed to:
Chairperson
National Technical Committee on Crop Biotechnology (NTCCB)
Ministry of Agriculture
Bangladesh Secretariat
Dhaka-1000

The applicant should expect to receive a letter confirming the receipt of the application from the office of the Secretary. When it is completed the Ministry of Agriculture will forward the document to the Secretary of the Ministry of Enviornment and Forests, who serves as the chair of the National Committee on Biosafety. The applicant will be notified that the document has been forwarded to the NCB by the Member Secretary of the NTCCB.

Review of the application is expected to take 90 days.

Diagram III: The Regulatory Process of Cultivation Approvals in Bangladesh



Additional Processes Proscribed under the Cartagena Protocol on Biosafety

Bangladesh is a Party to the Cartagena Protocol on Biosafety (CPB) under the Convention on Biological Diversity (CBD). This treaty places several obligations on Parties, particularly related to the need to establish decision making procedures and to have decisions informed by risk assessments. There are two kinds of decisions and processes that require an administrative procedure related to the biosafety regulations of Bangladesh. The first is imports of "living modified organisms" (LMOs) (in this case analogous to seeds of GM plants) for the purpose of direct use in food, animal feed or for processing (FFP). The second is the Advanced Informed Agreement Procedure, which obligates Parties to provide information to other Parties when a LMO is exported from one to the other for the purpose of direct release into the environment.

Advanced Informed Agreement Procedures

The CPB also contains a requirement for Advanced Informed Agreement (AIA) whenever an LMO is going to be exported from on country to another, with the intention of releasing the LMO into the environment in the country of import.

AIA Procedure when Bangladesh is the Country of Origin/Export

The requirement under the CPB is that Bangladesh provide, or require the product developer to provide, notification in writing to the Party of import prior to the intentional transboundary movement of an LMO with the intention of introducing that LMO to the environment.

The simplest mechanism for doing this is to make this obligation on exporters of LMOs explicit in the Biosafety Rules. However, if the NCB expects to perform this role, the procedure below would satisfy the requirements under the Protocol.

Process Description

The exporter (who may be anyone – including the developer of the LMO) must provide the NCB with, at a minimum, the information required in Annex I of the CPB:

a) Name, address and contact details of the exporter.

b) Name, address and contact details of the importer.

c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

d) Intended date or dates of the transboundary movement, if known.

e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

j) Quantity or volume of the living modified organism to be transferred.

k) A previous and existing risk assessment report consistent with Annex III.

l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

o) A declaration that the above-mentioned information is factually correct.

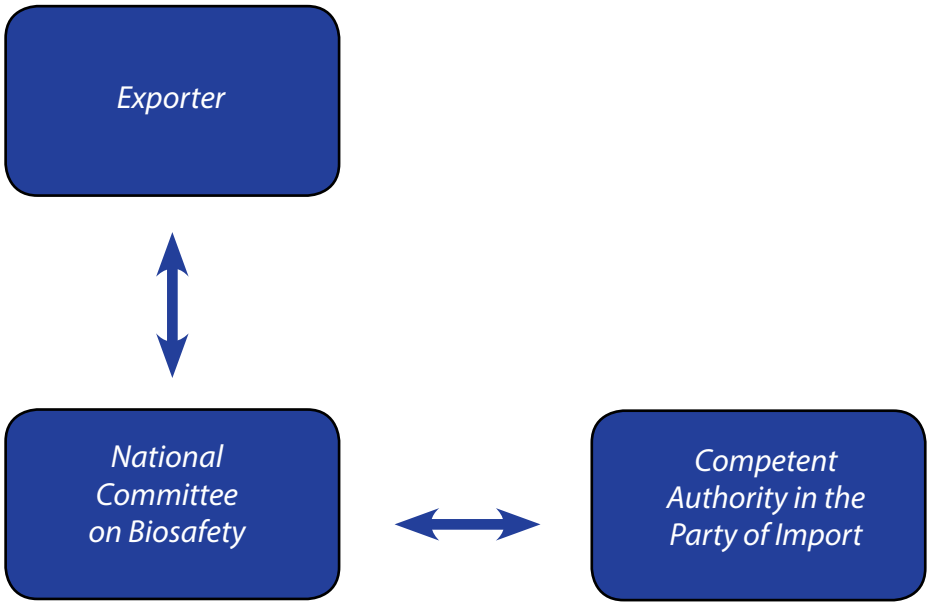
It is worth noting that this information includes a previous and existing risk assessment report consistent with Annex III. However, it does not require that the Government or any particular individual or organization produce that assessment. So this could be produced by the exporter and does not need to be validated by the Government of Bangladesh.

Regulatory Process Outline

Expected Timeline: 90 Days

1. The exporter notifies the NCB of the intention to export and provides the necessary information described in Annex 1 of the CPB.
2. The NCB has 90 days to review the information to ensure that it is accurate and then forwards the information to the competent authority in the country of import.

Diagram IV: The Regulatory Process of AIA when Bangladesh is the Country of Origin/Export



AIA Procedure when Bangladesh is the Country of Import

In the case where Bangladesh is the country of import, the application may come from an exporter or from the Party where the export originates. In either case, the importation would include, at a minimum the information described in Annex 1 of the CPB. Bangladesh has aligned this with domestic decision-making process. Therefore, the application for import of a biotech crop would arrive at the national focal point in the Ministry of Environment and Forests, then be forwarded to the Ministry of Agriculture for review by the NTCCB.

Regulatory Process Outline

Expected Timeline (after application arrives at the NCB): 180 Days (with exceptions)

1. The application arrives at the NCB. The NCB reviews the application to ensure that it contains the required information under article 8 of the CPB, and then to make a decision on whether to pursue a decision according to the domestic regulatory system or under the procedures described in Article 10. If the NCB elects to use the domestic regulatory framework then a request would be made to the exporter or Party of Export for information in accordance with a domestic application for environmental release (i.e. to address the Bangladesh ERA guidelines).

2. In the case of a LMO crop plant, the NCB forwards the application to the Ministry of Agriculture.

3. The Ministry of Agriculture forwards the application to The National Technical Committee, which reviews the dossier and provides feedback to the Ministry of Agriculture – specifically detailing any environmental safety concerns related to agriculture in the application that should be highlighted at the NCB.

4. The Ministry of Agriculture forwards to the NCB, along with any recommendations from the National Technical Committee.

5. The NCB forwards the complete application to the BCC. The BCC reviews the data to determine if the GM plant poses environmental risk and prepares a recommendation for the NCB.

6. If the GM plant is intended to be used for food, an Ad Hoc Food Safety Review committee is formed by the BCC, in cooperation with the Bangladesh Standards and Testing Institute (BSTI) to review the food safety of the GM plant. This body prepares a recommendation which accompanies the BCC recommendation back to the NCB.

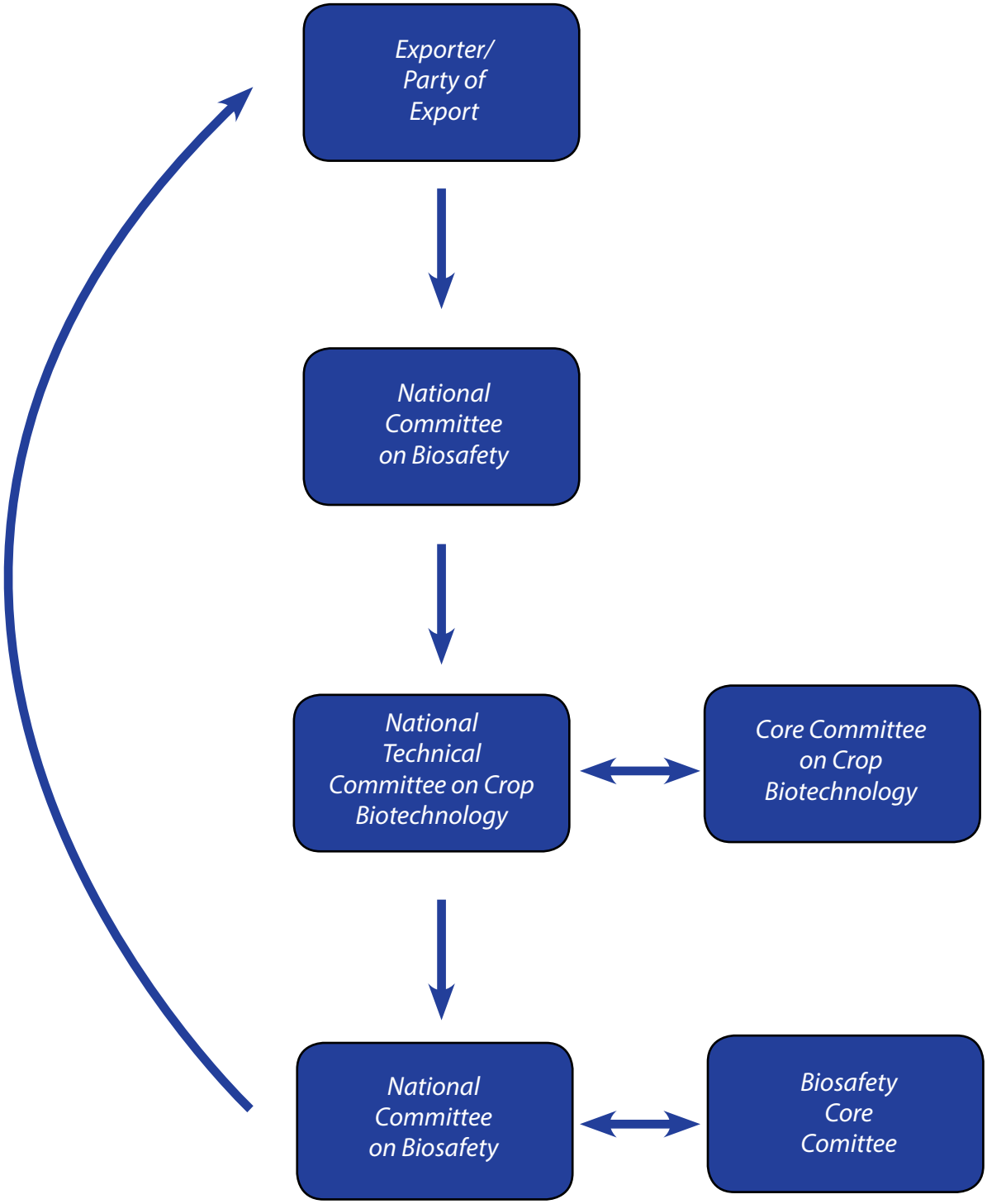
7. Informed by the technical opinions of the BCC, the NCB issues a decision back to the exporter/Party of Export.

    a. The GM plant is authorized for release without conditions.

    b. The GM plan is authorized for release with conditions.

    c. The GM plant is not authorized for release.

Diagram V: The Regulatory Process of AIA when Bangladesh is the Country of Import



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