



# United Nations Environment Programme

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PROGRAMME DES NATIONS UNIES POUR L'ENVIRONNEMENT · PROGRAMA DE LAS NACIONES UNIDAS PARA EL MEDIO AMBIENTE  
ПРОГРАММА ОРГАНИЗАЦИИ ОБЪЕДИНЕННЫХ НАЦИЙ ПО ОКРУЖАЮЩЕЙ СРЕДЕ

## NOTE ON UNEP-GEF BIOSAFETY ACTIVITIES AS OF 16<sup>TH</sup> JULY 2004

### Introduction

1. As an Implementing Agency of the GEF, UNEP has been assisting eligible countries for the implementation of the Cartagena Protocol on Biosafety (CP). In addition to assisting the GEF Secretariat to prepare its initial strategy on biosafety, which was endorsed by the GEF Council in 2000, UNEP is currently implementing a portfolio of US\$ 56 million comprising of three categories of activities: a) assisting 123 countries to prepare their draft national biosafety frameworks; b) assisting eight demonstration projects for the implementation of national biosafety frameworks; c) assisting all eligible countries to access and benefit from the Biosafety Clearing-House. These activities are being carried out by the UNEP-GEF biosafety unit with a central administrative unit in Geneva handling technical, financial and administrative functions for all three projects, complemented by UNEP-GEF staff in Nairobi. An Information officer in Geneva assists all projects in recovery and dissemination of information needs and is supporting the updates on the central website at: [www.unep.ch/biosafety/](http://www.unep.ch/biosafety/). This website is central to our work and allows any stakeholder to download or look at the work being carried out.
2. Capacity building materials are made available in four UN Languages and all other documents in English. In addition to the technical staff headquartered in Geneva, the African and Pacific Island countries are serviced by staff in Nairobi and Samoa. In fulfilling its tasks, the biosafety team has developed close cooperation with all the GEF partners, including STAP, the CBD Secretariat and other international organizations such as the EU, ICGEB, ISAAA, ISNAR, IUCN, FAO, OECD, UNIDO, WHO, GTZ, CIDA and the USAID-PBS Programme, as well as with a number of donor nations.

### I. Assisting 123 countries to Develop their National Biosafety Frameworks

3. During the negotiation of the biosafety protocol, a UNEP/GEF pilot project for US\$ 2.5 million assisting 18 countries to prepare national biosafety frameworks and promoting regional and sub-regional collaboration was successfully implemented during the period 1997-1999.
4. Building on the experience gained, a UNEP-GEF project for US\$ 43.6 million, aimed at assisting 120+ countries to develop their national biosafety frameworks (NBF), is under execution. Out of the 1300 GEF projects, this is the first project with the participation of such a number of countries.
5. The development of National Biosafety Frameworks takes countries from a zero stage up to a draft national biosafety framework and capacity building is offered to assist them in areas related to 5 key components (Biosafety Policy, Regulatory regime,

System to handle requests (admin., risk assessment & management, decision-making), Follow up actions (monitoring, inspections and enforcement) , Public Awareness and Participation).

6. For at least the duration of the project, a National Coordinating Committee is set up to manage the preparation of a draft NBF where all stakeholders are represented, while a full-time paid National Project Coordinator (NPC) runs the project under the supervision of a National Executing Agency. Surveys are carried out of existing national resources of biotechnology, experts, regulations and administration before moving on to gap analysis, consultation with stakeholders, and this all eventually leads on to the actual drafting of the NBF. Countries are fully supported by Regional Coordinators, who have provided continuing support and help in all aspects of project implementation and are each responsible for fifteen or more countries. This relationship is the core of the project and has been seen as one of the major successes of the project.
7. At the start of the project, a series of 4 regional workshops were held with 263 participants from 124 countries to raise awareness on the obligations under the Cartagena Protocol and about the project, and to share experiences. These workshops were also seen to have potential for subregional cooperation. In addition, 979 country representatives from 138 countries have attended 12 sub-regional workshops. Material for all these workshops has been designed with full international expert review. Each workshop took place over 4 days in one of the six subregional regional groupings and allowed participants to build up and share experiences and gain knowledge in setting up systems for decision-making (including risk assessment), the involvement of the public, and the design of regulatory regime and administrative systems. One-day training has also been provided for the NPCs in financial and project management in the margins of these workshops.
8. 4 Toolkits, mirroring the 4 phases of NBF development, have been prepared with international experts to assist the national teams in understanding and carrying out of project activities, and made freely available in four UN languages and placed on the website. The heavy demands on countries to carry out the full functions of an NBF lead them to the need to consider sub-regional cooperation and good progress has been made in supporting this activity, working with organizations such as SPREP, ASEAN, ASARECA, SARB, CARDI and SARC.
9. By July 1<sup>st</sup> 2004, 5 countries had already finished their NBFs (Slovenia, Estonia, Czech Republic, Latvia and the Republic of Korea) and their draft frameworks are posted on the website. By August 1<sup>st</sup>, a further 9 countries are expected to have completed their NBFs and by December 31<sup>st</sup>, a 50 additional countries should have finished. The original duration of the projects had been set up for 18 months, but many countries have sought extensions as a result of the complexity of the national processes required. It is expected that by the end of the Project (December 1, 2005), the remaining 80 countries will have finished their national projects. The achievement of a draft NBF will also allow countries to move onto the Implementation stage, provided that they are Parties to the Cartagena Protocol. It is expected that many of these countries will wish to maintain their partnership with UNEP in the Implementation stage.

## **II. UNEP-GEF Demonstration Projects for Implementation of National Biosafety Frameworks**

10. UNEP-GEF manages 8 of the 12 GEF-funded Demonstration Projects on Implementation of National Biosafety Frameworks in Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. These were all Pilot phase countries and finished their original projects in 1999. The demonstration projects started in September 2002 and will last, on average, 3 years, with budgets ranging between 0.5M and 1.0M US\$. The aim for each country is to have the national biosafety framework fully operational by the end of the 3-year project period. i.e., the participating countries will have:
- A regulatory regime for biosafety in place, which is in line with the CP and other relevant international obligations,
  - Workable and transparent 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.
11. Establishing an adequate NBF involves an iterative process of developing a draft, implementing the draft and carrying out continuous evaluation and feedback. Considering that most working NBFs were created over a period of several years of ‘trial and error’, it is clear that the targets set under these projects are quite ambitious.
12. The role of UNEP focuses on responding to countries’ needs and providing expert assistance and guidance as well as ensuring accountability through adequate and transparent reporting. This process of working with the countries can be described as a series of actions:
- (i) Review the status of the NBF and the draft legislation at the start of the project;
  - (ii) Carry out a start-up workshop on the 5 key components of the NBF;
  - (iii) Joint preparation of a detailed work plan.
  - (iv) Countries carry out work plan and report on results
  - (v) Continuous provision of legal, scientific and technical support by UNEP-GEF
  - (vi) Make all reports and documentation available on website
13. Expert support has been provided in a number of areas such as:
- Collection and analysis of biosafety policies and public information practices from countries all over the world
  - Expert panels assembled to provide reviews of drafts of biosafety legislation and draft regulations
  - A Guide prepared on regulatory regimes, processing of notifications and requests, risk assessment, decision making, enforcement, monitoring, public information, public participation and international information exchange
  - Guidance provided on interim measures and assistance in drafting implementing regulations
  - Training given in the scientific and practical aspects of risk assessment
  - Support was provided in drafting operational manuals and work plans for enforcement

14. A study tour was made by the National Project Coordinators to a number of countries in Europe where biosafety frameworks have been in place for many years. In addition, a training workshop was held in Geneva from 19 - 30 January 2004. Comparable courses and other training activities will be run in future years in response to the needs of the countries.

### **III. Assisting 140 countries to build their Capacity for their Effective Participation in the Biosafety Clearing-House (BCH)**

15. A US\$ 5.1 million UNEP–GEF Biosafety Clearing-House project was approved in November 2004 to help build capacity in countries that need to use the Biosafety Clearing-House. Since the BCH contains all the information that is required of, and by, countries in order to carry out all the functions of the CP, the project is aiming to help all Parties use, access and set-up national BCH access.
16. The project originated from the needs of countries to use the Biosafety Clearing-House and in close collaboration with the CBD Secretariat. This project was designed to assist up to 50 countries, with eligibility restricted to countries that were Parties to the CP by COP/MOP1 in February 2004. 61 countries were therefore eligible under GEF rules, and 46 of these have so far endorsed. However, guidance to the GEF from COP/MOP1 led to a request for expansion of eligibility to include all Parties to the Convention on Biological Diversity or all countries that provide clear political commitment towards becoming Parties. This will increase the eligible countries to 140 countries, in total. As a result of results from the May 2004 GEF Council, an add-on project for up to 90 additional countries is being developed.
17. The Biosafety Unit hired the Task Manager in November 2003 in order to be able to start the project soon after GEF Council endorsement and meet countries' urgent needs by starting the training in Autumn 2004. The BCH Capacity Building Project has a training component to strengthen capacity by training key stakeholders and an equipment component to create an enabling environment by providing some computer hardware and software for data storage and exchange. A minimal support for equipment is provided to countries in this project with complementary funds to be available at the Implementation stage.
18. The first Training of Trainers workshop, involving at least 5 experts from each of the 4 regions is scheduled for October 2004. The first national workshops will then begin from December 2004. It is anticipated that there will be a need to hold one national workshop for each of the 50 countries, and this number will be increased if eligibility is extended to an additional 90 countries. A variety of training activities will be needed to respond to the specific needs of each country and it is likely that this will involve workshops, consultancies, advice, ongoing support and use of the training documentation that is now being prepared for the purpose. In addition, a high level of follow up and support from these above-mentioned regional experts will be needed in countries after the initial discussions and country-level training, including one-on-one support in assisting countries makes choices for national BCH access and to set-up and use the BCH.