



United Nations
Environment Programme

UNEP-GEF Projects on Implementation of National Biosafety Frameworks



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Introduction

A national biosafety framework is a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology. These frameworks often focus on living modified organisms or, as they are often referred to, genetically modified organisms (GMOs).

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

- A Government policy on biosafety, which is usually part of a broader policy such as policy on biotechnology in general, agricultural production, health care or environmental protection.
- A regulatory regime for biosafety, which often is a combination of an Act or Decree, complemented with implementing technical regulations and guidelines.
- A system to handle notifications or requests for authorisations for certain activities, such as releases of GMOs into the environment. Such systems typically include administrative functions, risk assessment, decision making and public participation.
- Systems for 'follow up' 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.
- Approaches for public information and public participation, i.e. informing and involving stakeholders in the development and implementation of the national biosafety framework.

Establishing an adequate level of biosafety is typically an ongoing, iterative process of developing a draft national biosafety framework, implementing the draft framework, and continuous evaluation and feedback.

In November 2000, the GEF Council approved the GEF Initial Strategy on biosafety, which aims to support countries to prepare for the coming into force of the Cartagena Protocol on Biosafety. Part of the GEF Strategy is the UNEP-GEF Project on Development of National Biosafety Frameworks, which started in June 2001.

In November 2001, the GEF Council approved 12 demonstration projects to support countries with the implementation of their national biosafety frameworks. Two of those projects are coordinated by the World Bank, two by UNDP and eight by UNEP.

The UNEP-GEF demonstration projects on Implementation of National Biosafety Frameworks last on average 3 years, and the budgets range between 500,000 USD and 1,000,000 USD.

Detailed information about the UNEP-GEF projects on Implementation of National Biosafety Frameworks can be found on the UNEP-GEF Biosafety web site (www.unep.ch/biosafety, under 'Implementation projects'). The UNEP-GEF Biosafety web site also provides information about other of UNEP working on the GEF Initial Strategy on Biosafety, such as the UNEP-GEF Project



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on Development of National Biosafety Frameworks.

This information paper is a printed version of some of the main parts of the pages on the UNEP-GEF Biosafety web site that deal with the UNEP-GEF projects on Implementation of National Biosafety Framework.

Project execution.

1. The approach taken in the projects.

The UNEP-GEF Projects on Implementation of National projects are country driven projects, i.e. the projects are requested and 'driven' by the countries.

The role of UNEP focuses on providing expert assistance and guidance as well as on ensuring accountability through adequate and transparent reporting. Cash advance payments for the implementation of the projects are based on detailed quarterly reports.

The target of each of country projects is to have the biosafety framework "up and running" by the end of the 3-year project period.

In concrete terms this means that by the end of the projects, the participating countries will have:

- a regulatory regime for biosafety is in place which is in line with the Biosafety Protocol and other relevant international obligations,
- workable and transparent implementing systems for handling of notifications or requests for approvals (including systems for administrative handling, risk assessment and decision making), enforcement and monitoring, as well as public information and public participation.

Taking into account that many of the national biosafety frameworks that are currently in function were created over a period of several years of 'trial and error', it is recognised that the above targets are ambitious for countries where the regulatory regime is still in an early draft phase. However, with the support of other countries and organisations it can be done.

In this context, it is very encouraging that a number of countries where biosafety frameworks have been in place for many years have offered to make their experts available for activities such as training workshops and peer review. In addition, close collaboration is sought with other projects and organisations. (see below under 'coordination')

The practice of the UNEP-GEF Projects on Implementation of National Biosafety Frameworks projects can be summarised with the following steps:

- a) Laying a firm foundation for each country project.
- b) Providing continuous expert advice and support to the participating countries for the remainder of the project.



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- c) Close collaboration and coordination with Governments and national and international organisations, to promote coordination and harmonisation.

a. Laying a foundation for the projects

In laying a foundation for the demonstration projects, the following activities were carried out during the start up period of the projects.

- obtaining a detailed picture of the state of developments,
- review of draft legislation
- organisation of workshops on national biosafety frameworks,
- preparation of a fine tuned work plan.

These activities are addressed in more detail in the section below “Summary of activities up to September 2003” below.

b. Providing continuous expert support

After the start up phase of the country projects, which resulted in a fine tuned plan of activities, the UNEP-GEF Implementation Team continues to be available to provide legal, scientific and technical support for the remainder of the projects.

Such support may vary from intense and frequent involvement in one or more of the workshops organised by the countries to general guidance by email, depending on the priorities and wishes of the participating countries.

c. Coordination and collaboration

To promote synergy and harmonisation as possible, the ‘Implementation Team’ and the team working UNEP GEF Project on the Development of National Biosafety Frameworks are working closely together to promote consistency between these two phases of the GEF Initial Strategy.

To help the participating countries to make optimal use of the available sources and to ensure synergy of activities, close cooperation is sought with international organisations such as the CBD Secretariat, IUCN, BIO-EARN, FAO, WHO, UNDP, UNIDO, World Bank, ISAAA, ISNAR, OECD and the USAID-PBS Programme, as well as with a number of governments, including Austria, Belgium, Canada, Germany, France, the Netherlands, Sweden, Switzerland, the United Kingdom and the United States.

As regards ‘peer review, it is recognised that it is no help to countries if the support they are being given consists of an approach that is not widely viewed as being valid and workable. It is therefore important to regularly present the approach taken to review by peer experts. This is particularly important for the scientific components of the Implementation projects.



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2. Summary of the activities up to September 2003.

Activities in the period September 2002 – December 2003

In September 2002, a cash advance was transferred to the eight demonstration countries for the purpose of laying the groundwork for the projects, e.g. procurement of computers, arrangement of office space, etc.

Activities in the period January 2003 –September 2003

1. Obtaining a picture of the state of developments at the start of the Projects

The national coordinators and coordinating committees of each of the participating countries developed a detailed picture of the state of development of the main components of the national biosafety frameworks at the start of the Implementation Projects. Summaries of the state of developments are made available under '[participating countries](#)'

2. Review of draft legislation by international panels of experts.

Drafts of biosafety legislation and regulations of Bulgaria, Cameroon, Kenya, Namibia and Uganda were reviewed by international panels of experts from the CBD Secretariat, countries where biosafety frameworks have been in place, academia, NGOs and the private sector.

3. Workshops.

Intense, 'hands on' workshops were held to address the main 5 components of the national biosafety frameworks in detail. In most cases these 'start up' workshops were preceded by a one-day introductory seminar for parliamentarians. These workshops were open to observers from NGOs, the private sector, media and other countries. In the workshops, resource persons included experts from international organizations, such as the CBD Secretariat, ISNAR and OECD, countries where biosafety frameworks have been in place for several years, as well as from academia, NGOs and the private sector.

4. Fine tuned work plans

Following each start up workshop, the national coordinators, the national coordination committees, the resource persons and the Programme Manager of the UNEP-GEF projects on Implementation of National Biosafety frameworks met to discuss fine tuned work plans for the remainder of the project, including the targets to be reached within the project period for each of the main components of the national biosafety framework. These work plans, together with the summary of the state of developments at the start of the projects and the progress reports are made available under '[participating countries](#)'.



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3. Next steps and future projects.

In the years to come, the following activities are envisaged:

- Assisting the participating countries with the implementation of their projects.
- Assisting countries that have indicated a wish to carry out a UNEP-GEF Project on Implementation of National Biosafety Frameworks with the preparation of a proposal and – if granted - implementation of the projects.
- Further development of practical tools for the implementation of national biosafety frameworks, such as:
 - a manual with practical guidance on regulatory regimes for biosafety, handling requests for permits (including administrative systems, risk assessment, decision making), enforcement and monitoring for environmental effects, and public information and participation,
 - a database called “Gene Files” with relevant information about genes that are frequently used in genetic modification, and a database called “Botanical Files” with relevant information about crop plants that are frequently used for genetic modification.

4. Further information and contacts.

Questions about the UNEP-GEF Projects on Implementation of National Biosafety Frameworks can be directed to Piet van der Meer, Programme Manager, (Piet.vanderMeer@unep.ch) and David Heron, Task Manager, (David.Heron@unep.ch).



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Participating countries

The countries listed below are currently participating in a UNEP-GEF Project on Implementation of National Biosafety Frameworks. A click on the name of that country will open a page with a brief introduction as well as links to project documents, such as progress reports:

- Bulgaria
- Cameroon
- China
- Cuba
- Kenya
- Namibia
- Poland
- Uganda

Note: the project documents, as submitted to UNEP-GEF by the national coordinators, often contain references to annexes that are attached to the reports. Some of those annexes are internal documents, such as drafts for legislation. As a matter of policy, the UNEP-GEF Implementation Team refers all requests for copies of documents that were attached to the operational reports to the national coordinators of the projects.

Documents and links

This page will provide access to documents that are used in the UNEP-GEF Projects on Implementation of National Biosafety Frameworks, as well as links to websites, databases and other resources that are relevant to the implementation of national biosafety frameworks.

One example of such a document is a manual for the implementation of national biosafety frameworks with practical guidance for Regulatory regimes for biosafety, Handling notifications and requests for authorisation, Systems for enforcement, including inspections, Approaches for monitoring for environmental effects, Methods for public information and public participation The manual will be a 'living document', i.e. it will be regularly reviewed and updated, building on the experience and feed back from the participating countries and involved experts.

An example of a web based database with information relevant for the implementation of national biosafety frameworks is the so called "Gene Files", which is a web based database with information about genes that are frequently used in genetic modification. A pilot of such a database has been developed in the context of the 3-year capacity building "Implementation of National Biosafety Frameworks in pre-accession countries in Central and Eastern Europe", and can be found on www.genefiles.org.