



United Nations
Environment Programme

UNEP-GEF Project on Development of National Biosafety Frameworks



Global Environment
Facility

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PROPOSED FORMAT FOR PREPARATION OF A DRAFT NATIONAL BIOSAFETY FRAMEWORK

**(AS PREPARED UNDER THE UNEP-GEF PROJECT ON THE DEVELOPMENT OF
NATIONAL BIOSAFETY FRAMEWORKS)**

GENERAL INTRODUCTION

A national biosafety framework (NBF) is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Although national biosafety frameworks vary from country to country, they often contain a number of common components:

- A Government policy on biosafety
- A regulatory regime for biosafety
- A system to handle notifications or requests for authorisations
- Systems for 'follow up' such as enforcement and monitoring for environmental effects
- Mechanisms for public awareness, education and participation.

The purpose of description of the draft NBF is twofold:

1. Give an overview what has been done in the country during the NBF Development Project and what is in place in this country (ie legislation, administrative systems etc);
2. Indicate what still needs to be done in order to complete NBF (missing legislation that still needs to be drafted/adopted, gaps in administrative or enforcement systems etc).

INTRODUCTION TO THE DRAFT NBF

- The UNEP-GEF Project on the Development of the National Biosafety Framework of *Name of Country* started in *Month & Year* and ended in *Month & Year*.
- The National Executing Agency for the UNEP-GEF project was the *Name of the Institution and person, email address and other contact details*.
- The National Project Coordinator was *Name of the NPC*.
- The National Project Coordinator can be reached via: *Postal address*.
- The National Coordination Committee consists of *Number of* members, being representatives from the following *List of the Institutions and People*.

(NB Please replace words in italics with actual data for your own NBF)

DESCRIPTION OF THE DRAFT NATIONAL BIOSAFETY FRAMEWORK

1. Biosafety policy

A policy on biosafety could either be a stand-alone policy, or it could be part of a more general policy or policies on biodiversity conservation, biotechnology, science and technology, food production, food safety, environment protection or even sustainable development.

Description of national biosafety policy:

- If your country has a biosafety policy, please provide a brief description, highlighting the main objectives and principles, and explaining how it relates to other national development policies and priorities.
- If your country does not have a specific policy on biosafety, then state how (if at all) biosafety is addressed in the other policy areas listed above.
- What are the priorities and targets for the country in relation to biosafety?

Additional information required:

Please provide the status of your country with respect to ratification of the Convention on Biological Diversity and Cartagena Protocol.

2. Regulatory regime

Description of a regulatory regime for biosafety, which often is a combination of an Act or Decree, complemented with implementing technical regulations and guidelines.

Brief description of main relevant laws, acts, decrees etc:

- (i) Title of the laws, acts, decrees, etc.;
- (ii) Status (draft, adopted, year of adoption);
- (iii) What does it regulate (releases, marketing, contained use of LMOs, transit, etc.);
- (iv) brief summary of the procedures and content (couple of paragraphs);
- (v) Responsible institution(s) for implementing these laws, acts, decrees, etc.

Please also provide information about any gaps in legislation on biosafety (i.e. legislation that still needs to be drafted in order to complete the NBF).

Please indicate where relevant laws (in the original language or translation) could be accessed (bibliographic reference, hyperlink, etc.)

You may attach the **full inventory of the relevant national legislation** or hyperlinks. If relevant, attach any other guidelines published during the project or hyperlink.

3. System to handle notifications or requests for authorisations

Please give a brief description of your country's system to handle notifications or requests for authorisations for activities, such as release of LMOs into the environment. Such systems typically include administrative functions, risk assessment, decision-making and public participation.

In your description, please provide details of::

- The Competent Authority/ies responsible for receiving and handling requests for permits (import, export, domestic use, including placing on the market, intentional introduction into the environment, field trials, contained use, transit, etc.)
- The system(s)/procedure(s) for handling notifications and requests for permits. (A flow-chart is a useful way to illustrate and explain the system).
- Future plans, where relevant.

Please attach any relevant forms, if applicable.

4. Monitoring and enforcement.

Systems for 'follow up' for biosafety, such as enforcement and monitoring for environmental effects. Monitoring is a term used for evaluating actual impacts on the environment and human health, whereas enforcement typically focuses on compliance with the regulatory regime.

Please provide details of:

- Your country's system(s) for monitoring;
- Your country's system(s) for enforcement;
- The institutions responsible for these actions;
- Future plans for monitoring and enforcement systems, where relevant.

5. Mechanisms for promoting and facilitating public awareness, education and participation.

Mechanisms for promoting and facilitating public awareness, education and participation, i.e. informing and involving the public in the development and implementation of the national biosafety framework.

Please provide details of:

- Your country's system(s) for public awareness, education and participation.
- Examples of best practices and lessons learned, if available.
- The address of national component of the BCH or any other biosafety related database or website, if these are available.
- Future plans for systems for public awareness, education and participation, in biosafety, where relevant